REPORTS OF BOARD OF TRUSTEES

The following reports, 1-41, were presented by Timothy T. Flaherty, MD, Chair:

1. NEW SPECIALTY ORGANIZATION REPRESENTATION IN THE HOUSE OF DELEGATES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

The Board of Trustees and the Specialty and Service Society (SSS) considered the application of the American Academy of Pharmaceutical Physicians for national medical specialty organization representation in the American Medical Association House of Delegates. The application was first reviewed by the SSS Credentials Committee and presented to the SSS Assembly for consideration.

The application was considered using criteria developed by the Council on Long Range Planning and Development and adopted by the House (Policy H-600.020, AMA Policy Database). A summary of the guidelines is attached under Exhibit A. Objective guidelines include: A, C, D, E, F, G, H, I and J. The subjective guideline is: B.

Organizations seeking admission are asked to provide appropriate membership information to the AMA. That information was analyzed to determine AMA membership, as required under Criterion C. A summary of this information is attached to this report as Exhibit B.

In addition, organizations must submit a letter of application in a designated format. This format lists the above-mentioned guidelines followed by the organizations' explanation of how it meets each.

Before a society is eligible for admission to the House of Delegates, it must participate in the SSS for three years. The American Academy of Pharmaceutical Physicians was admitted to the SSS in 1997 and has been a member in good standing since.

Review of the materials and discussion during the SSS meeting at the 2001 Interim Meeting indicated that the American Academy of Pharmaceutical Physicians meets the criteria for representation in the House of Delegates.

RECOMMENDATIONS

Therefore, the Board of Trustees recommends:

1. That the American Academy of Pharmaceutical Physicians be granted representation in the American Medical Association House of Delegates.

2. That the remainder of this report be filed.

APPENDIX

Exhibit A - Summary of Guidelines for Admission to the House

A. The organization must not be in conflict with the Constitution and Bylaws of the American Medical Association by discriminating in membership on the basis of race, religion, national origin, sex, or handicap.

B. The organization must (a) represent a field of medicine that has recognized scientific validity; (b) not have board certification as its primary focus; and (c) not require membership in the specialty organization as a requisite for board certification.

C. The organization must meet one of the following criteria:

1. A specialty organization must demonstrate that it has 1,000 or more AMA members; or

2. A specialty organization must demonstrate that it has a minimum of 250 AMA members and that thirty-five percent (35%) of its physician members who are eligible for AMA membership are members of the AMA; or

3. A specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that thirty-five percent (35%) of its physician members who are eligible for AMA membership are members of the AMA.

D. The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application.

E. Physicians should comprise the majority of the voting membership of the organization.

F. The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges and are eligible to hold office.

G. The organization must be active within its field of medicine and hold at least one meeting of its members per year.

H. The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.

I. The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.

J. If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

Responsibilities of National Medical Specialty Organizations

1. To cooperate with the AMA in increasing its AMA membership.
2. To keep its delegate to the House of Delegates fully informed on the policy positions of the organization so that the delegate can properly represent the organization in the House of Delegates.
3. To require its delegate to report to the organization on the actions taken by the House of Delegates at each meeting.
4. To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.
5. To provide information and data to the AMA when requested.

Exhibit B - Summary Membership Information

ORGANIZATION	NUMBER OF PHYSICIAN MEMBERS	NUMBER/PERCENT AMA MEMBERS
American Academy of Pharmaceutical Physicians	741	260 (35%)

2. AMA STRATEGIC DIRECTION FOR 2003 AND BEYOND

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 607 AND REMAINDER OF REPORT FILED

INTRODUCTION

This report responds to American Medical Association Policy H-625.020 (AMA Policy Database), "AMA Strategic Planning," which calls for the AMA Board of Trustees to submit, at each Annual Meeting of the House of Delegates, a report that proposes strategic directions for the upcoming year as well as longer-term directions for our AMA.

OVERVIEW OF AMA PLANNING CYCLE

Our AMA's annual planning cycle starts with a Board planning session in February of each year. At these meetings, the Board considers a variety of topics including:

- The relevance and appropriateness of the AMA's Vision Statement;
- Current and likely future trends in the environment of medicine;
- Issues and concerns that should be considered as our AMA develops its strategic plan;
- The AMA's communication and advocacy strategy on current and emerging issues;
- The financial and membership status of the Association; and
- Assumptions and strategies on key activities of the Association (e.g., membership, advocacy, communications, etc.).

Based on its analysis of these topics, the Board prepares a report for each Annual Meeting of the AMA House that identifies broad strategic directions that then serve as a basis for the development of a more detailed strategic plan for the upcoming year. The AMA's Executive Vice President follows through on the strategic directions that are approved by the House by developing detailed program plans and budgets for the next year. These plans are reviewed and approved by the Board's Finance Committee and, ultimately, by the entire Board. Information on the AMA's program plans and budget for the next year are presented to the House at its Interim Meeting.

PARTICIPATION IN AMA STRATEGIC PLANNING

As suggested in AMA Policy H-625.020, the Board has continued to encourage participation in the AMA's strategic planning process by the AMA Councils, Sections, Special Groups, and other "stakeholders." For the Board's February 2002 planning session, each Council, Section, and Special Group provided the Board with suggestions on issues and concerns that should be considered as the AMA's plan for 2003 is being developed. Consistent with its role as a strategic advisor to the Board, the Council on Long Range Planning and Development (CLRPD) summarized and synthesized the suggestions of the Councils, Sections, and Special Groups, provided the Board with information on current trends in the health care sector, and made suggestions on AMA's strategies. In addition, the Board reviewed information on the health care environment that was provided by Federation organizations, consulting firms, academics, and other health care experts. The Board also heard a presentation by a consultant on how demographic trends are likely to affect associations and strategies that medical associations might employ to make themselves more attractive to medical students and young physicians.

AMA VISION STATEMENT

The Board of Trustees reviewed the current AMA vision statement and concluded that it continues to be relevant, appropriate, and provides sound direction for 2003 and beyond. However, the Board believes that the AMA Vision Statement should provide more emphasis on medical science. Accordingly, the Board proposes a modification in the AMA vision statement (See Recommendation 1).

KEY ACTIVITIES

This section provides an overview of the nine major activity areas that are key to our AMA's effectiveness in pursuing its overall strategic vision in 2003 and beyond. At its February planning session, the Board discussed the assumptions and strategies for each of these activities.

Membership

Membership is critical to the ability of our AMA to fulfill its mission. Members are our key source of strength and credibility, particularly in advocating on behalf of patients and the medical profession. Consequently, membership must be a prime consideration in everything our AMA does.

Attracting and retaining members is likely to continue to be a major challenge for the AMA and other medical associations. Environmental trends such as more intense competition for physician membership, the changing demographics of the physician population, and more intense economic pressures on medical practices are factors that are contributing to the membership challenge.

Proposals for fundamental change in the AMA's membership base and membership system have been under discussion for years. The Special Advisory Group Extraordinaire (SAGE) has recently suggested such a change. However, implementation of any fundamental changes in the AMA's membership system probably would not occur in the immediate future. Consequently, our AMA's membership strategy should be based on the assumption that the basic elements of the AMA's current membership system will be retained for 2003. In other words, individual medical students and physicians will continue to constitute the membership base of our AMA. And, except for medical students and physicians who belong to societies that are unified in membership with the AMA, the decision on whether or not to belong to our AMA will continue to be voluntary.

The membership strategy that the AMA Board proposes to pursue for the foreseeable future includes the follow elements:

- Strengthening the incentives for Federation organizations to promote AMA membership;
- Ensuring that the AMA has control over the decisions and processes that affect AMA membership recruitment and retention--our AMA must have access to its membership market if it is to succeed in attracting and retaining members;
- Pursuing ways to better align the AMA's membership structure, product mix, and governance processes; the AMA must create products and services that resonate with members and demonstrate the value of membership;
- Targeting our advocacy and representational agenda to issues that are important to physicians and on which our AMA can achieve and demonstrate real wins;
- Expanding communication activities to continually inform physicians about the AMA's advocacy and representational agenda, successes, and how the AMA's efforts are directly relevant to physicians' day-to-day lives;
- Delivering the AMA's messages in ways that resonate with specific segments of the physician population;
- Enhancing the AMA's web site to facilitate more member involvement in the activities of the AMA and to promote two-way communication between the Association and its members;
- Though the Section on Medical Schools and through other outreach mechanisms, working to increase awareness among academic physicians of the AMA's efforts to support medical education and increase the AMA's membership market share among academic physicians.
- Continuing to provide first-class service to members who contact the AMA;
- Investigating the concept of "mentoring" of young physician members of our AMA;
- Continuing to improve the AMA's membership database and its membership marketing and processing capabilities; and
- Making AMA membership a responsibility and goal for all AMA units.

Advocacy for the Medical Profession and Medical Practice

Advocacy is one of the AMA's core competencies. Strong, effective, and successful advocacy is the principal expectation that physicians have of our AMA. Physicians expect that the AMA will successfully represent their interests and those of patients on a wide variety of issues. One of the major challenges that the AMA faces is to represent the interests of patients as well as the professional and economic interests of physicians. In 2003, our AMA must intensify its efforts, on behalf of patients and physicians, to address the deterioration that is occurring in the medical practice environment.

The increasing heterogeneity of the physician population and the complexity of the US health care system have resulted in an issue agenda that taxes the capacity of the AMA, or any association, to address at any one time. Because of this situation, the AMA's overall advocacy strategy must incorporate four tactics:

1. Prioritization of issues;
2. Promotion of unity of voice and action in the Federation;
3. Participation in coalitions with organizations outside of organized medicine; and
4. Expansion of the AMA's capacity to pursue advocacy objectives by facilitating the participation of delegates, alternate delegates, and members in advocacy activities.

At its February planning session and at most other Board meetings, the AMA Board reviews information on the environment, identifies issues that are of concern to physicians, and establishes priorities for AMA advocacy efforts. In setting priorities, the Board considers a variety of factors including:

- The overall significance of the issue to physicians and their patients;
- The "lifecycle stage" of the issue (e.g., emerging, mature, resolving, etc.);
- Whether or not our AMA has a unique contribution to make on the issue;
- The degree of involvement by other organizations and interest groups in addressing the issue;
- The likelihood that our AMA can succeed in having a significant influence on how the issue is resolved; and
- How addressing the issue might influence AMA's membership performance.

As of mid-2002, the top advocacy priorities for our AMA for the next year or two are likely to include:

- Bioterrorism and disaster preparedness;
- Professional liability reform;
- Health care accountability (insurance, managed care, etc.);
- Regulatory relief (fraud and abuse, "hassles");
- Access to health care services and coverage for health care costs;
- Payment levels and timeliness;
- Transforming Medicare;
- Patient safety and health system safety;
- Antitrust relief; and
- Privacy of confidential information (HIPAA).

As the environment changes, the Board reassesses issue priorities. By the time the AMA begins to implement its strategic plan for 2003, the Association's issue agenda and priorities probably will have changed somewhat from what is presented above.

Unity of voice and action within the Federation is critical to the ability of the AMA and other Federation organizations to achieve their advocacy objectives. As resources become more limited and the number of advocacy "targets" increases, cooperation among Federation organizations in the advocacy arena becomes more important. Our AMA supports, and will continue to support, a wide variety of mechanisms to coordinate the advocacy efforts of the Federation. Additional mechanisms will also be explored.

The coalition style of politics that has developed in recent years requires that our AMA continue to explore ways to pursue specific elements of its advocacy agenda by working with organizations outside of the Federation. Coalitions can expand the AMA's capacity to pursue advocacy objectives, but they can also present risks. Consequently, the AMA will continue to assess these opportunities through formal risk assessment procedures.

Facilitating the ability of AMA delegates, alternate delegates, and members to participate in advocacy is another tactic that can expand the capacity and effectiveness of the AMA. Working through the e-Medicine Advisory Committee (EMAC), the Board and the CLRPD have been working to redesign the AMA's Policy and Advocacy web page so that it can better support the efforts of members to identify advocacy opportunities and promote the AMA's policy positions.

In attitudinal surveys and focus groups, physicians have consistently indicated that advocacy is the AMA's most important "product." Consequently, better communication with physicians about AMA's advocacy efforts and successes must be one of the AMA's strategies to attract and retain members. However, communicating with busy physicians has always been a major challenge. As discussed below, the AMA Board is continuing to work to improve the Association's communications. The redesign of the AMA's Policy and Advocacy web page is one way improved communications with physicians is being pursued.

Advocacy for Medical Science and Public Health

Our AMA has a long and distinguished record of working to improve public health. Part of the AMA's mission is the betterment of the public health. Further, the AMA *Principles of Medical Ethics* now state that physicians have a responsibility to participate in activities that contribute to the betterment of the public health. In addition, our AMA promotes scientific research and the rapid dissemination of scientific findings to physicians for use in clinical settings.

Recent events have highlighted the weaknesses in our public health infrastructure. Trends in morbidity and mortality also indicate a need for greater attention to preventing acute and chronic disease. In today's world, physicians must focus on the health needs of the community as well as those of the individual patient.

Our AMA's strategic plan for 2003 will address public health advocacy in a number of ways:

- Intensifying AMA advocacy for expanding the capacity of the medicine/public health infrastructure;
- Encouraging and facilitating greater involvement of state and local medical societies with local public health agencies;
- Through the Council on Scientific Affairs, continuing to develop information that helps physicians address public health issues and provides the conceptual basis for AMA advocacy efforts on public health;
- Striving to become a definitive voice on preventive behaviors by disseminating "tools" for physicians on alcohol, tobacco interventions, foodborne illness, infection disease, health risk behaviors, immunizations, etc;
- Capitalizing on *JAMA*'s rich contributions to public health;
- Serving as a "broker" for information networks on ways to achieve better medical and public health outcomes; and
- Building stronger working relationships with other organizations that are concerned with public health issues.

Medical Education

Improving the quality of medical education has been a strategic objective for the AMA since its inception. Environmental trends indicate that the AMA must continue its efforts to maintain the viability and effectiveness of our medical education system. The financing of medical education and the level of medical student debt continue to be major concerns. Questions about whether the US will face a shortage or surplus of physicians have arisen again. Pressures on academic physicians are constraining the time they can spend providing guidance to residents in clinical settings. Electronic knowledge transfer is likely to have a significant, but not entirely predictable, impact on medical education. Changes in curricula may be needed to accommodate self-directed learning, health promotion and disease prevention, evidence-based medicine, and population-based health care.

AMA strategy in medical education will include the following components:

- Through the Council on Medical Education and established AMA advocacy conduits, continue efforts to resolve the financial pressures on the medical education system and ensure its long-term viability.
- Intensify our campaign to explain to legislators, the media, businesses, and others that the US medical education system is a "national treasure" that must not be allowed to erode.
- Continue to work with Accreditation Council for Graduate Medical Education, Accreditation Council for Continuing Medical Education, and Liaison Committee on Medical Education to ensure effective medical education programs.
- Strengthen the AMA's relationships with public and private sector groups that address aspects of the medical education system. These groups include academic organizations, accrediting agencies, physician credentialing organizations, medical specialty societies, educational institutions, and other health care organizations.
- Through the Council on Medical Education, research and identify ways to address key issues in medical education such as medical student debt and resident work hours.
- Expand and promote AMA continuing physician professional development programs and focus on the development of Internet CME programs.
- Ensure that the AMA is at the forefront of emerging technology in medical informatics and the use of electronic media in medical education.

Communications

Good communications is essential for everything our AMA does. Our message must be clearly and consistently delivered to all appropriate audiences.

Communicating effectively with our target audiences has always been a challenge. The number and volume of communications of all types have increased in recent years, increasing the difficulty that our AMA has in reaching any of its target audiences. Communicating with physicians is particularly difficult because they are very busy individuals. Further, rapidly changing modes of communication technology and information exchange have created new communication challenges. To succeed in this environment, the AMA must be attuned to the needs and interests of its audiences and must provide those audiences with information that is valuable, concise, accurate, and timely.

The goals of the AMA's integrated communications program are to enhance our AMA's reputation and "brand identify" and to facilitate the achievement of the Association's strategic objectives in advocacy, representation, standard setting, distribution of information on medicine and medical practice, and membership. In pursuing these goals, the communications programs will employ the following strategies:

- On an ongoing basis, reinvent the AMA's communications technologies. Move our AMA up the "communications technology curve" in order to enhance, focus, and expand the Association's communications. Increased use of e-mail will be part of this strategy. Our AMA will also more closely track media coverage and, thereby, enable the Association to respond quickly and effectively.
- Expand the stature and scope of the AMA's presence on the Internet. The AMA web site will be enhanced to make it more valuable as an essential resource for physicians, the public, and the media. It will also be use to advance the AMA's role as the voice of medicine and elevate the AMA's identify.
- Achieve better integration of communications efforts. The focus here is on shared communications planning and partnering among AMA units to ensure that their communication activities reinforce each other.
- Seek opportunities to leverage the power and reach of our AMA. Strategic partnerships will be identified and, where appropriate, pursued in order to expand the ability of our AMA to reach its target audiences and achieve its strategic goals.
- Continue to make effective use of AMA leaders and others in serving as spokespersons for the AMA.
- Consider new communications vehicles. The Board will consider the desirability and feasibility of a "house organ" for our AMA.

Ethics

Our AMA was established around the tenets of professionalism, of which the Code of Medical Ethics is a central component. The AMA's Code of Medical Ethics is the recognized medical ethics base in this country. Consequently, the AMA's strategy must include maintaining the Association's preeminence in the field of ethics.

The environment of medical practice today requires that our AMA pursue an active and dynamic strategy on ethics. Advances in medical and communication technologies are leading to entirely new questions about medical ethics and confidentiality. The changing structure of medical practice and pressures on physicians to become more productive are creating concerns about the ability of physicians to practice in a manner that is consistent with the basic tenets of medical excellence. Maintaining an effective and appropriate patient-physician relationship is becoming more and more difficult for physicians.

In 2003 and beyond, our AMA will continue to pursue the following strategies on ethics:

- The Council on Ethical and Judicial Affairs will continue to serve as the steward of the AMA Code of Medical Ethics and will develop ethics policies that provide practical guidance to physicians.
- The AMA will continue to conduct methodologically sound research on the tenets of professionalism and ethics; the AMA must be seen as a credible source of information on these issues.
- The Ethics Resource Center will provide educational materials that translate the ethics work of the AMA into practical solutions for physicians.

- Our AMA will continue to make use of the Internet to heighten awareness of the AMA's activities that support professionalism and ethics in medical practice. Mechanisms such as the Virtual Mentor and the Code of Medical Ethics Online will continue to be employed to provide medical students, residents, and other physicians with the knowledge that they need to address the ethical challenges they face today.

Relationship Building

Our AMA will expand its efforts to establish positive relationships with other organizations in order to increase the Association's capacity to fulfill its mission. As mentioned above in the descriptions of several components of the AMA's overall strategy, success in many of the Association's activities is dependent on good working relationships with other medical societies, other organizations, and key individuals in the public and private sectors.

The growing pressures on our health care system may presage new initiatives to change the system in fundamental ways. The need for unity of voice and action among Federation organizations has never been greater. Accordingly, the AMA will continue to emphasize its role in the Federation as the convener and integrator of the advocacy and representational activities of medical associations. Our AMA currently supports a wide variety of mechanisms that are intended to promote unity of voice and action in the Federation. These mechanisms will be evaluated for their effectiveness. New mechanisms will be identified and assessed.

Our AMA will also intensify its efforts to establish cooperative relationships with a wider variety of organizations than in the past. The objective will be to enhance the ability of the Association to achieve its advocacy and representational objectives. Great care will be taken to assess the risks associated with these sorts of relationships and to avoid undesirable outcomes.

Publishing and Business Services

As the membership market has become more competitive, the AMA's reliance on the financial contributions from publishing and business services has increased. Achieving growth in non-dues revenues is, therefore, a key part of our AMA's overall financial strategy. However, activities that generate non-dues revenues must be consistent with the guidelines for corporate relationships, as established by the House.

Over the past several years, the financial contributions from publishing and business have increased. However, many of the AMA's business lines are maturing and could face more intense economic competition in the future. Consequently, our AMA must explore new business opportunities.

Our AMA has good prospects for developing new products and services and entering new markets. The AMA is an attractive business partner. Further, distribution of AMA products and services abroad is potential growth area.

Strategies that the publishing and business services areas will pursue in 2003 and beyond include the following:

- Expand existing markets and enter new market by leveraging the strength of our AMA's "brand," distribution channels, and intellectual assets. New products and services will be developed. However, these must be consistent with the AMA's overall mission. Business development efforts will focus on solutions that are directly relevant to the daily practice life of the physician. Whenever possible, new products and services should be designed to help our AMA demonstrate its relevance to the individual physician and enable physicians to conduct clinical or business activities in new, more effective ways.
- All existing AMA business lines will explore ways to diversify and enter new markets.
- All AMA business lines will explore the possibility of expanding into international markets in order to find new sources of revenue for the Association.
- Efforts to achieve operational improvements and cost reductions will continue.

E-Strategy

The continuing rapid growth of the Internet indicates that it will become an ever more significant aspect of how medical associations relate to their members, work to achieve their strategic objectives, and generate non-dues revenues. The Internet is also is becoming an increasingly important part of the way physicians practice medicine and relate to their patients. Consequently, developing a good E-strategy has become an imperative for the long term success and viability of our AMA.

Specific strategies that will be pursued include the following:

- Identify areas of the AMA that can benefit substantially from the development of an E-strategy and work to develop strategies for those areas.
- Undertake Internet opportunities that are consistent with our AMA's mission and overall approach to E-strategy. Specific screening criteria will be used to ensure that the AMA's Internet initiatives do not become ends in themselves.
- Through the AMA's e-Medicine Advisory Committee, continue efforts to enhance our AMA's web site.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted and the remainder of this report be filed.

1. That American Medical Association Policy H-625.010, AMA Vision, be modified by addition to read as follows:

   The AMA vision statement consists of four elements: (1) a statement of core purpose; (2) a set of core values; (3) a statement of envisioned future; and (4) key objectives.

   AMA Core Purpose: To promote the science and art of medicine and the betterment of public health.

   AMA Core Values:

   1. Leadership and Service: the stewards of medicine, caring advocates for patients and the profession;
   2. Excellence in all we do: the highest quality service, products, and information; and
   3. Integrity and Ethical Behavior: the basis for trust in all our relationships and actions.

   AMA Envisioned Future: The AMA will be an essential part of the professional life of every physician and an essential force for progress in improving the nation's health.

   AMA Objectives: The AMA will pursue being:

   1. The world's leader in obtaining, synthesizing, integrating, and disseminating information on <u>medical science, public</u> health, and medical practice;
   2. The acknowledged leader in setting standards for medical ethics, practice, and education;
   3. The most authoritative voice and influential advocate for patients and physicians; and
   4. A sound organization that provides value to members, federation organizations, and employees.

2. That the modified AMA Vision Statement, as described in Recommendation 1 above, and the key activities described in this report serve as a basis for the development of the AMA Plan for 2003, which will be distributed to the House of Delegates at its 2002 Interim Meeting.

3. ANNUAL UPDATE ON VIOLENCE ACTIVITIES

HOUSE ACTION: FILED

This report provides an update on the activities of our American Medical Association's Campaign Against Family Violence and other violence-related activities. It is prepared for each Annual Meeting of the House of Delegates as an informational report, briefly summarizing activities over the past year.

NATIONAL ADVISORY COUNCIL ON VIOLENCE AND ABUSE

The National Advisory Council on Violence and Abuse consists of representatives from 24 specialty medical societies, six state medical societies, the National Medical Association, and several related medical groups such as Physicians for a Violence-Free Society and the Handgun Epidemic Lowering Plan Network. In addition, collaborating members, such as the American Bar Association and the Centers for Disease Control and Prevention

(CDC), work with the Advisory Council on the campaign. The Council meets in the spring and fall to share information about AMA, specialty society, and other family violence initiatives. J. Edward Hill, MD, represents the Board of Trustees at the Advisory Council's biannual meetings. A current roster of the Advisory Council is included as an appendix to this report.

The Advisory Council was formed in 1991. At its fall meeting last November, the Advisory Council focused on the development of a strategic plan to guide its efforts over the next few years. By the conclusion of that meeting, a draft plan had been developed, with the Council's steering committee charged with presenting the penultimate plan at the spring meeting.

The strategic plan was finalized at the Council's April meeting, which was hosted by the National Medical Association in Washington, DC. A new mission statement was also adopted:

The AMA National Advisory Council on Violence and Abuse will work in its advisory capacity to promote AMA practices and policies to ensure that all physicians are capable of recognizing and identifying violence and abuse in all its forms**,** of providing appropriate responses when these issues are identified in their patients, and of participating in its prevention.

As outlined in AMA Policy H-515.965 (AMA Policy Database), "Family and Intimate Partner Violence," our AMA's violence-related programs are guided, in part, by the Advisory Council, and the Advisory Council adopted the following goals:

- Promote AMA practices and policies that enhance physicians' capacity to recognize and identify the presentations and consequences of violence and abuse in all their forms;
- Ensure that physicians are capable of providing appropriate responses when these issues are identified;
- Educate the medical community to play an appropriate role in the prevention of violence and abuse; and
- Encourage other health care organizations to identify and work towards similar goals.

A subcommittee of the Advisory Council also met in March to develop plans to address Resolution 419 (I-00). Members of the Advisory Council will be meeting with a subcommittee of the Council on Medical Education during this annual meeting to formulate a strategy to conclude the work called for in the resolution, which as adopted calls on our AMA to (1) identify the knowledge and skills needed by physicians to adequately identify, respond to and prevent violence and abuse; (2) identify recommended components for training and developing these skills within the medical education process; and (3) explore the means to incorporate that training into current medical education.

Among other activities, the Advisory Council is still expecting the release in 2002 of its planned monograph on abusive behavior in the medical workplace, a project that has been ongoing since the HOD adopted an earlier report on violence in the medical workplace. The Advisory Council's project on children who are victims of violence, including children who are witnesses to violence, is also expected to conclude this year.

BOARD OF TRUSTEES AND HOUSE OF DELEGATES ACTIONS

Violence-related issues continue to come before the HOD regularly. At the 2001 Annual Meeting, Resolution 413 was adopted and resulted in a report from the Council on Scientific Affairs to be discussed at this meeting. The CSA's report examines research on the efficacy of intervention programs designed to reduce bullying and describes survey instruments that can be used to measure the incidence of bullying; the report will also establish AMA policy on bullying and associated behaviors. In addition, the CSA's prescient interest in bioterrorism provided an update report on medical preparedness for terrorism (CSA Report 4, A-01).

At the 2001 Interim Meeting, several reports and resolutions related to aspects of violence were considered. Eight resolutions dealt with various terrorism-related issues, and several elements from these resolutions were incorporated into an amended Board of Trustees Report 26-I-01 on the AMA's response to terrorism and disaster preparedness. Other related resolutions resulted in new AMA policies on the use of children as instruments of war and expressing support for local and state public health agencies. A resolution on the threat of bioterrorism and smallpox was referred for study by the Council on Scientific Affairs. Other violence-related resolutions resulted in the adoption of policy supporting continued AMA efforts to deal with youth violence and the non-adoption of a resolution calling for the licensure and registration of firearms.

NATIONAL COMMISSION FOR THE PREVENTION OF YOUTH VIOLENCE

The report on youth violence that was prepared by our AMA Commission for the Prevention of Youth Violence, a partnership of medical, nursing, and public health organizations that was funded by a grant from the Robert Wood Johnson Foundation, continued to be distributed. Using grant funds that remained after the Commission report was concluded, our AMA has prepared a *Training and Outreach Guide* as a companion to the report. The guide will assist physicians and other health care professionals increase awareness of the serious and pervasive nature of youth violence and the possibilities for prevention of such violence.

Material in the guide is designed to be used in a variety of settings from medical grand rounds to meetings of parents and teachers as well as with a range of audiences, including other health care professionals, students in the health professions, and both adult and youth community groups. The manual supplies information needed to deliver a speech or workshop on youth violence before any of these audiences. Information is built around training principles for youth violence prevention developed by researchers and educators from the CDC-funded Youth Violence Prevention Centers of Academic Excellence. Information on the guide is available from the AMA's Department of Medicine and Public Health or from the AMA web site. In the absence of additional funding, the Commission's activities will end with the development of the training guide, although the training sessions will be their legacy.

Presentations on both the youth violence report and the outreach guide have been made over the past year, and they have been positively received. Most recently, the Midwest Clinical Conference included the presentation on youth violence; the conference was held in conjunction with the Chicago Medical Society.

WORLD MEDICAL ASSOCIATION DECLARATION

At the 2001 annual meeting of the World Medical Association, our AMA introduced a declaration that condemns the research, development, production or use of biological weapons as morally and ethically unacceptable. The declaration stems from work that our AMA has been doing since 1999, studying how the medical community could diminish the consequences of a biological attack. Actual work on the proposed declaration began in January 2001 following discussions on how an outbreak anywhere in the world caused by a readily communicable agent could have international repercussions given the ease of travel and increasing globalization.

Along with an international prohibition of biological weapons, the critical components of the AMA proposal include calls to strengthen public health infrastructures and enhance medical preparedness and response capacity. The AMA proposal calls on the WMA and its constituent members to promote the establishment of an international consortium of medical and public health leaders to:

- monitor the threat of biological weapons;
- identify actions likely to prevent the proliferation of bioweapons; and
- develop a coordinated plan for monitoring the worldwide emergence of infectious diseases.

A vote on the proposed declaration is expected this fall at the 2002 annual meeting of the WMA in Washington, DC.

CASE STUDY IN INTIMATE PARTNER VIOLENCE

Working with the US Department of Health and Human Services, our AMA's unit on Medicine and Public Health is developing a series of case studies in disease prevention and health promotion entitled *Roadmaps for Clinical Practice*. The goal is to help physicians and other health care professionals identify and utilize strategies to reduce disparities in health through integration of disease prevention and health promotion into routine medical care.

The first topic addressed in the series is intimate partner violence, chosen because injury and violence are one of the leading health indicators in *Healthy People 2010*. In addition, intimate partner violence has been a central element in the AMA's campaign against family violence over the past decade, and the earlier diagnostic and treatment guideline on domestic violence has been highly regarded and consistently popular over the same time period. The new document is based on a case study and addresses a number of topics, including heterosexual and same sex relationships, documentation, and safety planning.

OTHER AMA ACTIVITIES

Last October, our AMA helped to promote "Health Cares About Domestic Violence Day," which is a project of the Family Violence Prevention Fund (FVPF). The day offers a chance for health care professionals to provide outreach to patients who might be victimized by intimate partner violence and makes available resources to facilitate both patient care and advocacy. A key element of the day is to encourage health care professionals to begin routine screening for domestic violence in their health care settings. An annual event, the day is next scheduled for October 9, 2002.

Our AMA is also working with the FVPF on the National Conference on Health Care and Domestic Violence, for which the AMA is serving as a co-chair. The Conference, which will be held in September in Atlanta, provides professional education on the latest research and innovative health care prevention and clinical responses to domestic violence for all health care professionals, including tracks for physicians. This year's theme is "Prevention and Response Strategies: Pushing the Envelope." J. Edward Hill, MD, Chair-Elect of the Board of Trustees, is the AMA representative for the conference planning effort.

In November, our AMA hosted an invitational forum on the prevention of firearm-related injuries as part of the effort of AMA President Richard Corlin, MD, to address public health aspects of firearm misuse. The forum, which included participants from all sides of the gun question, achieved some consensus on the need to collect better data on firearm injuries, although specifics about a data repository and the types of data to be collected were not fully agreed upon. All in all, the forum was a successful first step in moving the firearm discussion beyond arguments forcing one to choose one side over the other.

In April, our AMA was again a supporter of "National TV Turnoff Week." Our AMA's policy on media violence is clear, and this week affords an opportunity not only to promote those policies but also to encourage parents and children to engage in more active pastimes, promoting a healthier lifestyle. Along with the Alliance, other members of the Federation supporting National TV Turnoff Week are the American Academy of Child and Adolescent Psychiatry, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Psychiatric Association.

AMERICAN MEDICAL ASSOCIATION ALLIANCE, INC.

The AMA Alliance continues to provide substantial support and publicity to organizations that help victims of violence, as well as education for entire communities through the SAVE (Stop America's Violence Everywhere) program. In 2001, the AMA Alliance maintained school violence as its major focus of the SAVE campaign by encouraging county and state Alliances to SAVE Schools from Violence. The Alliance developed a new conflict resolution activity book entitled "I Can Handle Bullies" for children in grades kindergarten through fifth grade. The activity book generates a dialogue about bullying, its effects on children, and strategies to prevent it. Through mazes, picture finds and other coloring activities, children learn how three of their peers work together to resolve a conflict. Since its debut, Alliance members have distributed more than 50,000 copies of "I Can Handle Bullies" to children across the country.

APPENDIX

AMA NATIONAL ADVISORY COUNCIL ON VIOLENCE AND ABUSE
Membership Roster 2001 - 2002

James P. Ahstrom, Jr., MD, American Orthopaedic Association
Arlene D. Bradley, MD, American College of Physicians-American Society of Internal Medicine
Kim Bullock, MD, Medical Society of the District of Columbia
David Chadwick, MD, American Academy of Pediatrics
Marie Christensen, MD, Aesthetic Plastic Surgery Education and Research Foundation
Bonnie Connors Jellen, American Hospital Association
Michelle Copeland, DMD, MD, American Society of Plastic Surgeons
David L. Corwin, MD, American Academy of Child and Adolescent Psychiatry
Grant Cox, MD, Oklahoma State Medical Association
Anir Dhir, MD, American Society for Dermatologic Surgery
Dennis G. Egnatz, MD, American College of Occupational & Environmental Medicine

Bruce B. Ettinger, MD, MPH, American College of Obstetricians and Gynecologists
Bette Garlow, American Bar Association
Lori E. Hansen, MD, American Academy of Facial Plastic and Reconstructive Surgery
A. Stuart Hanson, MD, American Medical Group Association
J. Edward Hill, MD, American Medical Association
Thomas E. Hobbins, MD, MedChi, the Maryland State Medical Society
Mitra B. Kalelkar, MD, National Association of Medical Examiners
Sandra Kaplan, MD, American Psychiatric Association
Larry S. Lehmann, MD, Department of Veterans Affairs
David McCollum, MD, Minnesota Medical Association
Shirley F. Marks, MD, MPH, National Medical Association
Janice Massey, MD, American Academy of Neurology
Sara Naureckas, MD, The HELP Network
James P. Pilliod, MD, New Hampshire Medical Society
Jeffrey D. Roth, MD, American Society of Addiction Medicine
Desmond K. Runyan, MD, DrPH, American College of Preventive Medicine
Linda E. Saltzman, PhD, Centers for Disease Control and Prevention
F. David Schneider, MD, MSPH, American Academy of Family Physicians
Mary Stewart, MD, American College of Emergency Physicians
Ulonda B. Shamwell, MSW, Substance Abuse and Mental Health Services Administration
Zita Surprenant, MD, Kansas Medical Society
Ellen H. Taliaferro, MD, Physicians for a Violence-Free Society
Cheryl Vineyard, CMA, American Association of Medical Assistants
Ann K. Wadstrom, MD, American College of Medical Quality
Daniel W. Young, MD, Radiological Society of North America
Deborah L. Zeitler, DDS, MS, American Association of Oral and Maxillofacial Surgeons
Cynthia Ziemer, Mdiv, PsyD, American Society for Reproductive Medicine
Debra Zillmer, MD, American Academy of Orthopaedic Surgeons

4. EVIDENCE-BASED PERFORMANCE MEASURES AND USE OF SECLUSION AND RESTRAINTS

HOUSE ACTION: FILED

INTRODUCTION

At the American Medical Association 2001 Annual Meeting, the House of Delegates adopted Substitute Resolution 807, which asked "(1) that our AMA continue legislative efforts to enact legislation in Congress which would rescind the July 22, 1999, Interim Final Rule of the Health Care Financing Administration (HCFA) [now Centers for Medicare and Medicaid Services (CMS)] governing the use of seclusion and restraints; (2) that our AMA study, with report back at the 2001 Interim Meeting, evidenced-based performance measures which permit physicians to exercise reasonable clinical judgment in the ordering and use of seclusion and restraints for the protection and safety of the patient, other patients, staff, and visitors; (3) that our AMA provide all evidence-based performance measures to the Health Care Financing Administration for use in developing new regulations for the use of seclusion and restraints; and (4) that our AMA make available to physicians evidence-based performance measures on the use of seclusion and restraints." Board of Trustees Report 16-I-01 addressed the second resolved of Substitute Resolution 807. This informational report provides an update on Recommendation 1 of Board of Trustees Report 16, which asked that the issue of performance measures on the use of seclusion and restraints be referred to the Physician Consortium for Performance Improvement (The Consortium) for its consideration.

REPORT ON THE CONSIDERATION OF THE BOARD'S REFERRAL OF THE SECOND RESOLVE OF SUBSTITUTE RESOLUTION 807 TO THE CONSORTIUM

At its March 2002 meeting, The Consortium discussed the Board of Trustees' request that it consider the use of seclusion and restraints in relation to development of physician performance measures. The Consortium, which bases topic selection for performance measures on established criteria, determined that it will not develop performance measures for the use of seclusion and restraints at this time. However, The Consortium did indicate

that, if it were in the future to develop performance measures related to these issues, it would only consider developing performance measures that would permit physicians to exercise reasonable clinical judgment in the ordering and use of seclusion and restraints for the protection and safety of the patient, other patients, staff, and visitors, as called for in the second resolve of Substitute Resolution 807 (A-01).

5. CLINICAL PRACTICE GUIDELINES, PHYSICIAN PERFORMANCE MEASUREMENT, AND OTHER CLINICAL QUALITY IMPROVEMENT ACTIVITIES

HOUSE ACTION: FILED

INTRODUCTION

This informational report provides updates on (1) the Physician Consortium for Performance Improvement (The Consortium); (2) Consortium demonstration projects; (3) collaborative performance measurement work with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA); (4) the Clinical Quality Improvement Forum (CQIF); (5) the Practice Guidelines Partnership (PGP); (6) the National Guideline Clearinghouse™ (NGC); and the National Quality Forum (NQF).

THE PHYSICIAN CONSORTIUM FOR PERFORMANCE IMPROVEMENT (THE CONSORTIUM)

The Consortium, a physician-led initiative convened through the American Medical Association to identify and develop performance measurement resources for physicians, is comprised of clinical content experts, methodological experts from more than 50 medical specialty societies, the Agency for Healthcare Research and Quality (AHRQ), and the Centers for Medicare and Medicaid Services (CMS). The Consortium is charged with (1) improving patient health and safety by identifying, developing, and promoting the implementation of evidence-based clinical performance measures that enhance the quality of patient care and foster accountability, and (2) advancing the science of clinical performance measurement and improvement. Toward these ends, at its March 2002 meeting, The Consortium approved for pilot testing a performance measurement set for asthma. Measure development for preventive care and screening, major depression, and community-acquired pneumonia continues to progress.

Consortium members discussed several options for implementing quality measures following presentations about the state of the art in performance assessment for physicians. The Consortium also reviewed a call for pilot project participation initiated though the AMA Council on Medical Education to review a variety of methodologies for testing how AMA Physician's Recognition Award (PRA) Category 1 credit could be designated for participation in performance measurement activities.

CONSORTIUM DEMONSTRATION PROJECTS

Demonstration projects to test the validity and reliability of measures, as well as their usefulness to practicing physicians, continue.

- The feasibility phase of a project to establish automated onsite performance reporting capabilities using an existing electronic medical record (EMR) system at a small group practice in Kansas City is completed. This project integrates into clinical practice The Consortium's diabetes measures for quality improvement. As specified by The Consortium, patient-specific and aggregate reports are now available to the physician for his or her own practice enhancement efforts. The next phase of this project will examine if performance can be improved through focused review and enhancement, as permissible, of an existing EMR system.

- A pilot test to evaluate the reliability, validity, and feasibility of retrospective data abstraction for the chronic stable coronary artery disease (CAD) measures has been completed by the Iowa Foundation for Medical Care. An acceptable level of inter-rater reliability was achieved, demonstrating the soundness of the tool. Specific issues identified during the test (eg, which heart rate to abstract when multiple rates are noted in the medical record) will be referred back to The Consortium's CAD Work Group. Staff is in discussions with cardiology practices to next test the CAD prospective flowsheet.

- The Arkansas Foundation for Medical Care completed an evaluation of The Consortium's prenatal testing measures and presented results at The Consortium's 2001 conference. The test was found to be feasible in this environment.

- The AMA supports a project led by the American College of Cardiology (ACC) titled the Stable Angina GAP Project in Alabama. This project is aimed at improving care for heart failure with tool-based application of the ACC/American Heart Association/American College of Physicians-American Society of Internal Medicine Guidelines for Management of Patients with Chronic Stable Angina. Since The Consortium's CAD measurement set was derived from this guideline, the project is an opportunity to further explore measurement for improvement.

- The AMA, in collaboration with NCQA and JCAHO, continues its efforts to promote single data collection for multiple purposes, e.g., physician offices, hospitals, and health plans. The Maine Medical Assessment Foundation is no longer a contractor on this project; the AMA is in discussions with two other potential sites.

COLLABORATIVE WORK WITH JCAHO AND NCQA

Since the joint release of *Coordinated Performance Measurement for the Management of Adult Diabetes* in April 2001, collaborative performance measures development with JCAHO and NCQA continues. The cardiac care project has identified measurement recommendations and common data elements for several cardiac conditions, including heart failure, chronic stable coronary artery disease, and acute coronary syndromes. The third collaborative project, pregnancy and neonatal care, has progressed through tentative identification of measurement priorities, which include screening for asymptomatic bacteriuria, continuity of prenatal care, and neonatal mortality. Additionally, and as noted above (Consortium Demonstration Projects), discussions are under way with potential contractors for testing the concept of single data collection for multiple purposes, using the collaborative diabetes measures.

The three collaborating organizations signed an agreement in August 2001 to accept external, unrestricted funding for joint development of a core set of performance measures for pain management. The funds are being provided by Purdue Pharma, LP, although control and responsibility for the design and content of the pain management project and ownership of all project results belong solely to the AMA, JCAHO, and NCQA. A first meeting of the Pain Management Clinical Expert Panel in April 2002 included a review of pain management guidelines and an initial consideration of opportunities for measurement.

In January 2002, leaders from the AMA-JCAHO-NCQA collaboration met via videoconference with members of the Operations Group of the CMS-sponsored Diabetes Quality Improvement Project (DQIP). The group agreed to pursue a proposal to create a single "national" diabetes performance measurement group to include all organizations from AMA-JCAHO-NCQA and DQIP as well as additional relevant organizations. Discussions on the proposal continue.

The chief executives of the AMA, JCAHO, and NCQA met in December 2001 and are scheduled to meet again in May 2002 to review the ongoing projects, discuss the significance of the collaborative work in the context of other national performance measurement initiatives, and consider future collaborative opportunities. Two more executive meetings will be held in 2002.

The objectives and activities of the National Quality Forum (NQF), which encourages private-sector, collaborative development of performance measures applicable to multiple care settings, underscore the importance of the AMA-JCAHO-NCQA initiatives.

CLINICAL QUALITY IMPROVEMENT FORUM (CQIF)

The CQIF is a prominent annual conference that highlights emerging national health concerns. The next CQIF, which will take place October 30, 2002, will focus on physician performance measurement and clinical quality improvement. By moving the profession toward improving clinical quality and toward the development and implementation of physician performance measurement, the 2002 forum will be grounded in one of the AMA's key objectives--"promoting professionalism in medicine and setting standards for medical ethics, practice, and education."

Building on the 2001 CQIF, "Clinical Quality Improvement Forum: Virtual Medicine," the 2002 forum, which will be co-sponsored by the AHRQ, will continue to explore the challenges facing practicing physicians in implementing performance measurement and integrating electronic data collection and information dissemination into daily practice. Issues surrounding physician performance measurement; data collection, access, and confidentiality; electronic medical records; and use of personal digital assistants (PDAs) will be addressed. In addition, several recommendations highlighted in the Institute of Medicine (IOM) report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, will be considered in relation to each of the forum's topics--creating an infrastructure to support evidence-based practice, facilitating the use of information technology, and preparing the workforce to better serve patients in a world of expanding knowledge and rapid change.

PRACTICE GUIDELINES PARTNERSHIP (PGP)

At its February 8, 2002, meeting, PGP members continued to review the barriers to guidelines implementation and usage and attempted to identify mechanisms for overcoming the obstacles to guidelines compliance. The agenda included an examination and discussion of some of the implications of the IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, for clinical practice guidelines and physician performance measurement, as well as the role of patient preferences in the development and dissemination of practice guidelines and other patient materials. The next PGP meeting will be held in conjunction with the October 30, 2002, CQIF.

NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC)

The NGC is an Internet-based source of clinical practice guidelines designed to assist physicians in their clinical decision-making. The NGC, launched in 1999, is sponsored by the AMA, the AHRQ, and the American Association of Health Plans. The NGC currently includes summaries of more than 915 clinical practice guidelines from 117 organizations. In December 2001, the first annual review, which examined pre-1997 guidelines, was completed. Guidelines that failed to meet all inclusion criteria were removed from the NGC.

Since its inception, the NGC web site has documented more than more than 4.4 million visits and has processed approximately 43 million requests. On average, the NGC web site receives between 9500 to 12,000 visits each weekday. Users may search annotated bibliographies related to guideline development methodology, structure, evaluation, and implementation.

There were more than 6,200 responses to the Second Annual Customer Satisfaction Survey (July 2001); 94% indicated they are fairly or very satisfied overall; about 89% are satisfied with the NGC's content; 86% find the basic search fairly or very useful; 67% find it easy or very easy to navigate the site; and about 83% are fairly or very satisfied with "views" of NGC content. Forty percent (about 2,500) of respondents to the survey were physicians.

A new undertaking, the National Quality Measures Clearinghouse, has been initiated by the AHRQ. In May 2001, the AHRQ issued a request for proposals to identify an entity with which to contract for "production of an integrated suite of Internet-based tools for health care providers, managers, and policymakers." Due to its potential impact on physicians, the AMA is monitoring this activity closely.

NATIONAL QUALITY FORUM (NQF)

As noted on its web site, "The National Quality Forum is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. A shared sense of urgency about the impact of health care quality on patient outcomes, workforce productivity, and health care costs prompted leaders in the public and private sectors to create the National Quality Forum as a mechanism to bring about national change."

The NQF is governed by a 19-member Board of Directors representing health care consumers, purchasers, providers, health plans, and experts in health services research. The Board includes representatives from two federal agencies, the CMS and the AHRQ. Four additional voting members of the Board are elected by Member Councils.

The AMA is an inaugural organizational member of the NQF. AMA Immediate Past President Randolph D. Smoak, Jr., MD, serves as the AMA representative to the NQF. AMA President-Elect Yank D. Coble, Jr., MD, serves as a member of the Provider and Health Plan Council. The forum has also convened a standing panel of experts in quality improvement and measurement to identify the principles and priorities that will guide a national

measurement and reporting strategy. Building on this effort and the work of public and private quality improvement organizations, the forum will endorse quality measures for national use. The forum will also promote the use of quality information and develop a research agenda to advance quality improvement.

The NQF Strategic Framework Board (SFB), a group comprised of health care quality improvement and policy experts convened by the NQF to craft a strategic framework for health care quality measurement and reporting, concluded a public comment period on January 22, 2002, on its recommendations. The SFB issued a revised set of recommendations to NQF members for balloting in mid-February. In its comments, the AMA asked the SFB to clarify that it will select and promote the implementation of measures rather than develop measures itself. If the NQF were to agree that it will seek established measures, the AMA expressed agreement that a process should be initiated for identifying appropriate measures. The NQF Board took a positive step toward selecting established measures--rather than developing its own--by announcing its intention to review for potential endorsement the *Coordinated Performance Measurement for the Management of Adult Diabetes* document developed collaboratively by the AMA, JCAHO, and NCQA. Subsequent to its announcement, NQF learned of the proposal for a new "national" diabetes measurement group (described above) and has agreed to defer its review of measures until a recommendation is received from this new group.

The AMA expressed concern that performance measure design and use be consistent with their intended purposes, and that it should be made explicitly clear where measures are designed for quality improvement purposes and where for accountability purposes. In response to the SFB's recommendation that "public and private purchasers should *require* [emphasis added] providers and health systems to routinely and publicly report performance on a common set of measures," the AMA advised the SFB to "further investigate the feasibility and appropriateness of encouraging" such reporting until which time the science of measurement would support such a recommendation. The Consortium's performance measurement sets were cited as an example of excellent work that closely parallels the 10 priority areas cited as the SFB's "candidate goals."

CONCLUSION

Consistent with policy, the AMA is integrally involved in a wide range of activities related to clinical practice guidelines and physician performance measurement. Ongoing activities of The Consortium and its demonstration projects, collaborative performance measures development work with JCAHO and NCQA, convening the PGP and the CQIF, cosponsoring the NGC, and participation on the NQF, continue to provide AMA physician leadership regarding clinical practice guidelines and regarding the development, implementation, and appropriate use of physician performance measurement systems for physicians to use in their practices.

6. GUIDELINES FOR PHYSICIANS ON INTERNET PRESCRIBING

HOUSE ACTION: REFERRED TO BOARD OF TRUSTEES

BACKGROUND

Online transmission of prescriptions from physician offices to pharmacies via the Internet provides an alternative mechanism for prescription transmission. Many experts believe (and there are research studies to support) that computer order entry and online transmission of prescriptions can reduce errors that occur from failure to understand written and verbal (e.g., telephone) prescriptions. American Medical Association policy (H-120.956[2], AMA Policy Database) supports the use of the Internet as a mechanism to prescribe medications, with appropriate safeguards to ensure that the standards for high-quality medical care are fulfilled.

However, the prescribing of medications via the Internet also has created challenges. In particular, there are a number of Internet web sites that prescribe and dispense prescription medications (e.g., Viagra and Cipro) based solely on an online questionnaire, with no other interaction between the physician and patient. A number of national organizations, including the AMA and the Federation of State Medical Boards (FSMB), as well as regulatory (e.g., Food and Drug Administration) and law enforcement (e.g., National Association of Attorneys General) bodies believe this constitutes substandard medical care and is a threat to the public health. If physicians are participating in these web sites, they are failing to meet minimum standards of medical care and may be subject to disciplinary actions. AMA policy (H-120.956[3]) states, "our AMA will work with state medical societies in urging state

medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications."

PURPOSE OF REPORT

Recommendation 2 of Council on Medical Service Report 4, Medical Care Online (adopted, A-01), and Recommendation 1 of Board of Trustees Report 35, Internet Prescribing: An Interim Report (adopted, A-99), asked our AMA to develop guidance for physicians on the appropriate use of the Internet in prescribing medications. This report provides such guidance on the issues of licensure, criteria for an acceptable clinical encounter and follow-up, security of patient information, and web site disclosure for all physician prescribing, whether in private practice or for commercial web sites.

In developing this guidance, the Board relied on current AMA policy; Board Report 35-A-99 on Internet prescribing; AMA testimony before Congress on this issue in July 1999 (see www.ama-assn.org/ama/pub/print/article/4023-4136.html); Council on Medical Service Report 4-A-01; and an FSMB Report of the Special Committee on Professional Conduct and Ethics in April 2000 (see www.fsmb.org).

LICENSURE

Physicians who prescribe medications via the Internet must possess appropriate licensure in all jurisdictions where patients reside.

Under existing state laws, physicians who practice medicine, including the prescribing of medications, are subject to regulation by the state medical board in which the patient resides. Thus, physicians who prescribe via the Internet must be licensed in the states where their patients reside. Currently, the majority of states require a physician to have a full and unrestricted license.

CRITERIA FOR AN ACCEPTABLE CLINICAL ENCOUNTER AND FOLLOW-UP

Physicians who prescribe medications via the Internet should:

- *obtain or have ready access to a reliable medical history for the patient;*
- *perform or have a documented physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;*
- *have sufficient dialogue with the patient regarding treatment options and risks and benefits of treatment(s);*
- *follow-up with the patient to assess the therapeutic outcome;*
- *maintain a contemporaneous medical record that is readily available to the patient and his or her other health care professionals; and*
- *include the electronic prescription information as part of the patient medical record.*

Acceptable standards of medical practice must be upheld regardless of practice setting and the methods of communication used to deliver health care services. This includes an acceptable clinical encounter and follow-up within the context of a patient-physician relationship. The AMA has previously stated that diagnostic and treatment decisions made by physicians, including the issuance of prescriptions via the Internet, should be supported by appropriate information. The evaluation leading to diagnostic and treatment decisions generally includes an adequate medical history and an appropriate physical examination. web sites that offer a prescription solely on the basis of an online questionnaire with no other interaction between the physician and patient are insufficient.

The AMA agrees with the FSMB that *exceptions* to the above criteria exist in specific instances. These include:

- a medical emergency;
- treatment provided in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications; and
- on-call or cross-coverage situations in which the physician can have access to a patient's records.

SECURITY OF PATIENT INFORMATION

The AMA encourages physicians who prescribe via the Internet to consider using secure systems, such as the AMA Internet ID, that will protect patient privacy.

Protecting the confidentiality and privacy of patient information, including prescription information transmitted via the Internet, is imperative to ensuring patient trust. Current AMA policy (H-120.957[2]) supports the concept that public key infrastructure (PKI) systems or other signature technologies designed to accommodate electronic prescriptions should be readily adaptable to current computer systems, and should satisfy the criteria of privacy and confidentiality, as well as authentication, incorruptibility, and nonrepudiation. For example, the AMA and VeriSign, Inc. have collaborated to provide AMA Internet IDs to physicians for use on the Internet. AMA Internet IDs uniquely identify physicians over the Internet and provide a reliable authentication technique for secure Internet transactions.

DISCLOSURE OF IDENTIFYING INFORMATION ON WEB SITES

Physicians who practice medicine via the Internet, including prescribing, should clearly disclose on the web site physician identifying information, including name, practice location, and all states in which licensure is held.

The AMA agrees with the FSMB that physicians who maintain or participate in Internet web sites offering health care services, treatments, and medications should disclose identifying information. Difficulty in discerning the identity and practice location of physicians participating in Internet web sites both compromises accountability and raises questions about the legitimacy of the web site.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and the remainder of the report be filed:

1. That our American Medical Association provide the following guidance for physicians on the appropriate use of the Internet in prescribing medications:

   (a) Licensure

   Physicians who prescribe medications via the Internet must possess appropriate licensure in all jurisdictions where patients reside.

   (b) Criteria for an acceptable clinical encounter and follow-up

   Physicians who prescribe medications via the Internet should:

   i. obtain or have ready access to a reliable medical history for the patient;

   ii. perform or have a documented physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;

   iii. have sufficient dialogue with the patient regarding treatment options and risks and benefits of treatment(s);

   iv. follow-up with the patient to assess the therapeutic outcome;

   v. maintain a contemporaneous medical record that is readily available to the patient and his or her other health care professionals; and

   vi. include the electronic prescription information as part of the patient medical record.

Exceptions to the above criteria exist in the following specific instances:

- a medical emergency;
- treatment provided in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including use of any prescribed medications; and
- on-call or cross-coverage situations in which the physician can have access to a patient's records.

(c) Security of patient information

The AMA encourages physicians who prescribe via the Internet to consider using secure systems, such as the AMA Internet ID, that will protect patient privacy.

(d) Disclosure of identifying information on web sites

Physicians who practice medicine via the Internet, including prescribing, should clearly disclose on the web site physician identifying information, including name, practice location, and all states in which licensure is held.

2. That our AMA disseminate this policy to state and specialty medical societies.

7. RESCINDING PROVISIONS REQUIRING PHYSICIANS TO HAVE HOSPITAL ADMITTING PRIVILEGES (RESOLUTION 716, A-01)

HOUSE ACTION: RECOMMENDATION ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

INTRODUCTION

At the 2001 Annual Meeting, the House of Delegates adopted as amended Resolution 716, "Rescinding Provisions Requiring Physicians to Have Hospital Admitting Privileges," introduced by the Organized Medical Staff Section.

Resolution 716 asked the AMA to work with the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), to rescind the Medicare+Choice provision that required physicians to have hospital admitting privileges (i.e., medical staff membership) on a hospital staff. The language of the original resolution was amended by the reference committee to indicate that, if necessary, the AMA work with the CMS to rescind this provision. An additional resolved clause was also added asking the AMA to work with the American Association of Health Plans (AAHP), the Health Insurance Association of America (HIAA), and other appropriate organizations to rescind provisions requiring physicians to have hospital privileges in order to participate in health plans and report to the House of Delegates at the 2002 Annual Meeting. Physicians should not be required to have hospital admitting privileges as long as they have a plan to facilitate the admittance of patients needing hospitalization.

BACKGROUND

It was noted during the reference committee hearing that AMA had already begun discussions with CMS regarding the subject of Resolution 716. A new Medicare manual was expected soon that would eliminate any CMS-imposed requirement for Medicare+Choice plan physicians to have hospital admitting privileges. It was still uncertain however, whether individual Medicare+Choice plans would be allowed to require admitting privileges of physicians.

AMA staff continued to work with CMS staff on this problem, and on September 12, 2001, CMS published in the Federal Register, CMS-1160-F, "Requirements for the Recredentialing of M+C Organization Providers." These requirements clearly state that Medicare+Choice plans could not require physicians to have admitting privileges in order to participate in their health plans.

> "Not all physicians and other health care professionals have admitting privileges. Health care professionals who have the ability to have admitting privileges may not choose to have them, as they may not manage care in the inpatient setting. However, if a health care professional does have admitting privileges, they are required to list those privileges. *Lack of privileges does not exclude a health care professional from participation in a M+CO*." (emphasis added)

Before addressing the issue of health plans in the private sector requiring physicians to have hospital admitting privileges, numerous organizations and individuals were contacted and/or surveyed in an effort to discern the extent of this practice. The Organized Medical Staff Section (OMSS), sponsor of the original resolution, surveyed its membership regarding problems with health plans requiring physicians to have hospital admitting privileges, but no responses were received. Calls were placed to the Pennsylvania Medical Society (PMS), which had forwarded the original resolution to the OMSS. PMS indicated that the original resolution had only addressed Medicare + Choice plans, and that it had not heard complaints about health plans in the private sector requiring physicians to have hospital privileges for some time. Staff did note that in the past, the commonwealth of Pennsylvania required admitting privileges of all physicians, but as a result of ACT 68 below, this is no longer necessary.

> "Physicians must maintain hospital privileges or an *alternate arrangement for admitting an enrollee*, approved by the plan, that provides timeliness of information and communication to facilitate the admission, treatment, discharge and follow-up care necessary to ensure continuity of services and care to the enrollee." (emphasis added)

RESULTS OF REQUESTS FOR INFORMATION

All state medical associations and several medical specialty societies were surveyed or contacted regarding complaints about this practice by private health plans. Seven state medical associations formally replied to this request for information. Most replies indicated that this practice was not a source of complaints in their state. Several states indicated that some plans in their state do require hospital-admitting privileges for health plan participation. Although staff privileges may be technically required, various types of escape clauses frequently modify this requirement. Physicians are typically given the opportunity to show that they have a plan in place to allow for the hospitalization of their patients, or sign a waiver stating that they will transfer their patient's care to a physician with admitting privileges should a patient require hospitalization. Other similar exemptions from requiring staff privileges vary by health plan. The Medical Society of the State of New York reported anecdotal evidence that connecting physician health plan participation to admitting privileges is fairly common throughout New York, and noted that in past years, this had caused problems for physicians who were at least temporarily denied health plan participation for this reason.

The only active complaint came from the American Academy of Dermatology Association (AADA), which reported a physician that is currently being denied participation in two health plans because he does not have admitting privileges at participating hospitals. The AADA Advisory Board has passed a resolution asking the AADA Board of Directors to oppose any health plan requirement for physicians to have hospital staff membership. AADA has also sent a letter to the two health plans asking them to eliminate this requirement.

Although few instances of physician exclusion from health plans for lack of hospital admitting privileges can be documented, it is clear from the responses that this practice is not well received by most physicians. Many physicians are eligible for staff privileges who choose not to practice in the hospital setting. Physicians, who are primarily office based, often find it unproductive to travel to one or more hospitals where another personal physician or hospitalist is already caring for their patient(s). Physicians in certain specialty practices, such as dermatology, may find that they seldom see patients that need to be hospitalized for conditions closely related to their specialty.

Physicians that do not routinely admit patients may find it difficult to find a hospital willing to grant them privileges. Credentialing physicians can be very expensive, and hospitals may be reluctant to do so knowing that the physician will seldom admit patients. Some hospitals now require substantial fees to maintain hospital staff membership.

Hospitals that grant admitting privileges to physicians, who have a very low inpatient census, may also find it difficult to evaluate those physicians' quality standards that the hospital may require for recredentialing. Many physicians feel that health plans are forcing hospitals to do physician credentialing for the health plans by requiring hospital admitting privileges for plan physicians.

CONCLUSION

Although there appears to be a limited number of physicians who are being adversely affected by health plans requiring their physician participants to have hospital admitting privileges, there are numerous concerns about the wisdom of such a practice. The AMA has, therefore, communicated to the AAHP, the HIAA and the Blue Cross Blue Shield Association of America the concerns contained in this report, urging these associations to encourage their members to refrain from requiring physicians to have hospital admitting privileges. Every state and metropolitan county medical society has also been contacted by AMA and urged them to work with appropriate local health plans to put an end to this practice.

8. IMPAIRED DRIVERS (RESOLUTION 211, A-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 211 (A-01) AND REMAINDER OF REPORT FILED

INTRODUCTION

At the 2001 Annual Meeting, Resolution 211 was introduced by the Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont delegations. It was referred to the Board of Trustees for report back at the 2002 Annual Meeting. It calls on the American Medical Association (AMA) to:

- Adopt as policy that appropriate regulatory agencies have valid testing programs for people suffering from medical conditions that may impair operation of a motor vehicle

- Study legislative and regulatory mechanisms for the development of explicit guidelines to allow physicians, protected by legal immunity, to voluntarily report medical impairments that may cause hazardous motor vehicle operation as defined by the regulatory agency

- Identify educational materials on motor vehicle operation impairment for patients and physicians.

DISCUSSION

Relevant AMA Policy and Activity

AMA Policy H-140.925* (AMA Policy Database), and Ethical Opinion E-2.24, both entitled, "Impaired Drivers and their Physicians," state in part that:

> "....(3) Physicians should use their best judgment when determining when to report impairments that could limit a patient's ability to drive safely. In situations where clear evidence of substantial driving impairment implies a strong threat to patient and public safety, and where the physician's advice to discontinue driving privileges is ignored, it is desirable and ethical to notify the Department of Motor Vehicles. (4) The physician's role is to report medical conditions that would impair safe driving as dictated by his or her state's mandatory reporting laws and standards of medical practice. The determination of the inability to drive should be made by the state's Department of Motor Vehicles. (5) Physicians should disclose and explain to their patients this responsibility to report. (6) Physicians should protect patient confidentiality by ensuring that only the minimal amount of information is reported and that reasonable security measures are

* - AMA Policy H-140.925, cited above and reaffirmed by Recommendation 1, was rescinded at the 2001 Interim Meeting. However, AMA Ethical Opinion E-2.24, also cited above, remains current.

used in handling that information. (7) Physicians should work with their state medical societies to create statutes that uphold the best interests of patients and community, and that safeguard physicians from liability when reporting in good faith."

AMA Ethical Opinion E-10.01 states in part:

"…The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest."

The AMA's Code of Medical Ethics states in part:

"A physician shall...safeguard patient confidences within the constraints of the law."

The House of Delegates considered physicians' responsibility to report impaired drivers to appropriate regulatory agencies at its 1999 Annual Meeting. After initial support for the concept, the House voted to refer the issue to the Council on Ethical and Judicial Affairs (CEJA) for further study. House members were concerned that physicians could be held legally responsible under state medical practice acts if they failed to live up to the ethical obligation. Additionally, there was concern about physicians' ethical and legal responsibility to keep confidential information relating to a patient's medical condition. Similar concerns were expressed at the 2001 Annual Meeting, and the issue was therefore referred to the Board of Trustees.

State Laws and Requirements

Each year in the United States, motor vehicle crashes involving impaired drivers take a staggering toll in terms of lives lost, injuries, and property damage. Despite the progress that has been made, many states believe much still needs to be accomplished to reduce impaired driving and its consequences. To this end, a Department of Motor Vehicles (DMV) or like agency currently exists in every state and is responsible for determining whether or not a citizen is able to safely operate a motor vehicle. State laws, however, vary widely regarding physicians' legal responsibility to report impaired drivers to these agencies. Most states have enacted requirements for reporting of intoxicated drivers, but less than half have enacted laws pertaining generally to impaired drivers.

A state's determination of whether an individual's condition impairs his or her ability to operate a motor vehicle is complicated by privacy concerns of the individual. Although a physician may believe an individual's impairment may render him or her unable to operate a motor vehicle, the physician may be subject to liability for such disclosure to a state agency if the impairment is not one required to be disclosed pursuant to state law. The physician also risks liability in situations where the state does not grant physicians immunity for reporting. Consequently, the physician's ethical duty to report medical conditions that would impair safe driving must be balanced with the state's police power to determine whether the individual is unable to drive safely. States take a variety of approaches in an attempt to achieve such a balance, but most states have incorporated the fundamental tenets of the AMA Ethical Opinions summarized above in crafting statutes and regulations pertaining to reporting requirements and confidentiality in this area.

Mandatory Reporting Laws

According to the United States Department of Transportation, seven states--California, Delaware, Georgia, Nevada, New Jersey, Oregon and Pennsylvania--require physicians to report health conditions that may impair a person's ability to safely operate a motor vehicle. Every state that requires physicians to report conditions that could impair a person's ability to drive also provides immunity from liability for good faith reporting pursuant to the law. For example, Oregon law requires all persons authorized by the state to diagnose and treat disorders of the nervous system to report to the Department of Transportation individuals whose cognitive or functional impairment affects their ability to safely operate a motor vehicle. The report must be submitted on a form prescribed by the Department, crafted in consultation with medical experts. The information contained in the report is considered medical information. It is confidential and must be used only to determine the qualifications of persons to operate a motor vehicle. If a physician or other provider reports in good faith, he or she is immune from civil liability that might otherwise result from making the report.

Some states with mandatory reporting laws, like California, require physicians to report patients suffering from particular afflications. California law requires physicians to submit a confidential report to the county health department when an individual is diagnosed with any type of dementia. This information is forwarded to the DMV, which is authorized to take action against the driving privileges of any individual who is unable to safely operate a motor vehicle. The California DMV then follows specific guidelines in determining whether an individual is impaired. Likewise, New Jersey, Delaware and Nevada require physicians to report patients afflicted with epilepsy and restrict or deny licensure upon a determination that a person is impaired.

Permissive Reporting Laws

Most states with laws related to reporting of impaired drivers permit physicians to report, but do not require them to do so. In the vast majority of these states, physicians who report are protected from liability for good faith reporting. Missouri has thoroughly addressed issues relating to impaired drivers; its law has been hailed as the most comprehensive in the country. Although it does not require physicians to report impaired drivers, it does permit them to do so and specifically provides immunity to physicians who in good faith report an impairment pursuant to state law. Additionally, any report by physicians pursuant to the law is not considered a public record, and confidentiality is therefore preserved. Records may be released only pursuant to court order, of if the decision by the licensing agency is being challenged in court and the records are necessary for the review. Missouri law also includes guidelines for reporting of temporary conditions and steps for reinstatement of licenses following temporary impairment.

Wisconsin is another state that does not mandate physician reporting. Physicians may report concerns about a patient's driving ability to the Wisconsin Department of Transportation, and they do not need consent from the patient to do so. Physicians may report anyone whose physical or mental condition may affect his or her ability to safely operate a motor vehicle, based on the physician's judgment. The Department of Transportation has established a Medical Review Unit (MRU), which receives and reviews reports from physicians. Decisions of the MRU are based on individual signs, symptoms, behaviors and observation. Rather than basing its opinion purely on the medical diagnosis, the MRU considers whether a particular medical condition affects the person's ability to drive. Because reports from physicians to the MRU contain medical information, the report is considered confidential. However, the information is available to the patient/driver.

On the other hand, a number of states with permissive reporting laws do not protect physicians from liability for reporting. In Kentucky, for instance, patients must undergo a medical examination at the request of the state Department of Vehicle Operation. The examination is conducted by a physician, and the results are disclosed to the Department to assist its medical review board in rendering a determination as to an individual's capacity to drive safely. Confidentiality is a concern in this situation. Under Kentucky law, physicians are obligated to safeguard patient confidences pursuant to the patient-physician relationship. No exception exists that would clearly permit a physician to voluntarily disclose a patient's condition. Violation of patient confidentiality may be grounds for revocation of a physician's license under the Kentucky Medical Practice Act. Additionally, laws in Ohio and North Dakota do not specifically insulate physicians from liability for reporting.

Educational Materials and Programs

The National Highway Traffic Safety Administration (NHTSA), which is part of the US Department of Transportation, is the leading authority on impaired drivers. Although the agency defines "impaired drivers" as those impaired by alcohol and/or drug abuse, it recognizes that other serious conditions may impair a person's ability to operate a motor vehicle safely. NHTSA is currently funding and promoting research projects to validate the efficacy of driving assessments and retraining programs; to examine barriers to driving assessments; and to evaluate mobility alternatives. To promote awareness of impaired driver issues, NHTSA has adopted and published a report that highlights topics including reporting high-risk drivers to state authorities. NHTSA has also published patient education materials, including a pamphlet on adapting motor vehicles for people with disabilities.

The American Association of Retired Persons' (AARP) Public Policy Institute has researched issues surrounding safe driving for older persons and has published several reports. These reports are available on the AARP web site and include information on injury prevention. In addition, the AARP directly addresses the needs of older drivers through its brochure (developed jointly with NHTSA), *Driving Safely While Aging*, and its "55 ALIVE" Driver Safety Program, an eight-hour classroom refresher course available to motorists age 50 and older.

The American Automobile Association Foundation For Traffic Safety distributes educational materials for all drivers, including older and special-needs drivers, in the form of brochures, videos, and cd-roms, which can be ordered from its web site. The AAA Foundation also maintains a separate web site specifically for older drivers (seniordrivers.org).

In addition to the materials and programs described above, there are programs for impaired drivers who require active driving rehabilitation. The Association of Driver Rehabilitation Specialists lists 571 rehabilitation specialists/ programs across the US on its web site. Patients, who are mainly referred to these programs by physicians, undergo assessment and rehabilitation from occupational therapists trained in driving rehabilitation or certified driving rehabilitation specialists (CDRS).

AMA Educational Materials and Programs

The first AMA publication on medical conditions of drivers appeared in 1959. This publication, entitled *Medical Conditions Affecting Drivers*, underwent several revisions, most recently in 1986. The publication focused on classifying drivers and scientifically examining medical conditions that might affect a person's ability to safely operate a motor vehicle. It also addressed age and alcohol and other drugs as they relate to driving.

More recently, the Association for Advancement of Automotive Medicine has conducted a systematic literature review and reported its findings in "Medical Conditions and Driving: Current Knowledge." This comprehensive review will shortly be available through NHTSA.

Building on the work of the Council on Ethical and Judicial Affairs report, the AMA is currently preparing new educational materials relating to impaired drivers. The Division of Science, Quality and Public Health, with support from NHTSA, is developing a practical guide for physicians on assessing and counseling older patients on medical fitness to drive. The AMA guide will enhance the physician's ability to assess patients' impairments and safety risk, while helping patients maintain safe driving and independence as late in life as possible. The guide will be based on scientific evidence of driving impairment caused by medical conditions. It will include scientifically-proven assessment strategies, as well as rehabilitation techniques, counseling practices, and patient education materials.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 211 (A-01) and that the remainder of this report be filed:

1. That American Medical Association Policy H-140.925, "Impaired Drivers and Their Physicians," be reaffirmed.

2. That our AMA draft model state legislation allowing physicians voluntarily to report to the Department of Motor Vehicles or like agency individuals afflicted with an impairment that may prevent them from safely operating a motor vehicle, and protecting from liability physicians who report, or based on their best medical judgment do not report, such information to the Department in good faith.

3. That our AMA continue to identify materials that will be beneficial in informing and educating physicians and patients on motor vehicle operation and impairment, including the development by 2003 of a practical guide for physicians on assessing and counseling drivers.

4. That our AMA continue to monitor, collect, and disseminate information on state requirements for reporting of impaired drivers to appropriate regulatory agencies.

Note: AMA Policy H-140.925, cited in this report, and reaffirmed by Recommendation 1, was rescinded at the 2001 Interim Meeting. However, AMA Ethical Opinion E-2.24, also cited in the report, remains current.

9. CONSCIOUS SEDATION REIMBURSEMENT (RESOLUTION 806, I-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 806 (I-01) AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, Resolution 806, "Conscious Sedation Reimbursement," was introduced by the Michigan Delegation and referred to the Board of Trustees. This report responds to and clarifies issues raised in Resolution 806 (I-01), which called on the AMA to recommend that the CPT Editorial Panel consider certain procedures which involve conscious sedation for potential recoding or the utilization or development of appropriate modifiers.

In response to the resolution, this report discusses the current CPT codes for these services, their reporting/ reimbursement application, and the work of the joint Workgroup of the AMA/Specialty Society RVS Committee (RUC) and the CPT Editorial Panel to study and resolve the issue of conscious sedation coding. Finally, recommendations are made.

BACKGROUND

Sedation with or without analgesia (conscious sedation) is used to achieve a medically controlled state of depressed consciousness while maintaining the patient's airway, protective reflexes, and ability to respond to stimulation or verbal commands. Because of the widely variable practices in the reporting of conscious sedation, the CPT Editorial Panel added specific new codes to CPT in 1998 describing conscious sedation services. Historically, many third-party payors limited the use of codes in the anesthesia section of CPT to anesthesiologists or nurse anesthetists only. In 1998, CPT Codes 99141, *Sedation with or without analgesia (conscious sedation); intravenous, intramuscular or inhalation,* and 99142, *Sedation with or without analgesia (conscious sedation); oral, rectal and/or intranasal*, were added to allow for sedation with or without analgesia to be reported by physicians other than anesthesiologists or nurse anesthetists.

The *CPT 2002*, page 306 (standard edition), introductory notes for these codes outlines specific instruction related to the use of these codes and also specifies the services included. For CPT coding, conscious sedation includes performance and documentation or pre- and post-sedation evaluations of the patient, administration of the sedation and/or analgesic agent(s), and monitoring of cardiorespiratory function (i.e., pulse oximetry, cardiorespiratory monitor, and blood pressure).

In addition, the July 1998 *CPTAssistant* instructs:

> "CPT Codes 99141 and 99142 are specific to reporting of conscious sedation for those physicians also performing a simultaneous procedure (e.g., suturing of a child). If the conscious sedation is administered by other than the physician performing the procedure, codes from the anesthesia section should be used. In addition, using these codes requires the presence of an independent trained observer to assist the physician in monitoring the patient's level of consciousness and physiological status.
>
> "The use of the conscious sedation codes requires the presence of an independent trained observer to assist the physician in monitoring the patient's level of consciousness and physiological status. We at the AMA are often asked to provide a definition of an "independent trained observer." The following information from the American Society of Anesthesiologists (ASA) and the American Academy of Pediatrics (AAP) is provided to help clarify this issue.
>
> "The ASA guidelines for sedation and analgesia by nonanesthesiologists indicate that a designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. The individual responsible for monitoring the patient should be trained in the recognition of complications associated with sedation/analgesia. In addition, at least one qualified individual capable of establishing a patient airway and positive pressure ventilation, as well as a means to summon additional assistance, should be present whenever sedation/analgesia are administered. It is recommended that an individual with advanced life support skills be immediately available.

"The AAP guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures indicate that the practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be trained in, and capable of providing, at the minimum, pediatric basic life support; training in pediatric advanced life support is strongly encouraged.

"In the AAP's guidelines, it is also encouraged that the independent trained observer be trained in pediatric basic life support. This individual shall have specific assignments in the event of an emergency, and thus, current knowledge of the emergency care inventory."

DISCUSSION

Resolution 806 (I-01) pertains to the lack of reimbursement for conscious sedation when used to perform painful procedures such as suturing the face of a child or relocating a dislocated shoulder. It asks for the CPT Editorial Panel to consider codes for certain procedures which involve conscious sedation or the utilization or development of appropriate CPT modifiers.

During the Reference Committee hearing testimony was presented that the issue did not involve CPT coding, as there are existing conscious sedation codes, as much as it involved payment policy on the part of carriers. It was also noted that part of the problem in paying for conscious sedation is the difficulty of determining which services currently include conscious sedation as an inclusive part of the service, and which do not.

The Reference Committee was informed that the issue continues to be addressed by a joint Workgroup of the AMA/Specialty Society RVS Update Committee (RUC) and the CPT Editorial Panel to study and resolve the issue of conscious sedation coding.

The RUC previously recommended that 1.) the elements of physician work related to conscious sedation have changed over the past five years; and 2.) the Center for Medicare and Medicaid Services (CMS) allow separate reporting and payment of conscious sedation codes 99141 and 99142 when conscious sedation is NOT inherently included as a component of the physician work of the procedure code. An example would be a laceration repair performed for a child who may otherwise be uncooperative.

The AMA/Specialty Society RVS Update Committee (RUC) Conscious Sedation Workgroup met on August 1, 2001, and again at the February 2, 2002, RUC meeting, and reaffirmed its recommendation to the RUC that:

"The general approach to the conscious sedation issue should be to retain the conscious sedation services as bundled into the procedure only where it is an inherent part of the service. Separate reporting and payment of conscious sedation codes 99141 and 99142 should be allowed when conscious sedation is not inherently included as a component of the physician work of the procedure."

The Workgroup agreed that the next step in the process of determining appropriate payment for conscious sedation services is to identify which CPT codes describe services where conscious sedation is an inherent component of the procedure (e.g., gastrointestinal endoscopy). The workgroup is also interested in identifying which codes may require conscious sedation, but for which it is not a necessary component of the service (e.g., laceration repair for a child).

The process to identify these services will rely on specialty society review of the services performed by their members. Specialty societies may use the RUC database as a tool to identify codes in which conscious sedation is specifically mentioned in the description of physician work. The direct practice expense data may also indicate specific supplies related to conscious sedation.

CONCLUSION AND RECOMMENDATIONS

Specialty societies will provide a list of codes in which conscious sedation is an inherent component and another list of codes where conscious sedation may be utilized. The Conscious Sedation Workgroup will then review the compilation of both lists at the April 2002 RUC meeting.

The Workgroup agreed that the issues related to relative value evaluation and any changes to CPT code descriptors should be discussed after the specific lists of CPT codes have been developed.

The Board of Trustees recommends adoption of the following recommendations in lieu of Resolution 806 (I-01), and that the remainder of this report be filed:

1. That the Workgroup of the American Medical Association/Specialty Society RVS Update Committee and the CPT Editorial Panel continue to study and resolve the issue of conscious sedation coding.

2. That our AMA vigorously advocate for appropriate payment of CPT conscious sedation codes.

10. SMALLPOX VACCINATION: FEDERAL PLANNING EFFORTS

HOUSE ACTION: FILED

At the 2001 Interim Meeting, the Florida Delegation introduced Resolution 410, "Urgent National Vaccination for Smallpox." As amended and adopted the resolution calls for our American Medical Association (AMA) to "encourage federal health authorities to evaluate the risks and benefits of pre-exposure vaccination of the US population for smallpox and to continue planning for mass vaccination of the population if determined to be necessary." In addition, the Reference Committee added the following language, which was also adopted:

> RESOLVED, That the AMA Board of Trustees ensure that physicians are routinely updated on smallpox-related issues through the AMA's communication tools, that a report be prepared for the 2002 Annual Meeting on the status of federal planning efforts, and that a report on scientific matters be prepared for the 2002 Interim Meeting.

This informational report provides the requested report on federal planning efforts related to smallpox. A scientific report will be forthcoming at the 2002 Interim Meeting in New Orleans, and other actions called for by the resolution are addressed in other venues.

CURRENT RECOMMENDATIONS FROM THE ACIP

The focus of activity on smallpox-related immunization issues is the Advisory Committee on Immunization Practices (ACIP). In June 2001, the Centers for Disease Control and Prevention (CDC) published the ACIP's recommendations regarding vaccination for smallpox in the *Morbidity and Mortality Weekly Report* (*MMWR* 2001;50,RR-10). The recommendations were published because of growing concerns about the intentional use of smallpox as a bioterrorist agent.

Because the likelihood of the intentional release of smallpox is considered low and the population at risk is impossible to determine, the ACIP recommended continued surveillance and prompt reporting of suspected cases to local or state health officials as the primary mechanism to address the concern. Prerelease vaccination (ie, vaccination before the release of smallpox) was not recommended because the ACIP assessed the risk for exposure as low and argued that the benefits of vaccination were outweighed by risks of complications from vaccine administration, which are relatively common.

At the same time, the ACIP indicated that if the potential for a smallpox release increased, pre-attack vaccination might be indicated for selected groups who would have an identified higher risk for exposure because of work-related contact with smallpox patients or infectious materials. The ACIP also made recommendations for vaccination following an intentional release of smallpox and the vaccination of personnel involved in the care of patients and support of response activities. In general, the plan follows the surveillance and containment strategy that successfully eradicated naturally occurring smallpox from the world more than two decades ago. That is, in the event of a confirmed case of smallpox, special response teams would vaccinate individuals who had been in contact with the case, generally moving out in concentric rings centered on the index case(s).

ACTIVITY AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

In November 2001, the US Department of Health and Human Services announced the award of a contract to produce 155 million doses of smallpox vaccine by the end of 2002. The combination of these new doses with existing and other newly developed supplies will bring the total number of doses in the smallpox vaccine stockpile to 286 million, enough to protect every US citizen in the event of an outbreak of smallpox.

The vaccine will be produced by Acambis and Baxter using a purified strain of vaccinia virus grown in live tissue culture. (The etiological agent of smallpox is the variola virus, but smallpox immunity is conferred by vaccination with the related vaccinia virus.) The Food and Drug Administration will conduct a review of each vaccine production process along with testing of individual test lots of vaccine to assure the safety and effectiveness of the vaccine. The cost per dose of vaccine is $2.76.

An existing supply of 15.4 million doses of the Dryvax® smallpox vaccine has been stored since vaccine production ended in 1983, and it remains potent. The National Institute of Allergy and Infectious Diseases at the National Institutes of Health has been studying the possibility of diluting this supply of vaccine by a ratio of as much as 1 to 10 as a means of extending the supply. Early results indicate that the diluted vaccine produces a successful reaction in more than 97% of cases, which essentially will expand the existing Dryvax® vaccine supply to as many as 154 million doses. (It should be noted that even the undiluted vaccine does not result in 100% response.) Results from these studies were published in the *New England Journal of Medicine* on April 25, 2002.

Additionally, in late March, Aventis Pasteur donated some 85 million doses of smallpox vaccine that had been in frozen storage for more than 40 years. (The 15.4 million doses of Dryvax® vaccine were produced in the late 1970s and early 1980s.) Preliminary tests on the Aventis vaccine indicate that it has retained its potency and effectiveness. Because this vaccine was produced using old methods--it was grown on the skin of live calves--federal officials regard this new supply as more an insurance policy than a substitute for the vaccine to be supplied by Acambis and Baxter.

JOINT FEDERAL AGENCY ACTIVITY

Work on smallpox issues is ongoing in a number of health agencies within the federal government. "Smallpox Outbreak Response Plan and Guidelines" is available on the CDC web site and is undergoing review, and public forums have been held in New York, San Francisco, San Antonio and St. Louis to solicit public comment (the forums were held between June 6 and June 11, 2002). The plan will coordinate CDC, state, and local public health activities should a smallpox release occur, and it will help health officials define and control the outbreak. Information on the site will help health care providers become familiar with the disease and the vaccine that eradicated it (http://www.cdc.gov/nip/smallpox; Accessed June 12, 2002). The CDC web site is regularly updated.

To address ongoing concerns about a release of smallpox, the ACIP is reviewing its 2001 recommendations, and the ACIP and the National Vaccine Advisory Committee have formed a joint working group on bioterrorism preparedness. The working group includes the CDC, the National Institutes of Health, the Health Resources and Services Administration, the FDA, the Office of Emergency Preparedness, and state public health officers, as well as medical specialty societies such as the American Academy of Pediatrics and the American Academy of Family Physicians. Our AMA also is represented on the working group.

This working group is addressing four specific questions:

1. Should there be any change in the current recommendation for the pre-attack vaccination of the general population? That is, with no known cases of smallpox worldwide, should routine vaccinia (smallpox) vaccination be reintroduced in the United States? Should this recommendation be dependent or modified based on the supply of vaccinia vaccine (or the availability of a licensed vaccine vs. an Investigational New Drug [IND] vaccine)?

2. As part of smallpox preparedness, should public health and medical personnel identified as early responders be vaccinated at the federal, state or local level? If such persons should be vaccinated, what guidelines should be used to determine those categories of responders to vaccinate? Should this recommendation be dependent or modified based on the supply of vaccinia (smallpox) vaccine (or the availability of a licensed vaccine vs. an IND vaccine)?

3. Are there new data that would change the current recommendation for "ring" vaccination as the strategy of choice for the control of smallpox, along with the vaccination of personnel involved in the expanded smallpox response effort generated by such a release?

4. Other questions may be raised during the review process. One has to do with the results of the Dryvax® dilution studies and what amount of diluent should be used to reconstitute the vaccine for vaccination and revaccination. Another is whether there are circumstances during the response to a smallpox attack where jet injectors might be used to deliver vaccinia vaccine?

The working group had its first conference call in March 2002, and held a face-to-face meeting during the month of May. The Department of Health and Human Services has asked ACIP to provide updated recommendations on June 20, but announcement of those recommendations will likely come after the House of Delegates meeting adjourns. Official publication of the recommendations will follow thereafter.

SUMMARY

Federal planning efforts to address the possible intentional release of smallpox are ongoing in a number of federal agencies, and most of this work is being coordinated by a multi-agency working group. By late 2002, additional scientific data should be available with which the Council on Scientific Affairs can help formulate additional policy as called for in Resolution 410 (I-01). In the interim, ACIP recommendations will be released just after the House of Delegates meeting. If comment is sought from the medical community, our AMA will respond to the recommendations as required, following consultation with the Federation and other appropriate groups and experts.

11. INFLUENZA VACCINE AVAILABILITY: AN UPDATE ON AMA ACTIVITIES

HOUSE ACTION: FILED

At the 2001 Interim Meeting, Board of Trustees Report 28, "Influenza Vaccine Delays and the 2001-02 Influenza Season: Update," was adopted by the House of Delegates. This comprehensive report provided an update on our American Medical Association's leadership role in addressing problems associated with influenza vaccine production, delivery, and administration in the 2001-02 influenza season. It recommended that our AMA continue to work with the Centers for Disease Control and Prevention (CDC), other federal agencies, and other stakeholders involved in the production, distribution, and administration of influenza vaccine to: (1) resolve the specific problems (i.e., distributors engaging in price inflation, mass vaccinators who do not comply with Advisory Committee on Immunization Practices [ACIP] recommendations, and inadequate Medicare/Medicaid reimbursement) identified in the implementation of the plan to address influenza vaccine delays in 2001-02; and (2) address the long-term goal of adequate vaccine supplies to meet Healthy People 2010 goals.

Following debate at the House of Delegates, an additional recommendation was added to BOT Report 28-I-01 asking that the"AMA Board of Trustees report back to the House of Delegates at the 2002 Annual Meeting regarding the current status of our AMA's activities to address issues of price instability, vaccine availability, and liability related to the flu vaccine." This informational report responds to that request.

SUMMARY OF AMA ACTIVITIES IN THE 2001-02 INFLUENZA SEASON

In collaboration with the CDC, our AMA convened two separate roundtable meetings of all stakeholders to address the delay in vaccine delivery and to coordinate the communication of accurate, timely and consistent messages to physicians and their patients. Considerable success resulted from the efforts made by the AMA, the CDC, and other influenza vaccine stakeholders. Generally, vaccine available in October 2001 was prioritized to high-risk individuals, as physicians and mass vaccinators made a concerted effort to target these individuals in October and lower risk individuals in November. Supplemental ACIP recommendations advocating this tiered approach were released much earlier than in the 2000-01 season (when there were significant problems with vaccinating the high-risk populations) and they were much better communicated to health care professionals, facilitating better compliance. Communication from our AMA to physicians was achieved by multiple means, including the AMA's comprehensive web page on the 2001-02 influenza season, the use of print and media releases, and the use of AMA's email and print communication vehicles. The CDC also created an influenza-specific web site that provided the latest information on the 2001-02 influenza season and currently provides the latest information on the 2002-03 influenza season. As a result of these efforts, the uneven allocation of vaccine of the 2000-01 season was not as dramatic in 2001-02 despite the delay in delivery of almost 50% of the 2001 influenza vaccine doses until November and December.

However, some problems were identified during the 2001-02 influenza season. These include: (1) the delayed shipment from one manufacturer; (2) unexpected consequences from the new distribution system implemented by the manufacturers (particularly with respect to shipments to physicians serving exclusively higher risk patients); (3) timely publication and adoption of the annual Medicare payment rate for influenza vaccine; (4) reports of price gouging in October 2001 by a limited number of "rogue" distributors; (5) the failure of vaccination to continue beyond November, resulting in more than 10 million unused doses of flu vaccine; and (6) reports of some mass vaccinators not adhering to the July 13, 2001, supplemental ACIP recommendations.

Our AMA and the CDC worked together to address some of these problems, but in the evolving situation surrounding influenza vaccine, continued cooperation and communication among all stakeholders are essential to overcome the problems identified in the 2001-02 influenza season. Indeed, due to the efforts of and suggestions from the AMA, CDC, and other stakeholders, some very significant changes have already occurred for the 2002-03 influenza season. Two of these are the significant changes that will be made to the 2002-03 ACIP recommendations for influenza vaccination and the early advice to physicians to order vaccine earlier than in previous years.

The New 2002-03 ACIP Influenza Recommendations. In the past two influenza seasons, the ACIP has issued its influenza recommendations in April and then issued supplemental recommendations when it became clear that a delay in shipment of the vaccine was going to occur. These supplemental recommendations urged a tiered approach to vaccination; i.e., that high-risk populations be given priority for vaccination in the month of October and that low-risk individuals be deferred until November and December. These recommendations also advised vaccinating patients, especially those at high risk and in other target groups, in December, and that vaccination should continue as long as there is influenza activity and vaccine is available. However, at the end of November it became clear that influenza vaccination was declining and thus on December 3, 2001, the CDC issued a letter urging that health care professionals continue to offer influenza vaccine throughout the month of December and beyond for as long as vaccine was available.

At its February 20, 2002, meeting, the ACIP took a significant step toward addressing the problem of influenza vaccine supply by acknowledging that it is no longer reasonable to expect most influenza vaccine doses to be distributed by the end of September. This is because of the finite time frame during which vaccine components must be identified and vaccine produced, tested, approved, and distributed (detailed in BOT Report 36-A-01), and because vaccine production levels are at the highest levels in history (93 million doses are projected for the 2002-03 season).

As such, the ACIP voted to prioritize vaccination efforts in October and earlier to target persons at high risk of complications from influenza; health care workers; and children under 9 years of age with a high-risk condition who are receiving vaccine for the first time (prioritized because they need a booster dose one month after the initial dose). Our AMA will work towards ensuring that those physicians who care for these high risk populations receive vaccine in time to achieve the goals of these current ACIP recommendations. All other groups, including household members of high-risk persons, healthy persons aged 50-64 years, and others who wish to decrease their risk of influenza infection should begin vaccination in November. In particular, the ACIP states:

> This strategy was initiated during the last two influenza seasons because of significant vaccine distribution delays and is being continued for the 2002-03 influenza season because of the possibility of similar situations in future years and to provide continuity in the recommendations.

Additionally, the ACIP voted to encourage when feasible, influenza vaccination for healthy children aged 6 months to 23 months because children in this age group are at substantially increased risk for influenza-related hospitalizations. A recommendation to annually vaccinate healthy children aged 6 months to 23 months is expected within the next one to three years. Household contacts and out-of-home caregivers of children 0 to 23 months of age are also now encouraged to receive influenza vaccine in order to decrease the risk of contacts transmitting influenza virus to these children.

The new 2002-03 ACIP recommendations will also encourage the use of influenza vaccine after November, as many people who should or want to receive influenza vaccine remain unvaccinated after that time. Substantial amounts of vaccine have remained unused during the past two influenza seasons, and extended vaccination efforts after November are needed to decrease illness and to ensure full use of vaccine supplies. It is believed that vaccine

received after November is likely to be beneficial in most influenza seasons, as influenza activity has not peaked until late December through early March in the majority of recent seasons. Adults develop peak antibody protection against influenza infection 2 weeks after vaccination.

Early Ordering of Influenza Vaccine. On February 26, 2002, the CDC released its first Influenza Bulletin for the 2002-03 season. In this bulletin, the CDC urged all physicians to begin ordering their influenza vaccine immediately to ensure their supply for the 2002-03 season. The bulletin listed the ordering information for all three manufacturers of influenza vaccine in the United States and indeed, warned that in the 2001-02 season, vaccine was totally pre-booked by May. The AMA distributed this bulletin to its membership via the Federation and also posted it on the AMA's Home Page for a week following its release. Additionally, the information in the bulletin was the subject of an *AMNews* article published March 25, 2002 (available at: www.ama-assn.org/sci-pubs/amnews/pick_02/hlsa0325.htm). To ensure that vaccine is available, physicians should order it early, beginning in March.

UPCOMING AMA ACTIVITIES ON INFLUENZA VACCINE FOR THE 2002-03 INFLUENZA SEASON

The AMA-CDC Influenza Summit. Our AMA convened another Influenza Summit in collaboration with the CDC on May 22-23, 2002, in Atlanta, Georgia. The purpose of this summit was to address the problems that were identified as the 2001-02 influenza season progressed. All stakeholders from the previous two influenza vaccine summits were invited (see BOT Report 36-A-01 and BOT Report 28-I-01) as well as other appropriate stakeholders that were not at the previous summits. These new stakeholders included the American Hospital Association, the American Association of Health Plans, and other interested state medical societies.

To facilitate action from all stakeholders participating at the summit, the AMA and the CDC organized five workgroups to address five problematic areas identified during the 2001-02 season. These were: (1) reimbursement; (2) communications; (3) distribution; (4) mass vaccination; and (5) occupational health and businesses (almost 20% of influenza vaccine is administered in businesses to healthy individuals as part of an employer influenza vaccination program).

The working groups' presentations outlined the issues, problems/concerns, and questions related to that group's specific topic area. In addition, the presentation included suggested next steps, recommendations, and proposed solutions to address the issues that clearly remain challenges and will require further attention to resolve. Following presentation of the report, a professional facilitator led the entire group in a discussion of the area and the issues to reach an agreement among the stakeholders about the actions that need to be taken to address the identified problems. It is anticipated that the working groups will remain together to work on the issues that have been identified and agreed upon by the stakeholders at the summit, and on any new ones that may arise around each group's topic area. It is not expected that the working groups will implement the recommendations that arose from the May 2002 summit, but rather that they will facilitate implementation of the recommendations by maintaining the momentum initiated at the meeting. As this influenza season proceeds, if it is determined that one or more emerging topic areas need attention, additional working groups will be formed.

The California Medical Association Influenza Summit. The AMA participated in the CMA's Influenza Summit held on May 13, 2002. This Summit addressed many issues similar to those examined at the national summit and information learned from California's experiences was extremely useful at the national discussion.

Continued Communication to Physicians. Our AMA will continue working with the CDC and other stakeholders to communicate information about influenza vaccine for the 2002-03 influenza season. Our AMA will reestablish a comprehensive web page for physicians on the 2002-03 influenza season at www.ama-assn.org/ama/pub/article/1826-4907.html (currently this web site reflects information on the 2001-02 season). Among the information that will be placed on this web page are the new ACIP influenza recommendations, the CDC flu bulletins, any CDC-produced patient education materials, a list of state contacts, and information about Medicare reimbursement. The web page will be updated as necessary.

In addition, our AMA will continue to use other mechanisms to keep physicians informed about influenza vaccine for the 2002-03 season. For urgent CDC messages, our AMA will send blast emails to the Federation and to those AMA members for whom the AMA has an email address. Our AMA will continue to hold conference calls with the CDC, the American Academy of Pediatrics, the American College of Physicians-American Society of Internal

Medicine, and the American Academy of Family Physicians to coordinate and communicate appropriate information to respective members. As mentioned above, this has already happened for distribution of the first influenza bulletin and the information on ordering vaccine early.

Finally, as in the 2001-02 influenza season, the AMA will continue to provide information to the media on the importance of targeting the high-risk population first and encouraging the healthy population to defer influenza vaccinations to November and December, consistent with the new ACIP recommendations.

STATUS OF INFLUENZA VACCINE AVAILABILITY FOR 2002-03 INFLUENZA SEASON

As of mid March 2002, the influenza vaccine production schedule was in its early stages. Preliminary information from the three primary producers of influenza vaccine in the United States (Aventis-Pasteur, Wyeth-Lederle, and Evans Vaccines) suggests that more influenza vaccine will be available in the 2002-03 influenza season than in the 2001-02 season. Projected distribution of influenza vaccine for 2002-03, based on aggregate manufacturers' estimates as of February 20, 2002, is between 88 and 93 million doses. These early projections could change as the season progresses.

Selection of 2002-03 trivalent vaccine virus strains was completed on March 6, 2002. The influenza A(H1N1) and A(H3N2) strains for the 2002-03 influenza vaccine will be the same as 2001-02. The influenza B strain is a new strain, B/Hong Kong/330/2001-like, and is based on data regarding surveillance of the B strain expected to circulate in the United States this season. Manufacturers will select an antigenically similar strain for the B component of the 2002-03 influenza vaccine based on its growth characteristics.

Only one manufacturer has announced its prebooked pricing for the 2002-03 vaccine. Two manufacturers began taking orders in March and the third started taking orders in early April.

THE FUTURE OF THE INFLUENZA VACCINE SUPPLY

As discussed in BOT Report 28-I-01, production and distribution of the influenza vaccine in the United States is a free market system and currently, production and sale of influenza vaccine does not generate significant profits for the manufacturers involved. To achieve the goals of Healthy People 2010 for influenza vaccination, more doses than are currently being produced will be needed. Efforts must be made to increase the number of manufacturers involved in the production of the influenza vaccine and to increase the capacity of existing manufacturers to produce even more vaccine.

BOT Report 28-I-01 also stated that “it may no longer be reasonable to expect that all influenza vaccine will be delivered by the end of November, let alone the end of October....As such, the ACIP and the CDC must address whether future recommendations should reflect this new reality.” This indeed has occurred with the new 2002-03 ACIP recommendations for influenza vaccination. The important consequence of these new recommendations should be a gradual shift in the expectations of the public and health care professionals who administer influenza vaccine away from the current belief that influenza vaccine should be administered only in October, to a realization that it can and should be administered through the end of December. This would provide more opportunities for vaccination to achieve Healthy People 2010 objectives and also provide a longer production period for the manufacturers of influenza vaccine.

The influenza vaccine situation continues to evolve. Therefore, continued improvement in the communication between all stakeholders will be required to ensure that physicians remain informed about the most current status of the influenza vaccine and the reasons behind potential delays and shortages. Communications to both physicians and the public regarding the new expectations for the timing of influenza vaccine distribution and administration will substantially decrease the number of doses of unused vaccine left on the shelves of physicians, distributors, and manufacturers. Additionally, this will help to achieve Healthy People 2010 goals for influenza vaccination.

Finally, reimbursement issues with respect to influenza vaccine must be addressed. Physicians cannot be expected to lose money when administering the vaccine. Specifically, reimbursement must more accurately reflect what physicians are paying to distributors for the vaccine and not be based solely on the price quoted by the manufacturers.

12. UPDATE ON AMA ACTIVITIES WITH HEALTH CARE ACCREDITATION ORGANIZATIONS

HOUSE ACTION: FILED

INTRODUCTION

In response to Policy H-220.957 (AMA Policy Database), at each Annual and Interim Meeting the American Medical Association Board of Trustees reports to the House of Delegates on the AMA's activities with other health care accreditation organizations.

This report provides information on activities of the American Accreditation HealthCare Commission (AAHCC/URAC), which continues to use the acronym URAC in reference to its original name as the Utilization Review Accreditation Commission; COLA (formerly the Commission on Office Laboratory Accreditation); the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); and the National Committee for Quality Assurance (NCQA).

This report also provides information on the status of the resolutions and reports that were adopted at the 2000 and 2001 Interim Meetings and 2001 Annual Meeting, and that were referred to the appropriate accrediting organizations. Information regarding joint activities of the AMA, NCQA, and JCAHO related to performance measurement is included in another informational report submitted to the House at the 2002 Annual Meeting.

DISCUSSION

American Accreditation HealthCare Commission (AAHCC/URAC)

The AMA continues to successfully advocate AMA policy by participating in the development of AAHCC/URAC standards. URAC is a leader in the accreditation of health and managed care organizations. Founded in 1990, URAC currently offers 13 accreditation programs. It has issued more than 2,000 accreditation certificates to more than 500 health care programs since its inception. URAC-accredited organizations conduct business in all 50 states and provide services to more than 120 million Americans.

The AMA has been represented on the URAC Board of Directors since 1991 and is currently represented by Ardis D. Hoven, MD, a member of the Council on Medical Service. URAC periodically updates all its accreditation standards to promote continuing improvement in health care. The AMA is participating in the review and revision of the following URAC standards:

Claims Processing Standards: The URAC Board of Directors approved standards for the first-ever national claims processing accreditation program in November 2001. Through its representation on the URAC Claims Processing Advisory Committee, the AMA actively participated in the development of these standards, which address several key functions, including: the timeliness of the claims process, claims protocols, appeals processes, communications to claimants, staff training, and infrastructure. By establishing requirements for the administrative side of the claims process, these standards serve as a counterpart to URAC's Health Utilization Management Standards, which focus on clinical decision-making. URAC also developed these standards to co-exist with the claims regulations issued by the Department of Labor in November 2000.

Health Utilization Management Standards: The URAC Board of Directors approved the next generation of the Health Utilization Management (UM) Standards in December 2001. URAC's Health UM accreditation program is the largest and most recognized program of its type in the United States. The standards apply to a variety of health care organizations, including "stand-alone" UM organizations, as well as UM functions within health benefits programs, such as indemnity insurance, health maintenance organizations, or preferred provider organizations.

Through its representation on the URAC Health Standards Committee, the AMA actively participated in updating the Health UM standards to reflect the evolution of best practices, as well as to respond to changes in the health care environment. Important changes in the new standards include: the addition of URAC's Core Standards, which will enable URAC to move toward a fully modular accreditation system; the implementation of a new scoring methodology, which will improve feedback to applicants and enhance inter-rater reliability; standards that cover a

broader range of electronic or automated UM processes, such as web-enabled pre-authorization processes; more specific guidance for cases where the patient/provider does not submit adequate information to conduct a review; and language that is consistent with the November 2000 Department of Labor claims regulations, which address utilization review processes.

Disease Management Standards: In December 2001, URAC released a draft set of Disease Management Standards for public review and comment. As part of the development process, URAC also will test the draft standards at three to four disease management organizations of various types. URAC solicited interested organizations to participate in the beta site process in November 2001. When completed in the spring of 2002, the new standards will be available to accredit the full spectrum of organizations providing disease management. These organizations include stand-alone disease management organizations, disease management programs offered by integrated medical management organizations, and programs offered by health plans.

URAC's Disease Management Standards, which are being developed with guidance from a national advisory committee, are designed to promote best practices in a health management strategy for individuals with chronic diseases. The standards emphasize evidence-based practice, collaborative relationships with providers, consumer education, and shared-decision making. Specific standards address key areas of accountability such as: the scope and interventions offered by the disease management program; the types of performance measures and methods for measurement used by the disease management program; rights and responsibilities of participants; methods for population management, including stratification and engagement; and disease management program design, including assessment and education of participants. The Disease Management Standards also build on and include URAC's Core Standards, which address functions and issues common to all health care organizations.

Case Management Organization Standards: The Health Standards Committee is currently updating URAC's Case Management Organization Standards. URAC specifically designed these standards for organizations that provide telephonic or onsite case management services in conjunction with a privately or publicly funded benefits program. The standards cover several categories, including: staff structure and organization, staff management and development, information management, quality improvement, oversight of delegated functions, organizational ethics, and complaints. URAC released a draft set of revised Case Management Organization Standards for public review and comment in December 2001 and expects to release the revised standards in the spring of 2002. The most significant revisions in the draft standards involved the "modularization" of URAC's Case Management Organization Accreditation program. The Case Management Organization Standards now build on and include URAC's Core Standards.

Clinical Triage and Health Information Standards: The Health Standards Committee also is in the process of revising URAC's Clinical Triage and Health Information Standards (formerly known as Health Call Center Standards) to reflect the continuing evolution of telephonic triage services and to improve the value and efficiency of the accreditation process. URAC released for public comment a draft version of the next generation of these standards in January 2002 and plans to release the final revisions in mid-summer of this year. For this version, URAC adopted new strategies, most notably a new scoring methodology and a modular accreditation system, to improve the accreditation process.

Independent Review Organization Standards: In addition, the Health Standards Committee is currently in the process of updating URAC's Independent Review Organization Standards (formerly known as External Review Organization Standards). URAC released a draft version of the next generation of these standards for public comment in February 2002 and plans to release the final revisions in mid-summer of this year. Specific changes in the draft standards include: integration with URAC's Core Standards, implementation of a new scoring methodology, more specific interpretive language, and expansion of the scope of the standards to encompass administrative and legal review, as well as clinical issues.

COLA (FORMERLY THE COMMISSION ON OFFICE LABORATORY ACCREDITATION)

The AMA is represented on the COLA Board of Directors by Herman I. Abromowitz, MD, J. Edward Hill, MD, and Veronica C. Santilli, MD. COLA's major focus has been on its 2001 strategic business plan and internal operations, which include research and development of new products other than laboratory accreditation, product line extensions, and process innovations. COLA's Practice Site Services include: credentialing site reviews, Medicaid chart and site reviews, custom medical record reviews, and Health Employer Data and Information Set (HEDIS®) chart abstraction services.

COLA also introduced "LabUniversity," a distance learning program that currently has five course offerings. The courses are recognized by the University of Wisconsin Medical School for Category 1 CME credit.

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO)

The AMA is represented on the JCAHO Board of Commissioners by Ronald M. Davis, MD, Joseph T. English, MD, Timothy T. Flaherty, MD, Richard S. Frankenstein, MD, Donald J. Palmisano, MD, JD, J. James Rohack, MD, and Richard B Tompkins, MD.

Disposition of 2000 and 2001 Resolutions and Report Recommendations: The following resolutions and report recommendations from the 2000 Interim Meeting were transmitted to the JCAHO following that meeting:

- Recommendation 3, Council on Scientific Affairs Report 11 - Medical Preparedness for Terrorism and Other Disasters
- Recommendation 4, Council on Medical Service Report 5 - Physicians' Experiences with Retrospective Denials of Payment and Down-Coding by Managed Care Plans
- Recommendation 5, Council on Medical Service Report 6 - Mental Health "Carve-Outs"
- Recommendations 3 and 4, Council on Medical Service Report 7 - Hospital Mergers Study
- Substitute Resolution 802 - HCFA Seclusion and Restraint Rule
- Substitute Resolution 803 - A Physician as a Patient Safety Officer in a JCAHO Approved Health Care Facility

The JCAHO Board of Commissioners referred these resolutions and recommendations to the Standards and Survey Procedures (SSP) Committee. The SSP Committee referred them to the appropriate Professional and Technical Advisory (PTAC) Committees for recommendations on disposition. The recommendations of the PTACs were reviewed by the SSP Committee and action was taken at the October 2001 SSP Committee meeting. The AMA has representatives on the SSP Committee and on each of the six PTACs.

The full text of the resolutions and report recommendations and the JCAHO response are presented in Appendix A. Appendix A.1 [available from the Department of Clinical Quality Improvement] is a JCAHO attachment to its response to Recommendation 5 of Council on Medical Service Report 6-I-00.

The following resolutions and report recommendations from the 2001 Annual and Interim Meetings were transmitted to the JCAHO following the respective meetings:

- Recommendation 1, Council on Scientific Affairs Report 4-A-01 - Update: Medical Preparedness for Terrorism and Other Disasters
- Resolution 812 (A-01) - Cooperation Between AMA and JCAHO Regarding Credentialing and Privileging Standards
- Substitute Resolution 805 (I-01) - JCAHO Proposed Standard Implementation Cost and Impact
- Substitute Resolution 807 (I-01) - Physician Involvement in Disaster Preparedness

The full text of the resolutions and the report recommendations were transmitted to JCAHO and are awaiting response from JCAHO, as presented in Appendix B.

Field Evaluation of Proposed Standards and Standards Revisions: The JCAHO conducted field reviews of proposed standards and standards revisions in the following areas: disease management certification, long term care, medication use, network, assisted living, and patient safety. The AMA provided comments, based on AMA policy, on these proposed standards and standards revisions.

Critical Access Hospital Accreditation: The JCAHO launched an accreditation program for critical access hospitals in November 2001. The JCAHO is seeking deemed status for the program from the Centers for Medicare and Medicaid Services.

Disease-Specific Care Certification Program: In February 2002, the JCAHO launched a disease-specific care certification program. The certification program requires: compliance with consensus-based national standards; the effective use of established clinical guidelines to manage and optimize care; and the measurement and improvement of health processes, outcomes, and perceptions of care. The program is designed to evaluate disease management and chronic care services that are provided by health plans, disease management service companies, hospitals, and other care delivery settings. Standards address the various aspects of the disease-specific care model, and include delivering or facilitating clinical care, performance measurement, supporting self-management, program management, and clinical information management.

The JCAHO has established a Certification Advisory Committee on Disease-Specific Care Certification to advise and provide guidance in support of the program and to make recommendations to the Joint Commission regarding finalized certification modules. The AMA is represented on the Advisory Committee by Richard Hellman, MD, an internist who specializes in endocrinology, diabetes, and metabolism. Doctor Hellman is a member of the AMA Consortium for Performance Improvement and co-chairs The Consortium's work group on depression.

Services that apply for diabetes care certification will have one year to implement a subset or all of the core measures published in *Coordinated Performance Measurement for the Management of Adult Diabetes*. The core measures contained in this publication were collaboratively developed by the AMA, the JCAHO, and the NCQA. As agreement and consensus is reached on sets of core measures for other conditions, these sets will be announced and subsequently integrated into the performance measurement activities of the certified disease-specific programs and services.

Standards Review Project: The JCAHO has established a national task force to review existing hospital standards and documentation and compliance requirements. A separate Medical Staff Standards Review Task Force was established to review the Medical Staff chapter and other standards related to the medical staff and physicians. The AMA is represented on this task force by Carol L. Bayer, MD, and Stephen T. House, MD. The task forces are charged with: reviewing existing JCAHO standards, scoring guidelines, documentation requirements, and survey process; and identifying opportunities to modify or eliminate standards and reduce the burden of compliance. The criteria used to evaluate the standards are: relevance in promoting patient safety and improving quality and outcomes; redundancy with other standards, laws, and regulations; applicability to the hospital program; clarity of the standard and associated documentation requirements; and likelihood that compliance will be consistently scored. Review by the task forces is scheduled for completion in June 2002. The proposed changes will be reviewed by the Hospital Professional and Technical Advisory Committee and the Standards and Survey Procedures Committee, and revisions will be reflected in the 2004 *Comprehensive Accreditation Manual for Hospitals*.

Accredited Organization Performance Reports: The JCAHO Board of Commissioners approved a plan to revise the performance reports of all types of accredited organizations. The timeline for the completion and implementation of the report revision extends through mid-2004. In addition to basic accreditation status information, the revised report will include the following sections: patient safety management profile, national patient safety goals, quality assessment and improvement profiles, national quality improvement goals; and profiles regarding other important aspects of care.

Annual Joint Commission Patient Safety Goals: The JCAHO Board of Commissioners approved the establishment of annual Joint Commission patient safety goals. By July of each year, the JCAHO will select six patient safety goals for which recommendations are available in the expert/evidence-based pool. No more than two recommendations will be selected for each goal. Beginning January 1 of the ensuing year, organizations providing care relevant to the patient safety goals will be surveyed for compliance with the applicable recommendations. Non-compliance would result in a Type 1 recommendation.

JCAHO Corporate Members Planning Group on Patient Safety: The Corporate Members Planning Group on Patient Safety's charge is to identify and propose collaborative patient safety projects among the parent organizations: American College of Physicians-American Society of Internal Medicine, American College of Surgeons, American Dental Association, American Hospital Association, AMA, and the Joint Commission. The AMA is represented on this Group by Timothy T. Flaherty, MD, and Donald J. Palmisano, MD, JD.

Strategic Issue Work Groups: In early 2001, the JCAHO Board established five strategic issues work groups: Patient Safety, Improving the Value of Accreditation, Information Dissemination, Physician Engagement, and Impact of Accreditation.

The Physician Engagement Work Group established a strategic plan that was approved by the Board of Commissioners in November 2001. Having completed its task, the work group was disbanded and William E. Jacott, MD, former AMA Commissioner to the JCAHO, was retained by the JCAHO as a special advisor to lead the implementation of the strategic plan. The objective of this initiative is to enhance the relevance of accreditation to physicians.

In 2002, the JCAHO Board established the Public Policy Strategic Issues Work Group. The planned approach to public policy engagement will generally begin with the convening of an issue specific expert roundtable and conclude with the issuance of specific recommendations in the form of a white paper. The nurse staffing shortage is currently being pursued as a public policy issue. Two Nurse Staffing Roundtables have been convened. A Nurse Staffing Symposium will be held on May 20-22, 2002, after which, a white paper will be issued.

National Committee for Quality Assurance (NCQA)

The AMA is represented on the Practicing Physician Advisory Council of the NCQA by Ronald P. Bangasser, MD.

Disposition of 2001 AMA Resolution: One Annual 2001 amended resolution was transmitted to the NCQA following the 2001 Annual Meeting: Amended Resolution 708 - Physician Privileges Application--Timely Review by Managed Care. The full text of the resolution and the NCQA response are presented in Appendix C.

Draft 2003 HEDIS® Measures and 2003 Standards Revisions for Public Comment: In February 2002, the NCQA released draft HEDIS® measures for public comment. Draft 2003 accreditation standards for Managed Care Organizations, Managed Behavioral Healthcare Organizations, and Preferred Provider Organizations were released in March 2002 for public comment. At the time this report was prepared, the AMA was drafting comments, based on AMA policy, on the measures and standards.

Proposed Accreditation Program for Human Research Protection (HRP) Programs: In January 2002, the NCQA convened an HRP Advisory Council to provide guidance for the development of an HRP Accreditation Program. The program will focus on: privacy and confidentiality, informed consent, consideration of risks, institutional review board structure and operations, institutional responsibilities, and recruitment and subject selection.

Disease Management Accreditation and Certification: In December 2001, the NCQA announced the release of final standards for its Disease Management (DM) Accreditation and Certification programs.

The accreditation options include the following: Patient and Practitioner Oriented Accreditation, designed for organizations that work with both patients and practitioners; Patient Oriented Accreditation, designed for comprehensive DM programs that focus exclusively on patients and do not have regular contact with practitioners; and Practitioner Oriented Accreditation, designed for comprehensive DM programs that work through practitioners.

The NCQA's DM certification programs are essentially subsets of the DM standards that are appropriate for organizations that provide specific services such as designing, but not operating DM programs. The NCQA offers the following three types of certification for these organizations: DM Program Design Certification reviews DM content, e.g., printed, electronic, and in-person methods for working with patients and practitioners, according to clinical guidelines; DM Systems Certification reviews the design of clinical information systems, such as those used to identify patients, to support DM; DM Contact Certification addresses patient contact, and covers such areas as patient program information, patient participation, and access to health care professionals.

Medicare + Choice (M+C) Deeming Authority: In January 2002, The Centers for Medicare and Medicaid Services (CMS) granted the NCQA deeming authority for the M+C program. This deeming authority allows NCQA to review M+C organizations on behalf of CMS in six categories: access to services; antidiscrimination; confidentiality and accuracy of enrollee records; information on advance directives; provider participation rules; and quality assurance.

Patient Safety and Performance Measures: The Joint Recognition Program to Improve Patient Safety is a partnership among the NCQA, the American Medical Group Association, and Pharmacia. The program will provide $500,000 (10 grants of $50,000 each) to fund and evaluate medical groups' safety and error reduction initiatives.

The NCQA, with the Pacific Business Group on Health, has secured $1.8 million in grant funding from the California Healthcare Foundation. Under the grant, the project will create standardized performance measures for medical groups.

SUMMARY

Policies adopted by the AMA House of Delegates have been transmitted to the appropriate accreditation organizations for consideration during their standard revision process. The AMA is well represented on the boards and committees of these accreditation organizations. AMA representatives and staff will continue to monitor AMA issues to assure proper consideration is given as they proceed through the standards revision processes of the preceding organizations.

The Board of Trustees will provide an update on these issues at the 2002 Interim Meeting.

APPENDIX A - TEXT OF AMA RESOLUTIONS/REPORTS REFERRED TO THE JOINT COMMITTEE ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS AND THE JCAHO RESPONSE

Recommendation 3, Council on Scientific Affairs Report 11-I-00, "Medical Preparedness for Terrorism and Other Disasters"
Recommendation 3 asked that our AMA encourage the JCAHO and state licensing authorities to include the evaluation of hospital plans for terrorism and other disasters as part of the period accreditation and licensure visits conducted by their representatives.

Summary of Discussion Relating to the American Medical Association Recommendation 3, CSA Report 11-I-00; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments

- Major and timely revisions to these standards became effective on January 1, 2001.
- These standards require organizations to:
  - Address four specific phases of disaster planning: mitigation, preparedness, response, and recovery;
  - Determine how the community around them may be affected during an emergency or disaster;
  - Perform hazard vulnerability analyses that start with an unconstrained list of extreme events and then critically appraise their probability of occurrence, their risk to the organization, and the capacity for responding to each potential threat;
  - Participate in at least one annual community-wide practice drill.
- These standards were called to the attention of the SSP Committee at its October 2001 meeting. At that time, the SSP Committee was advised that the Joint Commission would be issuing additional guidance to accredited organizations, based on what had been learned through the experience of tropical storm Allison in Houston, Texas and the terrorist attacks in New York City and Washington, DC.
- Revisions were subsequently initiated to clarify the standards, emphasize an "all hazards approach" to emergency management, and make explicit the expectation that terrorist acts be among the hazards that are to be considered in the hazard vulnerability analysis. In addition, a revision to the intent statement of standard EC.1.4 was initiated.

Conclusion
These revisions were brought forward to the SSP Committee at its November 2001 conference call, at which time the Committee approved the revisions, which satisfy the AMA recommendation.

Recommendation 4, Council on Medical Service Report 5-I-00, "Physicians' Experiences with Retrospective Denials of Payment and Down-Coding by Managed Care Plans"
Recommendation 4 asked that our AMA work with private sector accreditation organizations to ensure that their health plan and utilization management accreditation standards adequately address fair and appropriate mechanisms for retrospective review.

Summary of Discussion Relating to the American Medical Association Recommendation 4, CMS Report 5-I-00; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments

- The Joint Commission standards have traditionally focused on issues related to the safety and quality of care, as opposed to financial issues; however, staff agrees that economic factors may be detrimental to the quality and safety of care, as well as to practitioner interests.
- Standards in the *Comprehensive Accreditation Manual for Health Care Networks* (*CAMHCN*) will soon be reviewed for potential future revisions. This review and revision process will offer an opportunity to explore the relationship of the standards to an array of financial issues, including retrospective denials of payment.

Conclusion

Given the foregoing, no further Committee action was taken.

Recommendation 5, Council on Medical Service Report 6-I-00, Mental Health "Carve-Outs"

Recommendation 5 asked that our AMA encourage private sector accrediting bodies collecting quality assessment data of managed behavioral healthcare organizations to widely disseminate such information to the public.

Summary of Discussion Relating to the American Medical Association Recommendation 5, CMS Report 6-I-00; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments

- The accreditation status of health care organizations surveyed by the Joint Commission is available through the Joint Commission's web-based Quality Check. The quality of care provided by an organization can be inferred from its accreditation status. Appendix A.1 [available from the Department of Clinical Quality Improvement] is a sample of the information typically available through Quality Check.
- The Joint Commission plans to make individual performance reports for managed behavioral healthcare organizations available in the future.

Conclusion

Given the foregoing, no Committee action was taken. In response to a request from the AMA, a sample of the information typically available through Quality Check is set forth in Appendix A.1 [available from the Department of Clinical Quality Improvement].

Recommendations 3 and 4, Council on Medical Service Report 7-I-00, "Hospital Mergers Study"

Recommendation 3 asked that our AMA urge its AMA Commissioners to JCAHO to add a standard to the JCAHO Hospital Accreditation Standards requiring a medical staff successor-in-interest standard in the hospital medical staff bylaws.

Recommendation 4 asked that our AMA seek inclusion of medical staff bylaw successor-in-interest provisions in the Medicare Conditions of Participation and in the rules and regulations of other public and private hospital accreditation agencies.

Summary of Discussion Relating to the American Medical Association Recommendations 3 and 4, CMS Report 7; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments

- The intent statement of standards MS.1-MS.1.1.3 in the *Comprehensive Accreditation Manual for Hospitals* (*CAMH*) states:

  A single, organized, self-governing medical staff provides clear responsibility and accountability for overseeing the quality of care being provided to a hospital's patient population. However, mergers and consolidations in the health care field have created a growing proliferation of new organization structures and relationships that can blur this traditional line of patient care accountability. This is particularly true when a single hospital serves different patient populations in geographically distant sites. To accommodate these realities, it is important to acknowledge that within a single organization, separate medical staffs--providing care to separate populations at *geographically distinct sites*--may comfortably co-exist and be capable of meeting the accountabilities envisioned within these standards.

- Additionally, standards MS.2 and MS.2.1 state:
  Each medical staff develops and adopts bylaws and rules and regulations to establish a framework for self-governance of medical staff activities and accountability to the governing body. Medical staff bylaws and rules and regulations are adopted by the medical staff and approved by the governing body before becoming effective. Neither body may unilaterally amend the medical staff bylaws or rules and regulations.
- Standard MS.2.3.7 requires that medical staff bylaws define "a mechanism for adopting and amending the medical staff bylaws, rules and regulations and policies."
- Joint Commission Official Accreditation Policies and Procedures require hospitals to notify the Joint Commission in writing not more than 30 days after a merger takes place. In the case of a merger, consolidation, or acquisition, the Joint Commission may decide that the hospital must be resurveyed or initially surveyed.
- Current Joint Commission standards neither mandate nor prohibit a "successor-in-interest" provision in an accredited hospital's bylaws. The standards allow for the discretion of the hospital and its medical staff in
- deciding whether to include such a provision in the hospital's medical staff bylaws.
- The Joint Commission standards have traditionally focused on issues relating to the safety and quality of care. The current standards relating to medical staff bylaws contemplate a cooperative effort between the governing body and medical staff to improve the safety and quality of care for patients.
- At its September 2001 conference call, the Hospital PTAC reviewed the AMA recommendation to include a "successor-in-interest" provision and discussed whether such a provision could be construed as relevant to the safety and quality of patient care.
- The PTAC and Joint Commission staff concurred that the "successor-in-interest" provision is not directly related to the safety and quality of patient care and, therefore, the standards for hospitals are not a suitable vehicle for addressing that issue.
- If a physician has a complaint related to the medical staff, he or she can contact the Joint Commission's Office of Quality Monitoring to voice the concerns. The Joint Commission's web page explains how to file a complaint with the Office of Quality Monitoring.

Conclusion
Given the foregoing, no Committee action was taken.

Substitute Resolution 802 (I-00) - "HCFA Seclusion and Restraint Rule"
Substitute Resolution 802 asked that our AMA prepare and support enactment of Congressional legislation which would rescind the July 22, 1999, Interim Final Rule of the Health Care Financing Administration governing the use of seclusion and restraints, and direct HCFA to engage in a negotiated rule-making process to develop rules which are consistent with AMA Policy 280.952, which states: "Our AMA uses the following principles in establishing policy regarding restraints and seclusion: (1) The patient has the right to be free of restraints and seclusion unless medically necessary. (2) The least restrictive means be considered first. (3) The use of restraints and seclusion is a medical decision and should not be dictated by government agencies. (4) When a physician is not physically present, a properly trained and authorized health care professional may institute seclusion and restraints when this is clinically appropriate. In such cases, the physician shall be contacted immediately. The patient must be examined by a physician within a period of time that meets an acceptable clinical standard."

Substitute Resolution 802 also asked that our AMA, through its representatives on JCAHO, encourage organizations to utilize evidence-based standards for patient safety which permit physicians to exercise reasonable clinical judgment in the ordering of restraints when such restraints are required for the protection and safety of the patient, other patients, staff, and visitors.

Summary of Discussion Relating to the American Medical Association Substitute Resolution 802; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments
The restraint and seclusion standards require that licensed independent practitioners evaluate patients/individuals and, when appropriate, order restraints because of the need for their clinical judgment. The intent of standard TX.7.15 states: As soon as possible, but no longer than one hour after the initiation of restraint or seclusion, a qualified registered nurse or other qualified staff notifies and obtains an order (verbal or written) from the licensed independent practitioner and consults with the licensed independent practitioner about the patient's physical and psychological condition.

The licensed independent practitioner:

- reviews with staff the physical and psychological status of the patient;
- determines whether restraint or seclusion should be continued;
- supplies staff with guidance in identifying ways to help the patient regain control in order for restraint or seclusion to be discontinued; and
- supplies an order. (Orders are limited to the time frames cited in standard TX.7.1.7.)

Conclusion

The Joint Commission standards relating to the use of restraints meet the RAND criteria for being "evidence-based" because their adoption was based on expert consensus; no Committee action was taken.

Substitute Resolution 803 (I-00) - "A Physician as a Patient Safety Officer in a JCAHO Approved Health Care Facility"

Substitute Resolution 803 asked that our AMA encourage medical staff physicians to take a leadership role in their hospital's patient safety activities.

Summary of Discussion Relating to the American Medical Association Resolution 803; Standards and Survey Procedures (SSP) Committee Meeting, October 2001 JCAHO

Comments

- Joint Commission standard LD.5 and its intent statement address leadership roles in a hospital's safety activities.
- Standard LD.5 states that "leaders ensure implementation of an integrated patient safety program throughout the organization." The Joint Commission definition of "leaders" in a hospital includes the elected and appointed leaders of the medical staff and the clinical departments, and "other medical staff members in organization administrative positions."
- The intent statement for standard LD.5 identifies clinical leaders as individuals who may be involved in the management of the patient safety program itself.
- Joint Commission staff believe the standards appropriately address the role of clinical leaders in patient safety.
- Effective physician engagement has been identified by the Joint Commission's Board of Commissioners as a critical success factor in achieving the Joint Commission's future goals. The Board's Physician Engagement Strategic Issues Task Force has developed a strategic plan for physician engagement and is working on finalizing the goals and objectives for the plan. Additionally, in January 2002, William E. Jacott, MD, assumed new duties as Special Consultant to the Joint Commission. In this position, he will head up the initiatives to strengthen the Joint Commission's ties with the physician community.

Conclusion

Given the foregoing, no Committee action was taken.

APPENDIX B - AMA RESOLUTIONS/REPORTS REFERRED TO THE JOINT COMMITTEE ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS THAT ARE AWAITING JCAHO RESPONSE

Recommendation 1, Council on Scientific Affairs Report 4-A-01, "Update: Medical Preparedness for Terrorism and Other Disasters"

Recommendation 1 of CSA Report 4 asked that our AMA work with the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, JCAHO, and other appropriate parties to promote our policies and recommendations for medical preparedness for terrorism and other disasters.

Resolution 812 (A-01), "Cooperation Between AMA and JCAHO Regarding Credentialing and Privileging Standards"

Resolution 812 , as amended and adopted, asked that our AMA work with JCAHO to ensure that discussion between these organizations takes place prior to the implementation of any new standards affecting credentialing and privileging.

Substitute Resolution 805 (I-01), "JCAHO Proposed Standard Implementation Cost and Impact"
Substitute Resolution 805 asked that our AMA request JCAHO to promulgate information from Item 5 of its standards development model, which states:

> "5. External evaluation activities assess, when possible, benefit/cost/impact of the proposed new or revised standards. Survey process development and testing starts to determine reliability of proposed survey procedures. Formal mailing of standards documents coupled with qualitative focus group work provides information about use and usefulness of proposed standards."

Substitute Resolution 807 (I-01), "Physician Involvement In Disaster Preparedness"
Substitute Resolution 807 asked that our AMA urge JCAHO to promulgate its revised Standard EC.1.4 on disaster preparedness which incorporates medical staff involvement.

APPENDIX C - AMA RESOLUTION REFERRED TO THE NATIONAL COMMITTEE FOR QUALITY ASSURANCE AND THE NCQA RESPONSE

Resolution 708 (A-01), "Physician Privileges Application--Timely Review by Managed Care"
Resolution 708, as amended and adopted, asks that our AMA: (1) work with the American Association of Health Plans, the American Hospital Association, the National Committee for Quality Assurance, and other appropriate organizations to allow residents who are within six months of completion of their training to apply for hospital privileges and acceptance by health plans; (2) establish the policy that the final acceptance of residents who otherwise are approved by a health plan should be contingent upon the receipt of a letter from their program director stating that their training has been satisfactorily completed; (3) establish the policy that health plans which require board certification should allow the completing resident to be included in their plan after showing evidence of having completed the required training and of working towards fulfilling the requirements in the time frame established by their respective Board for completion of certification; and (4) establish the policy that Medicare, Medicaid, and managed care organizations appropriately and expeditiously (within 60 days) credential established physicians whose practices relocate, merge, or otherwise change their status.

Amended Resolution 708 (A-01), "Physician Privileges Application--Timely Review by Managed Care," was sent to the AAHP, the AHA, and the NCQA for consideration. The AMA has not yet received a response from the AAHP or the AHA.

Following are excerpts from the NCQA response contained in a letter from Margaret E. O'Kane, President, dated September 26, 2001.

> *Allowing residents who are within six months of completion of their training to apply for hospital privileges and acceptance by health plans* - NCQA's current standards do not prevent health plans from contracting with physicians who are still in residency training. NCQA does not require that a health plan contract only with physicians who have current clinical privileges. Nor does NCQA require health plans to verify hospital privileges. Instead, managed care organizations (MCOs) must obtain from the practitioner an attestation regarding any history of loss or limitation of privileges or disciplinary activity.
>
> *Final acceptance of residents should be contingent upon the receipt of a letter from their program director stating that their training has been successfully completed* - In response to requests from the AMA and several state medical societies, NCQA currently allows health plans to provisionally credential practitioners who have completed their residency and/or fellowship training within the 12 months before the credentialing decision. NCQA made this policy change in recognition of the length of time required to obtain hospital privileges.
>
> *Health plans which require board certification should allow the completing resident to be included in their plan after showing evidence of having completed the required training* - NCQA does not require board certification. Nor have we established any guidelines or thresholds for the percentage of an MCO's practitioners who must be board certified.

Medicare, Medicaid, and managed care organizations appropriately and expeditiously (within 60 days) credential established physicians - NCQA does not currently specify the time frame in which the credentialing process should be completed. We agree with the AMA that the process should be completed in an expeditious manner. However, because health plans and other entities that credential practitioners are dependent upon external sources for verification of credentialing information and cannot control the response time of these external sources, 60 days may not be realistically achievable. Finally, NCQA's standards do not require health plans to recredential a practitioner who simply relocates or merges his/her practice. Instead, we would expect the health plan to recredential the practitioner once every three years.

In summary, it does not appear that NCQA's current credentialing standards are in conflict with the provisions of Amended Resolution 708.

13. UPDATE ON PATIENT SAFETY IN OFFICE-BASED SURGICAL FACILITIES AND STANDARDS OF CARE

HOUSE ACTION: FILED

INTRODUCTION

The Board of Trustees presented informational Report 13, "Patient Safety in Office-Based Surgical Facilities and Standards of Care" at the 2001 Annual Meeting. The report provided information on state and specialty medical societies, government agencies, accreditation organizations, state medical boards, and other groups who have activities and positions regarding surgery performed in the ambulatory setting. The report also included information from the National Patient Safety Foundation (NPSF) on proposed consensus initiatives on liposuction and on patient safety as it relates to procedures performed in the ambulatory setting.

BOT Report 13-A-01 concluded that the Board of Trustees would support and participate in the consensus initiatives of the NPSF, continue to monitor office-based surgery activities, and provide an update to the House of Delegates at the 2002 Annual Meeting.

BACKGROUND

This report updates the information contained in BOT Report 13-A-01. In February 2002, the Board of Trustees contacted the Federation, and other organizations that provided information for BOT Report 13-A-01. The Federation and the other organizations were provided a copy of the report and asked to review it and provide new or additional information. The state medical societies were also asked to provide information on proposed or enacted legislation and regulation of office-based surgery within their states. The organizations that responded to this request are listed in the Appendix. Additional information was obtained, when available, from organizational and governmental web sites.

DISCUSSION

Current Activities of State Medical Societies, Legislatures and Regulatory Agencies: 2002 Updated Information

California (Secondary source: www.aahc.org) - Licensure, Medicare certification, or accreditation is required for all outpatient settings where anesthesia is used, excluding local or peripheral nerve blocks. The American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), the Accreditation Association for Ambulatory Health Care (AAAHC), the Institute for Medical Quality (IMQ), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are state-recognized accrediting agencies. Legislation also requires liability insurance for physicians performing surgery in outpatient settings.

Colorado (Primary source: (www.dora.state.co.us) - On November 8, 2001, the Colorado Board of Medical Examiners issued a policy statement concerning office-based surgery and anesthesia. The policy defines office-based surgery as surgery that is performed in a facility "outside a hospital or ambulatory surgical center licensed by the Colorado Department of Public Health and the Environment." The policy applies to any procedure involving general and/or regional anesthesia and/or the use of conscious sedation. It does not apply to minor surgical procedures performed under topical or local infiltration blocks.

Connecticut (Secondary source: www.aaahc.org) - Legislation signed on May 31, 2001, requires that any office or unlicensed facility at which moderate sedation/analgesia, deep/sedation/analgesia, or general anesthesia is administered must be Medicare-certified or accredited by AAAHC, AAAASF, or JCAHO.

Florida (Primary source: www.doh.state.fl.us) - Florida law requires Department of Health inspections of physician office facilities where certain levels of surgery are performed, unless the office is accredited by AAAHC, AAAASF, or JCAHO. The Florida Board of Medicine amended Rule 64B8-9.009, Standard of Care for Office Surgery. The amendments were adopted on July 12, 2001 and effective August 1, 2001. A summary of the amendments follows:

- Written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.
- Liposuction performed in combination with another separate surgical procedure during a single Level II or Level III operation is restricted to specified circumstances.
- Anesthesia providers must follow the "Standards of the American Society of Anesthesiologists (ASA) for Basic Anesthetic Monitoring" (1998), although these standards do not apply to Level I care and may be waived by the supervising physician or anesthesiologist for individual patients or under extenuating circumstances.
- The surgeon establishes a risk management program with specified components.
- Level III procedures on patients classified as ASA III or higher may be performed only in a hospital or ambulatory surgery center.
- Preoperative work-up, including EKG, must be obtained for ASA class II patients more than 40 years of age, and patients with complicated medical conditions would require medical clearance, subject to waiver following the anesthesiologist's evaluation of the patient.

Georgia (Primary source: www.state.ga.us) - Legislation has been introduced to regulate office-based surgical settings where certain levels of anesthesia are administered.

Mississippi (Primary source: www.mississippi.gov and Mississippi State Medical Association) - The Mississippi State Board of Medical Licensure issued proposed regulations addressing office-based surgery in the summer of 2000. MSMA and a number of medical liability insurance companies submitted comments and proposed amendments to the regulations. The regulations were amended in February 2002 and become effective June 1, 2002. The regulations define and set standards for each of three levels of care. Physicians performing Levels II and III surgery must register with the State Board. A surgical event, defined as a potentially harmful or life-threatening episode related to either the anesthetic or the surgery in the immediate peri-operative period, must be reported to the State Board within 15 days after the occurrence.

New Jersey (Primary source: www.state.nj.us) - In November 2001, proposed amendments and a new rule to the New Jersey Administrative Code on surgical and anesthesia standards in physician offices were published for public comment. The proposed new rule sets forth eligibility requirements and the mechanism by which practitioners who do not hold privileges at licensed hospitals may seek privileges from the State Board of Medical Examiners, called the alternative privileging mechanism. The rule sets forth separate alternative privileging mechanisms for the provision of general or regional anesthesia, as well as conscious sedation; the provision of conscious sedation only; the performance of surgery (other than minor surgery) or special procedures; and utilization of laser surgery techniques.

New York (Primary Source: www.state.ny.us and the Medical Society of the State of New York) - MSSNY worked closely with the Committee on Quality Assurance in Office-Based Surgery, a subcommittee of the New York State Public Health Council to develop "Clinical Guidelines for Office-Based Surgery." The Guidelines identify essential components an office-based surgical practice should address, including recommendations for anesthesia, pre-and post-surgical evaluations, monitoring equipment, credentialing, informed consent, and emergency protocols. The guidelines also recommend that the use of an accrediting agency such as the JCAHO, AAAHC, or AAAASF be considered stating that accreditation is one means of assuring the public that care and services are being provided in a safe environment and that there is adherence to the highest standards of quality and professionalism. In February 2001, the State Health Commissioner announced release of the guidelines and recommended practitioner compliance as an effective way to promote care that meets generally accepted standards. The Commissioner also recommended that the Board for Professional Medical Conduct use the Guidelines in promoting and enforcing appropriate standards of professional conduct.

MSSNY conducted a series of regional Continuing Medical Education courses throughout the state to promote compliance, ensure understanding, and stress the importance of following the guidelines.

The New York State Association of Nurse Anesthetists opposed the guidelines because they required that nurse anesthetists be supervised by an anesthesiologist or other qualified physician. NYSANA filed a lawsuit against the Commissioner of Health, arguing that the Commissioner lacked the authority to regulate private office surgery, and therefore, could not promulgate regulations. A summary judgment was handed down in favor of NYSANA. The Department of Health has appealed the ruling. The guidelines are null and void, pending the outcome of the appeal.

Legislation that would implement regulations for office-based surgery and that would require reporting of adverse events has been introduced in the New York State legislature. MSSNY opposes this legislation and has asked that it be held in abeyance, pending a final decision by the court. If the ruling is favorable to the Commissioner of Health, the MSSNY has asked that the guidelines be given a year to prove their effectiveness. If there has been no improvement in patient safety after the year, then legislation to regulate office-based surgery might be considered. In the event that legislation is deemed necessary, MSSNY has asked to work with bill sponsors to promulgate legislation that will not be unduly burdensome or unfair to physicians, while ensuring patient safety.

North Carolina (Primary source: www.docboard.org/nc) - Effective September 2000, the North Carolina Medical Board adopted guidelines for office-based surgery. The guidelines address appropriate professional training for physicians performing office-based surgery, pre-operative patient assessment, qualifications of anesthesia personnel with reference to protocols of the ASA, facility considerations, emergency planning, follow-up care, and quality improvement.

Ohio (Source: Ohio State Medical Association) - The State Medical Board of Ohio has been developing rules to regulate the practice of office-based surgery since the fall of 2000; it is expected that they will be completed in 2002. The current draft of the rules categorizes anesthesia into three levels and outlines what a physician can and cannot do in the office setting, depending on the type of anesthesia administered. A separate rule is also being developed to regulate liposuction that is performed in a physician's office.

The Ohio State Medical Association formed an Office-Based Anesthesia Focus Task Force, consisting of nine physicians from various specialties, to review the draft rules and provide comments to the OSMA regarding how the rules would affect their practices. The OSMA Council, its governing body, will use the information provided by the task force to help form opinions or positions that the OSMA may wish to present to the Medical Board.

Oklahoma (Source: Oklahoma State Medical Association) - The Oklahoma State Board of Medical Licensure and Supervision adopted "Guidelines for Office-Based Surgery and Other Invasive Procedures" and "Desiderata: Anesthesia." There are currently no laws or rules on office-based surgery in Oklahoma.

The Oklahoma State Medical Association works closely with its wholly owned medical malpractice insurance company, Physician Liability Insurance Company, to educate physicians about the potential risks inherent in office-based surgery.

Oregon (Primary source: www.ormedassoc.org) - The Oregon Medical Association has Standards for Accreditation of Office Facility for Procedures Requiring Conscious Sedation. Accreditation is limited to the office facilities of practitioners in the state of Oregon who are duly licensed by the Oregon Board of Medical Examiners or the Oregon Board of Dentistry and who are currently practicing within the state of Oregon, or who are duly licensed by the medical or dental boards in Washington or Idaho and who are currently practicing in Washington or Idaho.

Pennsylvania (Primary source: www.pacode.com) - If a physician's office has a distinct part used solely for surgery on a regular and organized basis, the office is subject to the regulations for an ambulatory surgical facility.

Rhode Island (Secondary source: www.aaahc.org) - In August 2000, the Department of Health issued regulations requiring licensure for offices in which surgery, other than minor procedures, is performed.

South Carolina (Primary source: www.llr.state.sc.us) - In October 2001, the South Carolina Board of Medical Examiners adopted office-based surgery guidelines to provide guidance to licensed physicians. Offices are classified as Level I, II, or III based on the complexity of anesthesia and surgical procedures. Accreditation is recommended for Level II and Level III facilities.

Texas (Primary source: www.tsbme.state.tx.us) - The State Board of Medical Examiners adopted regulations governing physicians providing general or regional anesthesia, or monitored anesthesia care. Physicians covered under the rule must register annually with the Board and pay an annual site registration fee. The rule does not apply to physicians in an outpatient setting in which only local anesthesia or peripheral nerve blocks are used, and/or in which only anxiolytics and analgesics are used in doses that do not have significant probability of placing the patient at risk of losing life-preserving protective reflexes. Licensed hospital outpatient facilities, licensed ambulatory surgical centers, state, federal and federally recognized Indian tribal organizations, as well as facilities accredited by the AAAHC, the AAAAFS, and the JCAHO are also exempted from the rules.

Washington (Source: Washington State Medical Association) - At its Annual Meeting in September 2001, the Washington State Medical Association House of Delegates adopted guidelines for office-based anesthesia. The guidelines are applicable to any venue where surgical or other invasive procedures requiring analgesia or sedation are performed by a practitioner in a location other than a hospital or certified, free-standing ambulatory surgery center. The guidelines separate the continuum of analgesia and sedation into three levels based on the ASA document "Continuum of Depth of Sedation, Definition of General Anesthesia and Levels of Sedation/Analgesia."

Summary of State Activities from BOT Report 13-A-01, for Which There Is No 2002 Update

District of Columbia - The DC Board of Medicine issued an advisory in April 2000 that the Board would follow guidelines issued by the ASA in assessing whether an acceptable standard of care had been met in cases involving office-based anesthesia. Those guidelines address requirements for a medical director and standards for operating room personnel, facility standards, minimum equipment standards, standards for clinical and preoperative care, and a protocol for emergency and timely transfer of patients in emergency situations.

Massachusetts - At its 2000 Interim Meeting, the Massachusetts Medical Society brought forward to its House of Delegates at its Interim 2000 meeting a resolution to the Committee on the Quality of Medical Practice and Committee on Interspecialty. The resolution asked the MMS to study the existing standards of care for office-based surgery and anesthesia, how they are disseminated to physicians, and the available statistics on outcome data. A report is due to the MMS House of Delegates at its 2001 Annual Meeting. The MMS will also work to ensure that any regulations regarding office-based surgery are consistent with professional standards.

Michigan - In 1999, the legislature passed and the governor signed HB 4599. Under terms of this law, effective March 10, 2000, a private physician's office in which 50% or more of the patients annually served at the facility undergo an abortion must be licensed as a freestanding surgical outpatient facility. This facility would be exempt, however, from meeting the certificate of need requirements in order to be granted a license.

New Hampshire - The New Hampshire Medical Society is supporting a legislative effort (HB 396) to provide immunity for quality assurance (QA) in MD offices--New Hampshire has laws protecting QA activities in hospitals, nursing homes, Ambulatory Surgery Centers (ASCs), and home care. The NHMS House of Delegates passed a resolution in January 2001 to set up a task force with specialty society representation to develop guidelines for office-based procedures.

Virginia - In the 2000 legislative session, the Virginia legislature approved, but the governor vetoed, legislation that would have required any physician performing surgical procedures in his or her office to report outpatient surgical data to the Board of Health for inclusion in the Virginia Patient Level Data System. These data would have included such things as principal and secondary diagnosis, external cause of injury, comorbid conditions existing but not treated, procedures and procedures dates, revenue center codes, units and charges, and total charges.

The Medical Society of Virginia is in the preliminary stages of developing patient safety and office-based surgery guidelines for introduction in its 2002 legislative session.

Current Activities of National Specialty Societies: 2002 Updated Information

American Gastroenterological Association (Source: AGA) - In August 2001, the AGA published "The American Gastroenterological Association Standards for Office-Based Gastrointestinal Endoscopy Services." These Standards may be used to assess the quality of physical plant and environment, support services, and patient care issues

associated with endoscopy services for those adolescents and adults who can be safely treated in an office-based setting. The guidelines recommend that physicians providing office-based gastrointestinal endoscopic services should have proper training and be credentialed in a hospital and/or an ASC.

The AGA believes that patient safety is best protected if these standards are adopted by sites that also comply with state/federal laws for licensure or are certified as an ASC and/or are accredited by a nationally recognized accreditation program. Heretofore, relevant practice standards for the performance of endoscopic procedures in these settings have not been available, a situation that the AGA believes puts patients at risk. These standards have been developed to reduce that risk.

American Academy of Otolaryngology - Head and Neck Surgery (Source: AAO-HNS) - Although AAO-HNS has many members who perform office-based surgery, the AAO-HNS has no policies that specifically address office-based surgery. The AAO-HNS supports patient safety issues including prescribing errors and anonymous reporting of poor outcomes.

Summary of Medical Society Activities from BOT Report 13-A-01, for Which There Is No 2002 Update

American Academy of Dermatology Association - The AADA convened a Blue Ribbon Committee on Office-Based Medicine to examine issues surrounding surgical and other medical practices and consider guidelines and office-based accreditation options. The AADA is also working with the AAAHC. The AADA objects to requiring hospital privileges for dermatologists, contending dermatology is an outpatient specialty that is often subsumed under a larger department, and is rarely represented on credentialing committees. The AADA recommends alternative credentialing for dermatologists that would be comparable to hospital credentialing requirements.

American Academy of Facial Plastic and Reconstructive Surgery - The AAFPRS holds two seats on the AAAHC Board of Directors and subscribes to that organization's guidelines on accreditation of outpatient surgical facilities. The AAFPRS Foundation Board of Directors requires that all AAFPRS Fellowship Directors maintain accredited facilities.

American College of Surgeons - The Board of Governors Committee on Ambulatory Surgical Care of the ACS developed a set of guidelines in 1994 and revised them in 1996 and May 2000. The "Guidelines for Optimal Ambulatory Surgical Care and Office-Based Surgery" were designed to help the surgeons who performed surgical procedures in their offices to offer these services to patients in an appropriate manner and in a safe environment. The ACS promotes the guidelines for office-based surgical facilities and advocates that compliance with these guidelines be considered satisfactory for ensuring that the facility provides high-quality surgical care. The ACS indicates that it is not, and does not intend to be, an accrediting organization.

The ACS definition of an Office Surgical Facility is "any surgical facility organized in or for the surgeon's office for the purpose of providing invasive surgical care to patients, with the expectation that they will be recovered sufficiently to be discharged within a reasonable amount of time."

American Society for Dermatologic Surgery - The ASDS has published guidelines similar to the American Academy of Determatology's Liposuction Guidelines, which address: physician qualifications; pertinent medical history, physical examination, laboratory tests; the various techniques and use of anesthesia; patient monitoring and the need for fluid replacement, based on the volume of fat removed and the type of anesthesia employed; the appropriate surgical setting; and postoperative care and postoperative findings.

The ASDS supports community standards that are fair, appropriate, and manageable. In addition, the ASDS supports appropriate and effective patient education as an important factor in enhancing patient safety.

American Society for Aesthetic Plastic Surgery - The ASAPS with the American Society of Plastic Surgeons (ASPS) issued a policy statement requiring that ASAPS members perform surgery only in accredited facilities by July 2002. Currently, among ASAPS members who operate in office-based facilities, 65% report that these facilities are accredited state-licensed or Medicare-certified.

The ASAPS also engages in ongoing public education efforts and encourages prospective patients to ensure their office-based cosmetic surgery meets certain requirements. In addition to the requirement that surgery is performed only in accredited facilities, these include: the operating surgeon is certified by the American Board of Plastic

Surgery; the surgeon has privileges at an accredited acute care hospital for the specific procedures being performed; and if general anesthesia is used, it is administered by a board-certified anesthesiologist or Certified Registered Nurse Anesthesia (CRNA).

American Society for Gastrointestinal Endoscopy - The ASGE represents gastroenterologists and surgeons who have been trained in the performance of gastrointestinal endoscopy. Although ASGE does not consider endoscopy to be surgery, the procedure is often included in guidelines for office-based surgery because it frequently involves the administration of moderate (conscious) sedation.

The ASGE believes that moderate (conscious) sedation can be administered safely in the office setting if appropriate precautions and monitoring techniques, similar to those used in the ASC or hospital, are also used in this setting. The ASGE supports the recently revised guidelines from the ASA on "Sedation and Analgesia for the Non-Anesthesiologist."

The ASGE supports the principle that physicians should only perform procedures in the office for which they have been granted and maintain privileges to perform in the hospital.

American Society of Anesthesiologists - The ASA has been involved in establishing guidelines for safe office anesthesia practice for more than two years, and the ASA House of Delegates approved the "Guidelines for Office-Based Anesthesia in October 1999. These guidelines address quality of care, facilities and safety, patient and procedure selection, peri-operative care, monitoring and equipment and emergencies, and transfers of patients as they pertain to the office. The guidelines reference ASA's "Standards for Basic Anesthetic Monitoring," "Basic Standards for Preanesthesia Care," "Standards for Postanesthesia Care" and "Guidelines for Ambulatory Anesthesia and Surgery," all of which are applicable to an office setting. In addition, the ASA Task Force on Office-Based Anesthesia published an informational manual titled, "Office-Based Anesthesia, Considerations for Anesthesiologists in Setting Up and Maintaining a Safe Anesthesia Environment," in October 2000.

American Society of Plastic Surgeons - The ASPS has a Task Force on Patient Safety in Office-Based Surgical Facilities, which is examining a broad spectrum of issues related to patient safety in office-based surgery facilities. These include procedure-specific factors, patient-specific variables, anesthesia, state office-based surgery regulations, and accreditation organization standards. In addition, the Task Force is establishing a database of articles, proceedings, abstracts, and unpublished documents on this subject.

Current Activities of Other Organizations and the Federal Government

American Association of Nurse Anesthetists - In 2001, the AANA revised its "Standards for Office Based Anesthesia Practice" by adding the following language to Standard 10: "Prior to administration of any anesthetic in an office facility, the CRNA shall review the AANA minimal elements (Section II) and evaluate for compliance and applicability to the setting." The standards are intended to provide assistance to CRNAs and other practitioners by promoting a common base for the delivery of quality patient care in the office-based setting, assist the public in understanding what to expect from the practitioner, and support the basic rights of patients.

The AANA reported that CRNAs currently provide services in the offices of ophthalmologists, orthopedic surgeons, urologists, plastic and cosmetic surgeons, oral and maxillofacial surgeons, gynecologists, obstetricians, general surgeons, gastroenterologists, and hand surgeons.

Federation of State Medical Boards - In April 2001, the FSMB formed a Special Committee on Outpatient (Office-Based) Surgery to develop recommendations for use by state medical boards in regulating office-based surgery. A draft report was circulated to state medical boards and other interested parties in October 2001 for comment. A final report of the Special Committee on Outpatient (Office-Based) Surgery was approved by the FSMB Board of Directors in February 2002 and will be presented to the House of Delegates for adoption as Federation Policy at the FSMB annual meeting in April 2002.

National Patient Safety Foundation - The NPSF is an independent, nonprofit research and education organization dedicated to the measurable improvement of patient safety in the delivery of health care. The AMA, CAN HealthPro, 3M, and Schering-Plough Corporation founded the NPSF in 1997.

The NPSF is a neutral convener that has developed a methodology to frame discussion around complex problems in patient care through its National Patient Safety Consensus initiatives. The NPSF consensus initiatives are the Foundation's top priority. These projects focus on particular patient populations or special issues in health care. NPSF brings together multiple stakeholders involved in a complex problem in a structured fashion to reach a consensus on improving patient safety in the area of concern. The consensus process includes these steps: (1) identifying barriers that impede progress in solving the problem; (2) identifying and prioritizing action steps to overcome those barriers; and (3) an agreement to collaborate during the implementation phase.

Patient safety is the driving factor underlying increased activities related to surgery performed in the office-based setting. The NPSF's primary focus is patient safety. Its consensus process is neutral and provides for inclusion of all appropriate parties involved in or affected by an issue. Representatives of the AMA serve on the NPSF Board.

The NPSF had initially proposed two consensus initiatives: liposuction and patient safety as it relates to procedures performed in the ambulatory setting. In November 2001, the NPSF convened a conference call of the following stakeholders to explore approaches to the consensus initiatives: AAAHC; American Academy of Cosmetic Surgery; AADA; AAFPRS; American Academy of Family Physicians; American Academy of Ophthalmology; American Academy of Orthopedic Surgeons; AAAASF; American College of Radiation Oncology; American College of Surgeons; AMA; American Society for Aesthetic Plastic Surgery; ASDS; ASA; American Society of PeriAnesthesia Nurses; ASPS; Anesthesia Patient Safety Foundation; Cosmetic Surgery Foundation; Federated Ambulatory Surgery Association; Federation of State Medical Boards; Institute for Medical Quality; JCAHO; National Committee for Quality Assurance; and Society for Ambulatory Anesthesia.. It was agreed to combine the initiatives into a single consensus project, "Ambulatory Surgery in the Office Setting."

The project budget for Phase I is $175,000, and the NPSF is currently raising funds from potential donors that have been identified by the stakeholders.

Office of Inspector General (OIG), Department of Health and Human Services - In February 2002, the OIG released a report on ambulatory surgical facilities entitled "Quality Oversight of Ambulatory Surgical Centers: A System in Neglect." The inquiry for the report assessed how state agencies and accreditors oversee ambulatory surgical centers and how the Centers for Medicare and Medicaid Services holds them accountable. The report includes the following supplemental reports: "Supplemental Report 1, The Role of Certification and Accreditation," and "Supplemental Report 2, Holding State Agencies and Accreditors Accountable." A separate report to assess the quality oversight on procedures performed on Medicare patients in physician offices is expected in the Spring of 2002.

Current Activities of Accrediting Organizations

American Association for Accreditation of Ambulatory Surgery Facilities, Inc. - The AAAASF did not provide an update for this report. A brief summary of the AAAASF information that was provided in BOT Report 13-A-01 follows.

In 1980, the American Society of Plastic and Reconstructive Surgeons established the American Association for Accreditation of Ambulatory Plastic Surgery Facilities (AAAAPSF) to design and operate a single specialty accreditation program for outpatient plastic surgery centers. Based on inquiries by other surgical specialties, the AAAAPSF formed the AAAASF in 1992 to accredit other single- specialty and multi-specialty surgery facilities, owned and/or operated by surgeons in specialties certified by the American Board of Medical Specialties (ABMS).

The AAAASF currently accredits in excess of 600 facilities, which range in size from one to three operating rooms. The number of surgeons using a facility may be up to twelve. All surgeons must be ABMS-certified and hold privileges at a local hospital for procedures performed in their facility.

Accreditation by AAAASF is recognized by 90% of private insurance carriers for payment of allowed procedures, and has been recognized by the Doctors' Company for approval for malpractice insurance for office based surgery units. It has been approved by several state departments of health, in lieu of state licensure, and has been granted deemed status by the Centers for Medicare and Medicaid Services (CMS).

It is the position of the AAAASF that accreditation of ambulatory surgery facilities in which sedation or general anesthesia is administered should be a requirement in every state. In addition, state medical boards must implement swift disciplinary action when physicians are proven to have acted negligently in any surgical setting, whether in the office or the hospital. Surgery should not be performed in an unregulated manner with no guidelines, oversight or accountability, and oversight can only come from state medical boards. The AAAASF supports policies designed to further ensure patient safety and enhance patient care. However, such policies must be carefully considered, with input and consensus from the medical community to ensure that guidelines are consistent with accepted standards of surgical care and the best interests of patients are served.

Accreditation Association for Ambulatory Health Care, Inc. - The AAAHC did not provide an update for this report. A brief summary of the AAAHC information that was provided in BOT Report 13-A-01 follows: The AAAHC is a leading accreditation organization dedicated to enhancing health care quality. The AAAHC was formed in 1979 to assist ambulatory health care organizations in improving the quality of care they provide to their patients. Since its founding 20 years ago, the AAAHC has accredited a variety of ambulatory health care organizations and facilities including: including surgery centers; physician offices; community, student, and Indian health care centers; health maintenance organizations; independent physician associations; birthing centers; pain management clinics; podiatry offices; networks and groups of ambulatory care organizations; single and multi-specialty group practices; dental practices; and occupational health centers.

Currently, more than 1200 organizations are accredited by the AAAHC nationally, including more than 160 office-based surgery facilities. Several states recognize and utilize AAAHC accreditation as part of their regulatory requirements. The AAAHC has been granted deemed status by the CMS for the Medicare ambulatory surgical centers program.

American Osteopathic Association - The AOA, which was not mentioned in BOT Report 13-A-01, provided the following information for this report: The AOA Healthcare Facilities Accreditation Program (HFAP) has been accrediting health care facilities since 1945. The program currently accredits the following categories of facilities: hospitals and their clinical laboratories; substance abuse facilities; ambulatory care/surgical facilities; physical rehabilitation facilities; mental health care facilities; and critical access hospitals.

The AOA's HFAP surveys and accredits both ASCs and small office-based surgical practices. Among the areas of focus for the program and the program standards are quality assessment and improvement, and patient safety. The program is voluntary, grants accreditation for three years, and has applied for deeming authority from the CMS.

Institute for Medical Quality - Following is a summary of information on IMQ from BOT Report 13-A-01, as well as updated information provided by IMQ: The IMQ's Ambulatory Care Program accredits a wide range of entities, including ambulatory surgery centers, student health centers, occupational health centers, medical office/medical groups and other outpatient settings. California law requires that any setting in which anesthesia is administered in doses that have the probability of patients' loss of life-preserving protective reflexes, must be either licensed by the Department of Health Services, obtain Medicare certification, or be accredited by a recognized body. The IMQ's Ambulatory Care Program is recognized by the Medical Board of California to conduct these accredited surveys. The IMQ's Ambulatory Care Program offers separate standards for solo practitioners, accreditation review by physician peers, and consultation and education. Surveyors are practicing physicians who are knowledgeable about California laws and regulations. The IMQ standards cover essential quality of care domains including: administration; personnel and credentialing; quality management and peer review; medical records; care and treatment; facility and environmental safety; surgery/anesthesiology; and invasive diagnostic procedures.

Joint Commission on Accreditation of Healthcare Organizations - The JCAHO provided the following update: Supported by a combination of United States Census Bureau figures and surgical industry data, the JCAHO estimates approximately 41,000 independent office-based surgery (OBS) practices are in operation throughout this country. It is predicted that 2002 will be the first year that surgical procedures in the outpatient setting will surpass those provided in the inpatient setting. The JCAHO accredited 40 OBS practices in 2001 and expects to accredit 50 OBS practices in 2002. Organizations must meet the following criteria to be eligible for JCAHO accreditation: the practice is composed of four or fewer surgeons performing operative or invasive procedures; the practice must be physician owned or operated; invasive surgical procedures are provided to patients (procedures limited to the skin and subcutaneous tissues are typically not surveyed under the standards); and minimal sedation, conscious sedation, or general anesthesia are administered.

The JCAHO OBS standards focus on the following ten performance areas: patient rights and practice ethics; surgical and invasive procedures, including anesthesia and recovery; clinical support services; education; staff training, development, and competence; credentialing; environment of care and patient safety; planning and directing practice services; management of information; and improving practice performance.

National Committee for Quality Assurance - The NCQA provided the following update: The NCQA is actively interested in standard-setting and quality measurement activities for physician offices. It is currently exploring opportunities to define basic systems for physician offices that support delivery of preventive and chronic care and that promote patient safety and proper handling of confidential health information. The NCQA is exploring the evidence basis for such systems in research and in the experience of malpractice insurers. The NCQA is not currently focusing on office-based surgery facilities, but remains interested in how best to address these issues. The NCQA expressed interest in the NPSF consensus project, "Ambulatory Surgery in the Office Setting."

APPENDIX - ORGANIZATIONS RESPONDING TO SOLICITATION FOR INFORMATION

State Medical Associations

Iowa Medical Society
Mississippi State Medical Association
Medical Society of the State of New York
Ohio State Medical Association
Oklahoma State Medical Association
Washington State Medical Association

Medical Specialty Societies

American Gastroenterological Association
American Academy of Otolaryngology - Head and Neck Surgery

Other Organizations

American Association of Nurse Anesthetists
Federation of State Medical Boards

Accrediting Organizations

American Osteopathic Association
Institute for Medical Quality
Joint Commission on Accreditation of Healthcare Organizations
National Committee for Quality Assurance

14. EQUAL PAY FOR EQUAL WORK (RESOLUTION 119, A-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTIONS 126 AND 140 AND RESOLUTION 119 (A-01) AND REMAINDER OF REPORT FILED

BACKGROUND

At the 2001 Annual Meeting, the House of Delegates referred Resolution 119, "Equal Pay for Equal Work." The resolution, introduced by the Oklahoma Delegation, expressed concern about geographic variations in Medicare physician payment rates considering that training and board certification standards, Medicare rules and regulations, and performance expectations are the same for physicians regardless of their location. Resolution 119 called for the AMA to "seek to establish a sufficient minimum payment for the geographic payment cost indices (GPCI) portion of the Medicare fee schedule for physicians."

This report describes the genesis of the present system of geographically adjusting Medicare physician payment rates, problems with this system, and potential solutions. The Board of Trustees recommends that the AMA support development of a set of policy options to remedy any unjustified Medicare payment disparities and help promote physician recruitment and retention in rural communities.

PRESENT GEOGRAPHIC PAYMENT DIFFERENTIALS

The geographic differences in 2002 Medicare physician payment rates can be traced back to AMA policies and federal legislation from the late 1980s when the current Medicare payment system was designed. Wide disparities in Medicare payments for the same service, with two- and three-fold differences in some cases, provoked physicians nationwide to call for a more equitable policy. The disparities in Medicare payments produced even greater differentials in earnings, as physicians in rural areas frequently had a higher proportion of Medicare patients than their urban counterparts. Where Medicare payment rates were only 60% to 70% of the national average, physicians' earnings were often an even lower percentage of the national average.

To remedy this inequity, physicians in several predominantly rural states called for a single national Medicare payment schedule with no geographic variation. Adoption of such a policy, however, would have shifted the underpayment problem to metropolitan areas, as payments to physicians in cities such as New York, Miami, and Los Angeles would have been reduced an average of 27%. On the other hand, many physicians believed that the gaps in payment between metropolitan and nonmetropolitan areas should at least be narrowed. A compromise AMA policy adopted in 1988 to guide the initial development of the Medicare payment schedule called for payments to be geographically adjusted to account for differences in physicians' practice costs but took no position on cost-of-living differences (Policy H-400.991, AMA Policy Database). The 1989 legislation establishing the present Medicare payment system included a similar compromise: it called for geographic adjustments to reflect all differences in practice costs and professional liability insurance (PLI) costs, but only one-quarter of the cost-of-living differences between localities. The cost-of-living adjustments reflect differences in earnings between localities and are applied to the physician work component of the payment schedule.

Adoption of this policy brought about significant payment changes. Instead of being 60% to 70% of the national average, payment rates in rural states were increased to 89% or more of the national average. Payment rates in large metropolitan areas went from being as much as twice the national average to being 15% to 20% above the national average. The geographic differences in payment rates are determined by three GPCIs: a practice cost GPCI, a PLI GPCI, and a work GPCI. Because the payment schedule is supposed to reflect all of the differences in practice and PLI costs but only one-quarter of cost-of-living differences, which are reflected in the work GPCI, the variation in the work GPCI is much narrower than it is in the other two GPCIs. Most physician work GPCIs are from 3% below to 2% above the national average.

In addition to the geographic adjustments in payment rates due to the GPCIs, physicians in areas designated as health professional shortage areas (HPSAs) receive a "bonus" payment of 10% above what Medicare would otherwise pay in their locality.

PROBLEMS WITH THE PRESENT SYSTEM AND POTENTIAL SOLUTIONS

Since the late 1980s, physicians in rural and other areas with payment rates below the national average have cited several concerns with the present system. Some have argued that the GPCIs do not accurately reflect relative practice cost differences, and others have argued that neither the current geographic adjustment policy nor the HPSA policy go far enough to help rural areas recruit and retain physicians. In response to these concerns, the AMA has adopted policies supporting review and refinement of the GPCIs (Policies H-400.976, H-400.974, H-400.972). Policy H-400.972 also provided AMA support for several 1992 legislative initiatives that would have required the HHS Secretary to review, refine, and update the measures used in the GPCIs and adjust them to account for special local circumstances, including low utilization rates for medical equipment. Policy H-200.970 called for changes to HPSAs, including allowing a five-year grace period once an area exceeded the allowable physician-to-population ratio during which the 10% bonus payments would continue.

Recognizing that budget neutral solutions will generate opposition from physicians in metropolitan areas with higher GPCIs, some advocates of eliminating geographic payment differentials have sought to impose floors on the GPCIs but not ceilings. For example, H.R. 3569, introduced in the 107th Congress by Rep. Doug Bereuter (R-NE), would provide for a phased transition over four years to a floor of 1.00 on the work GPCIs but would not reduce work GPCIs that are above 1.00. H.R. 3569 has achieved support from 44 cosponsors. As the physician work GPCI in most localities is 0.97 or higher already, few payment localities would see average increases in payment rates of more than 2% under this legislation.

The Medicare Payment Advisory Commission (MedPAC) addressed several of the special circumstances facing rural areas in its June 2001 report to Congress, "Medicare in Rural America." The Balanced Budget Refinement Act of 1999 directed MedPAC to study and report to Congress on the adequacy of payments to rural providers under the inpatient and outpatient hospital prospective payment systems and the home health prospective payment system. MedPAC concluded that:

> ....Medicare has an obligation to adjust its payment policies to accommodate differences in market conditions that would affect efficient providers' costs but are beyond their control. Medicare has not always adapted its policies appropriately, but necessary changes in those policies are not large. Adjustments are needed, not fundamental changes in direction. (p. 4-5)

The MedPAC report included a number of recommendations, such as adjusting rural hospital payment rates to account for low overall volumes of discharges and raising the cap on the disproportionate share add-on payment a rural hospital can receive from 5.25% to 10%. At the direction of the Senate Appropriations Committee, MedPAC is continuing to explore several issues related to geographic variations in payments per beneficiary.

Although the 2001 MedPAC report did not specifically examine physician services in rural areas, the report includes a table indicating that beneficiaries utilize fewer services per physician in rural areas than in metropolitan areas (Table 1-4, p. 19). This finding suggests, for example, that it could be more difficult for rural physicians to recover the costs of medical equipment purchases. The same statistically significant utilization trend applies to inpatient and outpatient hospital services and post-acute care. These lower utilization rates explain why average Medicare payments per beneficiary tend to be much less than their urban counterparts. When the lower utilization rates for every type of service are combined with modest differentials in payments per service, average total Medicare payments per beneficiary are much higher in urban areas compared to rural areas.

INTERACTION WITH PAYMENT UPDATE PROBLEM

The failure of Medicare payment updates to keep pace with inflation in practice costs over the 11 years since the present Medicare physician payment system was first implemented has exacerbated the Medicare payment problem in rural areas. In 2002, the Medicare payment schedule conversion factor was reduced by 5.4%. This was the fourth decrease in average payment rates since 1991 and, as a result, average Medicare payment rates have fallen 13% below inflation in medical practice costs, as measured by the government's Medicare Economic Index or MEI. Because the proportion of Medicare patients is higher for physicians in rural areas than in metropolitan areas, the pay cut has had a disproportionately severe impact on rural physicians' revenues. Press reports from West Virginia, South Dakota, Kansas, North Carolina, Washington state and elsewhere indicate that the payment cut is forcing physicians in rural areas to make difficult choices about continuing to accept new Medicare patients, replacing failing medical equipment, and limiting services in underserved areas.

Returning the 2002 conversion factor to its 2001 level would increase Medicare payments to most rural physicians by more than a floor of 1.00 on the work GPCI would increase them. As most work GPCIs are already at the 0.97 level, and because physician work accounts on average for 55% of the total relative values for services, an increase in the work GPCI from 0.97 to 1.00 will increase payments in most localities by no more than 1.7%. Twenty localities would see payment increases of between 1.8 and 3.9%, and one locality, Puerto Rico, would see payments increase by 7.7%. The conversion factor applies to 100% of the total relative values for each service, however, so an increase in the conversion factor of 5.4% would increase payments for all services in every locality by 5.4%.

DISCUSSION

Problems recruiting and retaining physicians in underserved rural areas have persisted, and in some places worsened, despite the narrowing of gaps in geographic payment differentials that occurred with implementation of the Medicare physician payment schedule, and despite the government's policy of paying a 10% Medicare bonus to physicians in HPSAs. While the incremental payment increases that would be put in place by H.R. 3569 might bring about some limited improvement, the Board of Trustees believes that adoption of this legislation alone is unlikely to enhance the supply of physicians in rural areas in a meaningful way. In fact, payments would increase much more significantly in most rural areas if the current crisis in the Medicare conversion factor were remedied than they would if a floor were imposed on the physician work GPCI.

The Board believes that creative solutions need to be developed to address the underpayment problem in rural areas. To be politically viable within the House of Delegates and the US Congress, these solutions must avoid merely shifting the underpayment problem from rural to urban areas.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 119 (A-01) and that the remainder of the report be filed:

1. That our American Medical Association make its first legislative priority to fix the Medicare payment update problem because this is the most immediate means of increasing Medicare payments to physicians in rural states and will have the greatest impact.

2. That our AMA seek enactment of legislation directing the General Accounting Office to develop and recommend to Congress policy options for reducing any unjustified geographic disparities in Medicare physician payment rates and improving physician recruitment and retention in underserved rural areas.

3. That our AMA advocate strongly to the current administration and Congress that additional funds must be put into the Medicare physician payment system and that continued budget neutrality is not an option.

4. That our AMA will work to eliminate the unfairness inherent in the current wide geographic disparity in physician Medicare reimbursement.

15. APPLYING PRESSURE ON DHHS OFFICE OF INSPECTOR GENERAL FOR RESOLUTION OF ECONOMIC CREDENTIALING ISSUE

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, Resolution 812 was adopted as amended by the AMA House of Delegates. Resolution 812 (I-01) asks our AMA to continue to aggressively seek resolution with the Department of Health and Human Services Office of Inspector General (OIG) of the issues of alleged fraud and abuse associated with hospital-imposed exclusivity policies as a form of economic credentialing and to report back at the 2002 Annual Meeting.

AMA POLICY

Current AMA policy strongly opposes the practice of economic credentialing. AMA policy also (1) encourages physicians to work with their hospital boards and administrations to develop appropriate uses of physician hospital utilization and financial data; and (2) provides that the medical staff have an appropriate role in decisions regarding granting and maintaining exclusive contracts and closure of medical staff departments (Policies E-4.07 and H-230.975, AMA Policy Database).

BACKGROUND

In December 1999, the AMA formally requested that the OIG publish a fraud alert on an emerging hospital practice whereby economic criteria, unrelated to quality, are used to determine whether a physician's medical staff privilege is granted or renewed.

The AMA's request was in response to reports of these practices increasing throughout the country. Such practices are contrary to AMA Code of Medical Ethics and violate the Medicare or Medicaid Fraud and Abuse Statue ("Anti Kickback statute").

In March 2000, the OIG informed the AMA that the OIG would consider the request for a fraud alert. However, there was little, if any OIG activity thereafter.

In August 2001, President Bush appointed a new Inspector General and the OIG promised more public outreach to the medical community. In October 2001, the OIG indicated the AMA's December 1999 request would be a priority in 2002. AMA provided additional examples of economic credentialing. In March 2002, the AMA suggested a conference to discuss the examples of economic credentialing practices previously forwarded to the OIG. The OIG has recently agreed that a conference would be useful to more fully explore the kinds of practices that are being implemented by hospitals and the AMA indicated that it would forward additional examples of economic credentialing. The OIG reconfirmed its commitment to review this issue and to seek AMA input to any draft alert that it may be developed. In May, 2002, the AMA and the OIG met telephonically to discuss examples of economic credentialing practices that are being implemented by hospitals. The OIG indicated that it will review these reported practices, as well as examples of these practices provided by the AMA. It also indicated that it will consult with other interested agencies and associations as is considers this issue.

The AMA continues to receive calls from physicians who are affected by economic credentialing policies, loyalty oaths, or other medical staff criteria related to economics rather than professional competence. The practice of economic credentialing remains an important issue for physicians. The AMA believes that publication of a properly crafted fraud alert could provide useful guidance for physicians, hospitals, and health care organizations. The AMA is encouraged by the initial meeting with OIG and its assurance that it will review this matter.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and that the remainder of this report be filed:

1. That our American Medical Association continue to work with the Department of Health and Human Services Office of Inspector General to develop a fraud alert on economic credentialing.

2. That our AMA continue to provide examples of economic credentialing practices and policies to OIG staff.

3. That the AMA Board of Trustees report back at the 2002 Interim Meeting on work with the OIG and its review of economic credentialing practices.

16. PAPERWORK REDUCTION (RESOLUTION 603, I-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

BACKGROUND

At the 2001 Interim Meeting, the House of Delegates referred Resolution 603, "Paperwork Reduction," to the Board of Trustees. Resolution 603, introduced by the Michigan Delegation, asked "that our American Medical Association allow members who download House of Delegates information from the web site the ability to opt out of receiving paper copies."

The reference committee report noted that there was extensive testimony on the resolution related to reducing paperwork associated with House meetings, in general supporting moving toward a paper-free meeting. The reference committee believed that "a systematic approach, which would take into consideration logistical issues as well as delegates' preferences, is preferable to taking isolated intermediate steps." The report also stated that the administrative costs associated with carrying out delegates' wishes to opt out of receiving the handbook on an individual basis might negate any savings in postage and reproduction. Finally, the reference committee recommended referral to the Board, and that the Board "undertake a feasibility study on moving to a paper-free meeting."

DISCUSSION

The Speakers of the House of Delegates carefully considered Resolution 603 (I-01), as well as the reference committee report. There is in fact an easy and inexpensive way for delegates to opt out of receiving the handbook, simply by notifying the Office of House of Delegates Affairs. The addresses used for the handbook and supplemental mailings are taken from a database of the House, and translated into a spreadsheet from which mailing labels are produced. Any delegate can be deleted from the spreadsheet for the purposes of the handbook and supplemental mailings. Therefore, the intent of Resolution 603 (I-01) can be easily accomplished.

The larger issue considered in the reference committee hearing is moving toward a paper-free meeting. At this time, the amount of paper generated by the meeting, especially by printing of the delegate handbook, supplemental mailing, and Sunday morning handout, is very extensive. The Speakers and Board applaud any effort to reduce this paper and the associated costs.

However, the Speakers and Board do not believe it is feasible to consider any short-term move toward a paper-free meeting. First, it would be too costly to wire the House for laptop computers, and laptop batteries do not last for an entire day of reference committee hearings and/or House business. Second, charging stations for laptops would also be expensive, and could take delegates away from the business of the House.

The Speakers are amenable to searching for ways to reduce the amount of paper generated prior to and during House meetings, and intend to survey the House on electronic means of information distribution and delegate preferences on options for such distribution.

While the expense to wire the House for laptops is prohibitive, the Speakers have begun efforts to accommodate those members of the House who do not wish to receive paper copies of the delegate handbook. Prior to this meeting, an e-mail was sent to the House of Delegates outlining electronic means of distribution of handbook materials available to the House. The e-mail noted the materials already available on the web site, and how delegates can download such materials. (Reports and resolutions have been downloadable for several years; the meeting schedule has been downloadable in PDA format since 2001.) In addition, the e-mail notified delegates that the handbook would be made available on CD-ROM (in Microsoft Word format) on request, and that those asking for the CD-ROM version would not receive a paper copy.

The Speakers are very interested in the response to making the handbook available on CD-ROM, and in the results of the survey to be distributed during the Annual Meeting, and intend to work to reduce the amount of paper generated in the future.

RECOMMENDATIONS

Accordingly, the Board of Trustees recommends that the House of Delegates adopt the following recommendations and file the remainder of this report. The Board recommends:

1. That Resolution 603 (I-01), allowing members who download House of Delegates information from the web site the ability to opt out of receiving paper copies of the delegate handbook, be adopted.

2. That the Speakers analyze the results of a survey of the House of Delegates on electronic means of distributing the delegate handbook and other related materials, and work to reduce the amount of paper distributed prior to and during House meetings.

17. DRUG, DIAGNOSTIC AGENT, AND VACCINE SHORTAGES: AN UPDATE

HOUSE ACTION: RECOMMENDATION ADOPTED IN LIEU OF RESOLUTIONS 506, 507 AND 519 AND REMAINDER OF REPORT FILED

INTRODUCTION

Short-term back orders and long-term unavailability of drug, diagnostic, and vaccine products have presented a challenge to physicians and patients for many years. However, product delays and shortages have increased in frequency and severity in recent years. Such delays and shortages can have significant public health consequences, both in terms of compromised patient care and increased costs to the health care system.

At the 2001 Interim Meeting, Board of Trustees Report 7, "Drug, Diagnostic Agent, and Vaccine Shortages," provided background information about the various causes of drug, diagnostic agent, and vaccine shortages, described the responsibilities and limitations of the federal government in responding to these shortages, and identified possible areas for improvement so that shortages could be addressed more effectively. The House of Delegates adopted the recommendations to Board Report 7-I-01, as follows:

1. That our American Medical Association ask the Secretary of Health and Human Services to:

   (a) establish a departmental task force to explore the causes of drug, diagnostic agent, and vaccine shortages and maldistribution and to identify appropriate solutions to these problems (including liability, reimbursement, and availability to the most vulnerable populations) so that the health of the public is adequately protected. This task force should include (but is not limited to) representatives from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Agency for Health Care Research and Quality (AHRQ).

   (b) require this task force to seek the input of the pharmaceutical industry, wholesalers/distributors, physician and pharmacy organizations, and consumers in addressing the problem of drug, diagnostic agent, and vaccine shortages.

   (c) as part of this initiative, commission one or more studies by an appropriate body of experts to identify and recommend solutions for the underlying breakdowns in the drug, diagnostic agent, and vaccine manufacturing and distribution systems that lead to shortages.

2. That our AMA reaffirm Policy H-100.980[c] (AMA Policy Database), "continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively."

3. That our AMA:

   (a) work with the FDA to expand its list of "medically necessary products" to be more inclusive of important medicines, vaccines, and diagnostic agents; and

   (b) urge the FDA to monitor production, inventory, and planned cessation of production of "medically necessary products" in order to more effectively intervene when the public health is threatened.

4. That our AMA work with the FDA to educate physicians on how to report potential drug and vaccine shortages to the FDA.

5. That our AMA, in collaboration with the Federation, the FDA, the CDC, the pharmaceutical industry, and pharmacy associations, determine the feasibility, including costs, of establishing an effective means to communicate timely information about drug and vaccine shortages, including information about alternative therapies, to physicians.

6. That our AMA report back to the House of Delegates at the 2002 Annual Meeting.

The purpose of this report is to update the House of Delegates on actions taken by the AMA to implement the recommendations of Board Report 7-I-01.

REQUEST FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES TASK FORCE

In January 2002, the AMA recommended to the Secretary, Department of Health and Human Services (DHHS), that his office establish a departmental task force to explore the causes of drug, diagnostic agent, and vaccine shortages and maldistribution and to identify appropriate solutions to these problems (including issues of liability, reimbursement, and availability of products to most vulnerable populations) so that the health of the public is adequately protected. At a minimum, this task force should have representation from the FDA, the CDC, and the AHRQ. The task force should seek the input of the pharmaceutical industry, wholesalers/distributors, physician and pharmacy organizations, and consumers in addressing the problem of shortages. Furthermore, as part of this initiative, the AMA asked the Secretary to commission one or more studies by an appropriate body of experts to identify and recommend solutions for the underlying breakdowns in the drug, diagnostic agent, and vaccine manufacturing and distribution systems that lead to shortages.

In its communication to the Secretary of DHHS, the AMA identified a number of factors throughout the supply chain that could potentially lead to delays and shortages. While the AMA believed the FDA and other federal agencies were working diligently to address these delays and shortages, limitations in resources, and possibly in statutory authority, prevented an optimum response. For example, some possible areas for improvement in addressing drug, diagnostic agent, and vaccine shortages more effectively include: earlier notification of a shortage to the FDA; adequate resources for the FDA to address shortages; expansion of the definition of a "medically necessary" product; improved communication to physicians about shortages; possible financial incentives to manufacturers in some cases to market a medically necessary, but unprofitable product; and, in the case of vaccines, potentially creating a national stockpile of certain vaccines. Clearly, the development, coordination, and communication of information about drug, diagnostic agent, and vaccine shortages to physicians need to be improved.

The AMA urged the establishment of the aforementioned DHHS task force as soon as possible because shortages of drug, vaccine, and diagnostic products are an acute and significant problem that is undermining the ability of physicians to provide appropriate care for their patients. As of mid-March 2002 when this Board report was written, the AMA had not received an official response from the Secretary of DHHS regarding the establishment of a task force. Communication continues between the AMA and the Secretary regarding the establishment of a task force. Also, as discussed below, DHHS already has begun to investigate vaccine shortages.

NATIONAL VACCINE ADVISORY COMMITTEE/NATIONAL VACCINE PROGRAM OFFICE WORKSHOP: "STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES"

Vaccines for eight of 11 vaccine-preventable diseases currently are affected by supply problems. Manufacturers' business decisions, thimerosal-related vaccine changes, and (especially) production problems are the reasons for current vaccine shortages. It is anticipated that most of these shortages will be resolved by the end of 2002. However, as a result of these problems, DHHS has tasked the National Vaccine Advisory Committee (NVAC) of the National Vaccine Program Office (NVPO) to study methods by which the supply of routinely recommended vaccines can be strengthened.

On February 11 and 12, 2002, the NVAC/NVPO convened a workshop titled "Strengthening the Supply of Routinely Recommended Vaccines in the United States." The objectives of this workshop were: (1) to define and describe the scope of the vaccine supply problem in the United States; (2) to identify and discuss possible contributing causes of and potential strategies to address the problem; and (3) to develop a limited number of pragmatic strategy options to be presented to the NVAC/NVPO for consideration.

Perspectives from numerous stakeholders, ranging from vaccine manufacturers to consumers to health care professionals, were presented at this workshop. Our AMA presented its views as a result of our stated concern about vaccine shortages.

As a result of the discussion at this workshop, five basic strategies to enhance the supply of routinely recommended vaccines will be considered by the NVAC/NVPO as it works towards providing recommendations to the DHHS. These five strategies are:

1. Increasing financial incentives for research/development/production;
2. Streamlining the regulatory process;
3. Establishing government-directed programs;
4. Utilizing vaccine stockpiles; and
5. Increasing liability protections.

Comments on each of these strategies were provided by stakeholders, through invited presentations, such as that provided by our AMA, or via open-microphone sessions following the invited presentations.

Representatives from industry favored increasing financial incentives for research, development, and production. However, while economic incentives will always work in a for-profit private market, a major problem is determining the right economic incentives. The vaccine supply industry does not resemble standard economic markets, and protection of property rights is insufficient to guarantee adequate production. Agreement on proper incentives to increase vaccine supply is missing. For example, there is no consensus agreement among all stakeholders on the social (public health) goals for vaccination. Thus, a fundamental difficulty lies in properly pricing the value of vaccines. Current payment incentive policies are poorly matched to social objectives. Some measure of the societal impact must be considered along with the research, development, and production costs. Ultimately, the immense value of vaccines must be acknowledged by the public in order to maintain an adequate supply of vaccines for the future.

With regard to streamlining the regulatory process, stakeholders felt that some components of the FDA approval process for vaccines could be improved. These include the approval and release of vaccine lots; better harmonization of documents and testing requirements within the FDA, between federal agencies, and with international bodies; a more predictable process with better communications to manufacturers; and greater regulatory flexibility by the Agency. However, vaccine production is a fragile system. If a more robust and redundant system could be created, it would be more tolerant of production breakdowns and/or regulatory delays.

The third strategy, establishing government-directed programs, was considered unnecessary by most stakeholders. This included the establishment of a National Vaccine Authority, as recommended by the Institute of Medicine (IOM). It was suggested that strategies already exist by which the government can stimulate additional vaccine development and production through government requests for proposals (RFPs). This mechanism, which is how the additional doses of smallpox vaccine are being procured, is more flexible and responsive than a government-directed program.

Most stakeholders believed that many current problems with vaccine shortages, especially pediatric vaccines, would have been less severe if there had been adequate vaccine stockpiles (minimally, a six-month supply). Most discussion focused on the logistical and technical issues that would be involved in starting appropriate vaccine stockpiles. The initial monetary investment would be quite high if this strategy were pursued. Also, there was some debate as to whether current vaccine production capacities would be sufficient to meet the increased demand necessary to create stockpiles. Therefore, the NVAC/NVPO will study this issue in greater detail when forming its recommendations to DHHS.

There was consensus that liability, while not the reason for the current vaccine shortages, also is an important issue if adequate vaccine supplies are to be maintained in the United States in the future. The current Vaccine Injury Compensation Program (VICP) has been successful in ensuring vaccine availability in the United States by reducing manufacturer liability. However, the program is in need of revision to accommodate the development and addition of new vaccines to the market, to facilitate less burdensome claim filings, and to include coverage for adult vaccines. Continued protection of manufacturers as well as vaccine providers from liability is necessary for the continued success of vaccination programs in the United States.

Our AMA will monitor the report that is to be presented to DHHS as a result of this workshop and will respond as appropriate. The entire transcript of the NVAC/NVPO workshop as well as the slides of the presenters will be available online at www.cdc.gov/od/nvpo shortly.

ACTIVITIES OF THE INSTITUTE OF MEDICINE ON SHORTAGES OF VACCINES AND ANTIMICROBIAL AGENTS

The IOM intends to prepare a report on vaccine and antimicrobial agent shortages. Experts who participated in an IOM Planning Activity recommended that the IOM study the United States' ability to sustain a reliable pipeline of vaccines and antimicrobials for its population. A summary of the IOM Planning Activity is being prepared, but has not yet been released. The IOM is currently seeking sponsors for this study. Our AMA will monitor the progress of this IOM initiative.

RECOMMENDATION

The Board of Trustees recommends that the following recommendation be adopted and the remainder of this report be filed:

That our American Medical Association continue to implement the recommendations of Board of Trustees Report 7-I-01, "Drug, Diagnostic Agent, and Vaccine Shortages."

18. MAINTAINING THE MEDICAL STAFF CONDITION IN THE MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPITALS

HOUSE ACTION: FILED

This informational report is in response to Substitute Resolution 815, "Maintaining the Medical Staff Condition in the Medicare Conditions of Participation for Hospitals," adopted at the 2001 Interim Meeting . It asked the AMA to study the impact of the revisions of the Medicare Conditions of Participation that pertain to the medical staff and report back to the House of Delegates at the 2002 Annual Meeting.

On December 19, 1997, the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), published a proposed rule that would revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The proposed regulation deletes the Medical staff Condition of Participation (COP) (Section 482.22) and includes the medical staff under a proposed Human resources COP (Section 481.125).

Current Section 482.22 Condition of Participation: Medical staff.
The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) Standard: Composition of the medical staff. The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.
    1. The medical staff must periodically conduct appraisals of its members.
    2. The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) Standard: Medical staff organization and accountability. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.
    1. The medical staff must be organized in a manner approved by the governing body.
    2. If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.
    3. The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:
    1. Be approved by the governing body.
    2. Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)
    3. Describe the organization of the medical staff.

4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.
5. Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oro-maxillofacial surgery, by an oro-maxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.
6. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

Proposed Section 482.125 Condition of Participation: Human resources
All hospital areas are staffed with qualified personnel, who are present in sufficient numbers to meet the needs of the hospital's patients.
(a) Standard: Credentials/qualifications.
1. The hospital ensures that individuals who supervise and/or furnish services to hospital patients, including services furnished under contracts or arrangements, are qualified to provide or supervise the services, and that types of practitioners allowed to practice without direct supervision have delineated clinical privileges for those services.
2. The hospital grants clinical privileges, and periodically reappraises and renews (or denies renewal of) those privileges. If State law requires that an employee, contractor, or a practitioner with practice privileges be licensed, the hospital verifies (and periodically reverifies) compliance with applicable licensure requirements and documents that verification.
3. The medical staff operates under bylaws that are approved by the governing body, establishes the criteria for selection of members, examines the credentials of candidates and recommends eligible candidates to the governing body.

Some components of the proposed rule have been published as separate final rules, however the Medical staff COP remains part of the hospital conditions of participation.

HCFA received 60,000+ comments on the hospital conditions of participation proposed rule. Numerous organizations and individuals requested that the Medical staff COP remain in the final rule. In its April 16, 1998, letter to the HCFA Administrator, the AMA provided the following comments on the proposed elimination of the Medical staff COP:

> The AMA supports HCFA's focus on patient care and outcomes of care, increased flexibility in meeting quality standards, and elimination of unnecessary procedural requirements, **but believes it is essential to maintain the function of an organized, self-governing medical staff**. Because the medical staff has a critical role in ensuring high quality care, at a minimum, the existing condition (§482.22 - "Medical Staff") should be maintained because it requires that the hospital must have an organized medical staff that is responsible for the quality of medical care provided to patients by the hospital. Practicing physicians must be involved in patient assessment, care planning, service delivery, and quality assessment and performance improvement. The medical staff provides an organizational structure for members of the medical staff to develop, communicate, and implement changes that will improve patient outcomes.
>
> **Since the revision of the hospital requirements is part of HCFA's efforts to improve the quality of care to Federal beneficiaries, it is inconceivable that HCFA would propose the elimination of §482.22 ("Medical Staff")**. For example, on page 66749 of the proposed rule, HCFA states:
>
> "...we do not intend to discount the value of a hospital of having a carefully selected and well-organized medical staff. On the contrary, we believe it is self-evident that the medical staff has a critical role in ensuring that high quality care is delivered consistently and that any hazards to patients are promptly detected and eliminated."
>
> In addition, there are references to the medical staff throughout the proposed CoPs and §1861(e)(3) of the Act requires a medical staff.
>
> The existing medical staff CoP gives the hospital and its medical staff the flexibility to modify the medical staff's organizational structure and processes to incorporate innovations in hospital patient care delivery systems and quality assessment practices....

> Incorporating the medical staff into the new §482.125 ("Human resources") suggests that the independent physicians are equated with the employed staff and the medical staff is similar to hospital departments. It fails to recognize that most physicians and other independent practitioners are not employees of the hospital. In addition, it does not recognize their unique relationship with the hospital or that the hospital is not licensed to practice medicine.
>
> The increasing commercialization of health care requires more emphasis on an independent, self-governing medical staff and concomitant strengthening of the medical staff-related conditions of participation. **The AMA believes the existing CoP §482.22 should be strengthened to require an organized and self-governing medical staff as a counterweight to the market pressures for cost containment and inappropriate hospital interference**. The medical staff must be responsible for the quality of medical care and it must be effectively integrated into the hospital's outcome-oriented, data-driven, quality assessment and improvement program....

In addition to its April 1998 letter, the Organized Medical Staff Section Governing Council has met twice with HCFA representatives regarding the elimination of the Medical staff COP and the AMA's Federal Affairs staff continues to monitor the development of the final rule.

Although the Bush Administration has made no decision whether or not to advance a final rule package in the near future, the CMS is continuing its work on completing the final rule.

Although the CMS Clinical Standards Group has stated that it understands the AMA's concerns and will address them in the final rule, the AMA has sent a letter to the new CMS Administrator advising him that the Medical staff COP should be retained in order to maintain quality patient care and improve patient safety. In addition, the AMA addressed the retention of the Medical staff COP in its comments to the Secretary's Advisory Committee on Regulatory Reform. It is essential that the medical staff have the overall responsibility for the quality of medical care provided to hospital patients and is directly accountable to the governing body for patient care regardless of any contractual arrangement which may exist between the hospital and physicians. The AMA will continue to advocate to CMS that the existing Medical staff COP be strengthened rather than be incorporating the medical staff into the proposed Human Resources COP.

19. CLAIMS DENIAL AND PAYMENT DELAYS

HOUSE ACTION: FILED

At the American Medical Association 2001 Annual Meeting, a number of resolutions were introduced related to claims denial and payment delays by health insurers. The House of Delegates adopted as amended Resolution 705, "Claims Denial and Payment Delays," introduced by the American College of Surgeons, in lieu of Resolution 711, which had called on the AMA to develop policy associated with incompletely filed or interrupted claims. Resolution 705 (A-01), as adopted, calls on the AMA to establish policy that "insurers should not deny payment on lost claims discovered beyond the required filing date when the physician has proof that the electronic or paper claim was filed in a timely manner," and "provide a report on the progress" of its advocacy efforts associated with this policy at the 2002 Annual Meeting.

Due to the membership's ongoing interest in prompt payment related activities and policy implementation, this informational Board of Trustees report will update the House on recent AMA efforts to work with the Federation to advocate for changes in health insurer business practices associated with claims denial and payment delays. Recent activities and initiatives that will be discussed in this report include: existing AMA policy; the AMA Model Managed Care Contract; the ARC Campaign to Promote Timely Payment, including its survey process and legislative and regulatory components; the Health Plan Complaint Form; the AMA's recent interactions with health insurers and its ongoing efforts to raise the issue of prompt payment, including "lost claims," to the forefront of the debate regarding managed care hassles; and the AMA's activities associated with the review and implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) related to claims notification and reason codes.

AMA POLICY

The AMA has established considerable policy intended to reduce and eliminate payment delays by private and public payors to physicians for the provision of health care services (Policies H-190.972, H-190.981, H-390.904, H-390.973, H-390.976, H-390.978, H-390.997, and H-385.967, AMA Policy Database). A number of the existing policies seek legislative remedies for the delays in payment. Policy H-190.981 specifies that the AMA will continue to prepare and/or seek sponsorship of legislation requiring health insurers to pay for "clean" claims within 14 days if filed electronically and 30 days when filed manually (paper) and that interest should accrue thereafter. Still other policies dictate that the AMA continue to document delays in payments and aggressively advocate against delaying tactics initiated by third party payors. In fact, Policy H-190.969 calls on the AMA to continue to advocate for the use of the AMA Advocacy Resource Center Campaign to Promote Timely Payment materials by the Federation, including the payment timeliness survey template, as well as assess and communicate the scope of the payment delays and ensure prompt payment of health insurance claims. In addition, the AMA has adopted policy that directly addresses the issue of payment delays due to disputes among multiple insurers (H-390.943, H-335.984, and H-165.883).

The AMA also has established considerable policy associated with the time restrictions for claims submission established by commercial insurers and governmental agencies, as well as timely processing of claims by health insurers and the need for any filing deadlines to be reset when health insurers contend that claims have not been received or require additional information (Policies H-190.965, H-190.967, H-190.979, H-190.991, H-390.947, and H-390.883). In addition, the AMA has established policy associated with a physician's right to receive billing and remittance information, as well as policy that urges the health insurers to develop and utilize explanation of benefits language that is less misleading or inflammatory, while still consistent with applicable state and federal laws (Policies H-190.971 and H-190.994). In fact, AMA Policy H-190.964 calls on all third party payors to "acknowledge receipt of each electronic claim received within 24 hours" and to "accept or reject each electronic claim within 10 business days." The AMA has also established considerable policy concerning retrospective denial of payment and post-payment audit and review (Policies H-70.926, H-320.948, H-320.961, H-335.976, and H-335.997). These policies generally oppose retrospective denial of payment and call on health insurers and government agencies to provide rationale for any determination to deny payment, as well as provide for appeals mechanisms for patients and physicians.

In addition, the AMA has established extensive policy intended to promote greater use of electronic data interchange and improve the efficiency of electronic claims processing, including playing a leadership role in the National Uniform Claim Committee (NUCC), while encouraging health insurers to adopt standardized or open electronic claims submission protocol, reporting methods, including remittance advice, explanations of benefits, "reason codes," other explanations of third party payment adjustment and actions, as well as provide clear rationale for any delay or denial in payment (Policies H-190.976, H-190.977, H-190.978, H-190.980, H-190.982, H-190.983, and H-330.949). AMA Policy H-190.978 specifically calls on the AMA to advocate that all vendors, clearinghouses, and payors adopt the American National Standards Institute (ANSI) Accredited Standard's Committee (ASC) Insurance Subcommittee (X12N) "standards for electronic health care transactions." This policy also indicates that the AMA, through its participation in the NUCC, "work with third party payors to determine the reasons for claims rejection and advocate methods to improve the efficiency of electronic claims approval." However, the AMA continues to oppose the establishment of mandatory electronic submission requirements for data and/or claims by any private or public payors (Policies H-330.954 and H-190.992).

AMA MODEL MANAGED CARE CONTRACT

The AMA Model Managed Care Contract, most recently revised in 2000, contains reasonable alternative language to the often onerous and one-sided health plan contracts. This model contract contains suggested language associated with timely payment and retrospective audits, among other provisions. The prompt payment section and addendum speak to incorporating language in a contract that holds a health plan responsible for payment for services within an acceptable period of time from the date of submission. In addition, the Contract has provisions that require health plans to notify physicians within 15 days to request additional information if the claim is not considered "clean," and to provide the reason for the claimed deficiency.

An increasing number of health plan contracts now contain language associated with timely payment (some state prompt payment laws require timely payment provisions within physician contracts with health plans). However, physicians are starting to discover that health insurers are finding ways around the contract provisions, as well as the state prompt payment laws, through a number of unfair tactics. These include indicating that the claim is not clean; lacks some material piece of information; or was never received or received late. Health insurers then maintain that the contract provisions or the state law do not apply and the claim is paid late without penalty.

The AMA believes that one way to thwart recent methods by health plans to negate timely payment responsibilities is to incorporate language into the physician contract that requires health plans to provide physicians with notice of receipt, in addition to provisions that allow for an extension of time for submission of claims if the physician has a record of the original filing. The AMA will include language relating to timely notice of receipt, current claims status and claims submission time frames into the next iteration of the AMA Model Managed Care Contract consistent with AMA Policies H-190.965, H-190.967, and H-190.979.

AMA INTERACTIONS WITH HEALTH PLANS

Shortly after the 2001 Annual Meeting, the AMA sent letters to national health plan associations that outlined recently passed HOD resolutions related to physician payment, claims processing and coding of services using Current Procedural Terminology (CPT®). The letters also highlighted the growing concerns and frustrations of physicians over delayed and denied payments for claims, especially those claims that are determined to be "lost" by health insurers, as well as the perceived lack of accountability on the part of health insurers for these missing claims. The AMA urged these associations to promote the new AMA claims processing and payment policies and encouraged all health plans to recognize the inherent inequity in a filing deadline, if there is no notification of claim receipt or acceptance or rejection of the claim within a timely manner. These communications also highlighted the fact that there would be a report back to the House of Delegates at the 2002 Annual Meeting regarding what the health insurance industry was going to do to address physician concerns with the delays and denials associated with missing claims and filing deadlines.

Only one health plan association, BlueCross BlueShield Association (BCBSA), was responsive to the AMA's letter. In its letter of response, BCBSA indicated that its Office of Clinical Affairs had looked into the issues raised in the letter associated with timeliness of claims payment and failure of health plans to acknowledge receipt of electronic claims. BCBSA shared with the AMA the fact that it has adopted performance measures for all Blue Cross and Blue Shield plans that measure the timeliness and efficiency of claims processing cycles. According to these measures, plans are expected to process 97 percent of all claims within 30 calendar days of their receipt. However, BCBSA pointed out that claims suspended by the purchaser or under legal review are not counted toward the 30-day requirement. In addition, BCBSA does not have a standard in place for addressing acknowledgement of receipt of electronic claims, though BCBSA indicated that it was not aware of any problem with acknowledgment of receipt of an electronic claim. The AMA will continue to communicate its members' concerns regarding delayed payment, lost claims, and claims receipt to the BCBSA and hopes that the Blue Cross and Blue Shield plans will comply with the BCBSA performance measures associated with claims processing. In addition, the AMA hopes that BCBSA will work with its member plans on addressing the issue of delayed payments to physicians.

The AMA also recently sent a letter to health plan associations detailing policies and directives adopted at the 2001 Interim Meeting, including Resolution 706, which called on the AMA to point out to health plans that "existing error messages are generally inadequate" and that the AMA was willing to work collaboratively with them "to establish claims rejection codes" that specify "the particular data element in question" and "identify the specific deficiency" in detail.

In addition to these letters, the AMA has had a number of discussions with individual health plans related to the AMA's delayed payment and claims processing policies as well as the many physician complaints received associated with claims denial and payment delays. In fact, a number of local and national insurers have indicated that they would re-evaluate internal claims processing and payment practices in an attempt to pay physicians in a more timely manner. In addition, a growing number of health insurers have developed web-based (online) claims status and benefit review systems, and some have even established application service provider (ASP) systems that

allow physicians to check and receive claims processing information, including claims receipt and verification, in real time online. The AMA believes that these new online technologies are, in part, a result of the Federation's many efforts to bring delayed payments and claims processing problems to the forefront of the debate about physician administrative hassles. Unfortunately, most of these systems currently are not set up to allow physicians to actually submit claims or receive payment using this technology. In other words, physicians can only see where the claim is within the health plan's claim processing and payment system. Physicians still have to submit claims manually or electronically using billing entities, clearinghouses, EDI technology, or other methods and then wait for payment that often comes in the form of a paper check sent via regular mail.

AMA HEALTH PLAN COMPLAINT FORM

Resolution 701 (A-01) called for the AMA to establish an electronic information clearinghouse so physicians could report and exchange information about administrative disputes that they encounter with third party payors. The resolution called on Private Sector Advocacy (PSA) to administer and coordinate this project so that information is posted electronically and shared on a regular basis to identify trends and disseminate information in order to facilitate effective, legally appropriate action by physicians and their representative organizations to solve administrative and payment problems with third party payors.

Consistent with this resolution, PSA developed and posted on the PSA section of the AMA web site (www.ama-assn.org/go/psa) a "Health Plan Complaint Form." This form serves as the tool for the collection of information related to health insurers and third party payors. It gathers data on the types and the severity of the hassles physicians are experiencing on a day-to-day basis as a result of managed care. The Health Plan Complaint Form has a number of questions related to delayed and denied payment, including a specific question on lost claims by health plans and whether or not the claim was submitted in an electronic format.

The information collected through this process will be used to identify trends, and to facilitate appropriate meetings with national health insurers, physicians, and the Federation to resolve the hassles and complaints received regarding health insurers or third party payors. In addition, this information will be used to promote other advocacy initiatives and advocate for legislative and regulatory changes to benefit patients and physicians.

ARC CAMPAIGN TO PROMOTE TIMELY PAYMENT

The AMA's Advocacy Resource Center (ARC) developed the Campaign to Promote Timely Payment in 1998. A major component of the campaign, the ARC Payment Timeliness Survey Support Package, which was developed by the Center for Health Policy Research, has been used by medical associations to quantify and document the magnitude of the delays. The survey support package includes analysis tools such as a data spreadsheet with corresponding graphs and charts to be used to present the survey results. The AMA's Private Sector Advocacy unit continues to disseminate the ARC Payment Timeliness Survey Support Package and to work with medical societies to revise and adapt the survey template for their specific needs.

Since the ARC Campaign materials were distributed in June of 1998, PSA has worked with more than 80 state, county, and national medical specialty societies on the prompt payment initiative. PSA has assisted more than three dozen of these associations in developing 50 prompt payment surveys, analyzing data, and designing presentations to clearly demonstrate the magnitude of delays in payment by health insurers. Increasingly, PSA has assisted medical associations to incorporate questions into their prompt payment surveys that evaluate the frequency of "lost claims," those claims that health insurers indicate were not received. These surveys are finding that, according to physicians, one of the most often cited reasons for delays in payment by health plans is that they never received the claim, even when physicians have record of the claim being sent as well as notice of receipt by health insurer.

Approximately 25,000 physicians, who provide care to more than 8 million patients and have contracts with more than 500 health plans, have been surveyed by state and county medical associations with PSA assistance as part of the AMA's prompt payment initiative. These survey findings from across the country clearly demonstrate that many health insurers are failing to comply with fair business practices and current state prompt payment laws by delaying payments to physicians.

STATE PROMPT PAYMENT LAWS AND REGULATIONS

The AMA, through PSA and the ARC, has worked with more than 30 state medical associations in the past several years to draft state legislation and the associated regulation requiring health insurers to pay in a timely fashion. The AMA has worked with many medical associations more than once because prompt payment legislation has been introduced on a number of occasions in these states. Increasingly, medical associations have used the prompt payment survey data to successfully advocate for new or revised state prompt payment laws and assist in the development of the associated legislation and regulations. Forty-seven states currently have prompt payment laws and/or regulations, and a number of states have recently passed revisions to existing legislation that provide stronger monitoring and enforcement mechanisms, as well as stricter payment periods (i.e., 30 days vs. 45 days). In 2001, claims payment legislation was introduced in at least 21 states, most with prompt payment laws already in place.

The AMA has assisted these state medical associations in promoting prompt payment laws that include components such as definite time frames for payment of clean claims (paper and electronic), definite time frames for notice of incomplete contested claims, definition of "clean claims," interest penalties, other penalties such as fines and attorney fees, anti-retaliation language, and auditing mechanisms. Most recently, and most germane to the issue of "lost claims," AMA staff worked with state medical associations to promote the incorporation of claims notice, claims receipt and claims status language in prompt payment legislation and promulgated regulation, as well as language prohibiting or limiting retroactive denials or adjustments. An increasing number of state prompt payment laws now include claims notice, retroactive denial and auditing provisions.

The AMA believes strongly that one way to limit, if not prevent health insurers from justifying delayed payments to physicians associated with "lost claims" is to have health insurers provide notice of receipt of the claim. This acknowledgement of receipt starts the clock running related to time frame for payment under most state laws and provides the physician with a critical piece of information - that the claim has been received and its current status, if for example, the health insurer deemed the claim "unclean." The notice of receipt essentially prevents resubmission of an "unclean claim" and possible duplication of a "clean claim;" two other reasons often cited by health insurers to physicians for delays in payment in excess of state prompt payment laws.

Since most states have prompt payment laws in place, recent legislative efforts have focused on enhancing these provisions. The ARC has developed a Legislative Template and State Model Legislation that provide examples of language to incorporate into state prompt payment legislation, including language associated with the amount of time allowed between claims submission and payment, time for resubmission of claims, incomplete and contested claims. Both of these documents are available on the Virtual ARC (www.ama-assn.org/ama/pub/category/2914.html). In addition, the Virtual ARC contains detailed information on state prompt payment laws, including a summary of state laws, and a compilation of specific state provisions on the definition of a "clean claim," retroactive denials and adjustments, and when a claim is deemed "received" or "mailed."

The AMA has also assisted state medical associations in the presentation of their prompt payment survey results to state regulators and legislators. State regulatory agencies and officials from a number of states have reviewed this survey information and, in part, have used the data to justify auditing and reviewing health plans to determine their compliance with state prompt payment laws. In fact, year after year, prompt payment fines have continued to increase both in quantity and in magnitude. In the past five years, state level prompt payment fines have totaled more than $28 million (in aggregate), and this dollar figure has been climbing recently. These fines generally go into state funds earmarked for health related expenses, including monitoring and enforcing state health insurance regulations. Physicians do not financially benefit from the fines, though physicians may receive applicable interest on late payments as specified and defined by state prompt payment laws.

Finally, PSA recently worked with a number of state medical associations to assist in the development of prompt payment complaint forms to be used by physicians to document and report violations of state prompt payment laws by health insurers, including delays associated with "lost claims." These forms allow physicians to document when a service was provided, when the claim was submitted, when the health insurer acknowledged receipt of claim, if at all, and when payment was received. Most notably, the AMA recently assisted the Oregon Medical Association (OMA) in the development of its delayed payment complaint form. This form serves as a tool to formally file a complaint of no-compliance with the Oregon Insurance Division (OID). Using this form, Oregon physicians will now be able to submit a complaint of no-compliance directly to the OMA, alleging a violation of the state prompt payment law by a particular health plan. The OMA has committed to delivering all of these forms to the OID.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Claims status information and requirements are not limited to private contractual matters or state prompt payment laws. HIPAA included a number of provisions tied to the submission and processing of a claim that may go a long way to addressing some of the claims processing concerns raised by physicians. HIPAA's Administrative Simplification Transaction and Code Sets Final Rule outlined a set of transaction standards and code sets for data transmission, including Claim Adjustment Reason Codes, Claim Status Codes, Claim Status Category Codes, Health Care Services Decision Reason Codes, and Remittance Remark Codes. These code sets may actually address claims notification, receipt and status difficulties that currently exist. However, it is critical to point out that these transactions and code sets have nothing to do with when, or even if, payment for services must be made to physicians by health plans. The electronic nature of claims submission and the standardization of data on claims may simplify and streamline claims payment, but it will not change health plan payment deadlines. However, these guidelines will require health plans to use standardized reason codes as part of payment remittance advice on the 835 (electronic transmission) form. These reason codes will provide physicians with an understanding of what is missing and/or required on a claim.

The NUCC was formally named in HIPAA as one of the organizations to be consulted by the American National Standards Institute's accredited Standards Development Organizations (SDOs) and the Secretary of Health and Human Services (HHS) as they develop, adopt, or modify national standards for health care transactions. As such, the NUCC is intended to have an authoritative voice regarding national standard content and data definitions for non-institutional health care claims in the United States.

The NUCC was essentially created to develop a standardized data set for use by the non-institutional health care community to transmit claim and encounter information to and from all third party payors. It is chaired by the AMA, with the Centers for Medicare and Medicaid Services (CMS), as a critical partner. The Committee includes representation from key provider and payor organizations, as well as standards setting organizations, state and federal regulators and the National Uniform Billing Committee (NUBC).

The NUCC provided comments on the Transaction Codes Implementation proposed regulations and the AMA also participates in the process established for the Designated Standards Maintenance Organizations (DSMOs) for proposed changes to the standard transactions. In addition, the NUCC is responsible for the maintenance of the provider taxonomy codes. However, the NUCC, as a committee, does not participate in the claims adjustment/reason code discussions. The claims adjustment/status code committee has been established externally to the X12N group and the committee includes individual representatives from various segments of the health care industry. The remittance remark codes are maintained by CMS with no representation from the health care industry.

CONCLUSION

The AMA will continue to assist the Federation in its efforts to identify health insurer business practices that result in delays and denials of payment to physicians through continuation of private sector initiatives, including the Health Plan Complaint Form and ARC Campaign to Promote Timely Payment. In addition, PSA will continue to work with health insurers to address the issue of "lost claims," recognizing that claims status information is invaluable in documenting receipt of a claim. PSA will continue to disseminate the ARC Payment Timeliness Survey Support Package and work with the Federation to revise and adapt the survey template to assist physicians in tracking "lost claims," as well as identifying persistent and pervasive practices by health insurers to circumvent existing prompt payment laws. Likewise, as the prompt payment issue continues to evolve, the ARC will continue to work with medical associations across the country on legislative advocacy that includes promotion of language that protects physicians from retrospective audits and review, as well as addresses statutory time limitations for submitting claims. Finally, the AMA will continue to work through the NUCC to provide comments on guidelines and standards associated with the HIPAA transactions and codes and continue to promote AMA policy associated with the use of electronic claims submission methods as a mechanism for decreasing claims processing delays.

20. ANNUAL TOBACCO REPORT 2002

HOUSE ACTION: FILED

In Memoriam: John Slade, MD (1949-2002) - Distinguished Leader in Addiction Treatment and Tobacco Prevention (excerpts from an obituary by the Robert Wood Johnson Foundation).

John Slade, MD, an expert on the treatment of alcohol, tobacco and drug addiction, and one of America's pioneer advocates for tobacco control, died January 29, 2002 at the age of 52. Dr. Slade suffered a stroke in July 2001. An internist who projected the quiet air of a small-town doctor, Dr. Slade had a deep, personal concern for people struggling with addiction, and he devoted his life's work to fighting that public health pandemic. He provided treatment to patients as Director of the Program for Addictions at the University of Medicine and Dentistry of New Jersey (UMDNJ) School of Public Health, where he was appointed Professor of Medicine in 1998. He spoke out vigorously about the advertising and promotion of tobacco products, and his knack for collecting tobacco promotional items--from T-shirts to model cars--led to the creation of one of the largest repositories of its kind, which he dubbed, "Trinkets & Trash."

He was a member of the team that conducted the first scholarly analysis of previously secret documents from the Brown & Williamson Tobacco Company. Dr. Slade's analysis led to a landmark series of articles in the *Journal of the American Medical Association* in 1995 as well as a book, *The Cigarette Papers*. His groundbreaking research to prove that cigarettes are nicotine delivery devices helped make it possible for the Food and Drug Administration (FDA) to claim regulatory authority over tobacco products under then-FDA Commissioner Dr. David Kessler. In his recent book, *A Question of Intent: A Great American Battle with a Deadly Industry*, Kessler credits Dr. Slade with playing a major role in influencing the FDA's fight against tobacco.

Dr. Slade was selected by The Robert Wood Johnson Foundation to direct two national programs in substance abuse leadership--to attract and inspire new leaders in the field, and to recognize and support leaders who have demonstrated outstanding achievement. He co-edited the first major clinical textbook on nicotine addiction, founded the Committee on Nicotine Dependence of the American Society of Addiction Medicine (ASAM) and, since 1988, directed a program in New Jersey to help treatment and addiction programs address tobacco and nicotine addiction that has become a national model. He was a founding member of the national Society for Research on Nicotine and Tobacco, and was honored with awards including: Emory University's Moore Award for outstanding contributions to community health; The Koop Award of the New Jersey Group Against Smoking Pollution; the Award of the New Jersey Public Health Association: two leadership awards from the ASAM; and the Goethe Trophy from the German Medical Association for outstanding contributions in global tobacco control. He had been listed since 1994 in *The Best Doctors in America*.

AMERICAN MEDICAL ASSOCIATION ACTIVITIES AND ISSUES

The beginning of 2001 marked the start of the new SmokeLess States National Tobacco Policy Initiative. The National Program Office (NPO) at the AMA received 51 applications for funding in two proposal cycles, and awarded $35 million in grants to 40 statewide coalitions. SmokeLess States supports the work of statewide tobacco control coalitions focusing on reducing exposure to secondhand smoke, increasing tobacco excise taxes, or ensuring cessation services and treatment.

The NPO sought to strengthen the coalitions around the country, using the national influence and reach of the AMA. This work is ongoing with the aim to expand the base of support among the medical community by engaging and including state medical societies and specialty societies in tobacco control. The Federation and specialty society staff at the AMA have been brought on board to help build a strong foundation of understanding and synergy among those working on a statewide and local level. It is now regular practice for a liaison officer to hold a discussion with the executive director or president of a state medical society as well as internal AMA Federation staff before conducting site visits.

The SmokeLess States web site (www.smokelessstates.org) was expanded to provide a greater resource to the public and grantees. Information on the activities of each coalition was made available on the web, as well as various resources on tobacco control. The "Clearing the Air in Enclosed Public and Work Places" presentation from

Americans for Nonsmokers Rights was made available for download to Internet visitors, and a "Model Ordinance Eliminating Smoking in Workplaces and Public Places" was endorsed by the AMA and put on the Advocacy Resource Center's web site.

Another vehicle used by the NPO to disseminate information was the newsletter. Stories in the newsletter focused on grantee policy work and NPO activities, such as program expansion and addition of new staff. The press run of each issue averaged about 6,000 copies. The newsletter was redesigned and renamed "SmokeLess States Policy Focus" late in the year, and the first new issue was published in January 2002.

The NPO also commissioned a report "Preemption: Taking the Local out of Tobacco Control," which it plans to publish in 2002. Another report, "Fundamentals of Clean Indoor Air Policy" was prepared and shared with grantees late in the year.

Many readers will recall that the House of Delegates adopted a resolution in 1963 establishing an educational campaign to discourage the use of tobacco among young people. While the Surgeon General's famous report on smoking and lung cancer was issued the following year, the House considered the statistical data only inferential in nature, and did not formally endorse the Surgeon General's findings. Instead, it charged the AMA Education and Research Foundation to oversee research related to tobacco and health, pledging $500,000 for the project. Shortly after this project was started, the tobacco industry joined the effort, with a $10 million grant to the AMA-ERF for the project. By June of 1964, an oversight committee had begun to award grants in a variety of areas, including the effects of smoking on the pulmonary, cardiovascular, and metabolic systems; the addictive and carcinogenic properties of tobacco use, and the pharmacology of nicotine. Between 1963 and 1975, 844 researchers in the United States and scientists in 13 foreign institutions received grants, producing 795 publications and reports.

The Tobacco Institute, through which the industry's money was donated, met to discuss the AMA research project in 1972; the meeting summary was captured in the following internal document:

Tobacco Institute Meeting - Monday, March 13, 1972
Present: Senator Clements, Horace Kornegay, William Kloepfer, Fred Panzer, Anne Duffin, Dr. Heubner, Dr. Kastenbaum, Bill Shinn (Shook, Hardy, Ottman, Mitchell and Bacon) C.B. Wade, Jr., H.C. Roemer, Jr., J.S. Dowdell

Mr. Wade opened the meeting by reviewing the current status of the AMA-ERF contract and asked for opinions from those present relating to alternative courses of action that the industry might take should the present AMA contract be terminated prior to the expiration of the agreement in 1973. The following are excerpted quotes:

Shinn: The problem is how to terminate the agreement without creating an absolute vacuum. It is essential that the industry continue to support research, but where should we be looking? There are many research projects that the industry could spend money on--cancer, heart, respiratory diseases--but our money should be spent to produce results. Not necessarily confined to smoking and health per se, but on some of the new promising developments which are beginning to point up other factors relating to disease. Look for areas where the results will relieve the pressures on the industry. For example, study the kind of people who smoke to identify differences from nonsmokers which would explain the statistical association. Research in this area looks promising. There are plenty of projects, but we need to look at the people doing the work in relationship to their standing in the medical-scientific research community. Industry can't afford to sponsor anyone second-rate. There are many good people with established reputations who have made overtures to us, but we have not zeroed in on any of them because of money.
Huebner: The AMA is not looking at their research with the critical eye we are. They give it out to people who are trying to prove just how bad smoking is. Not much different than the Public Health Service. Believe we all recognize AMA-ERF is a bad investment, but how do we get out with honor? For the moment, we are stuck with a bad situation. Before we get out, we need to look carefully at where we will go. The AMA research has no direction. Their people are taking tobacco money for work in other areas. We need to make some fundamental decisions, and there are some significant opportunities to get some directed research done now. We need to know what type of person is a chronic respiratory risk. We need valid tests, the same as we have for diabetes. Who are these people? We should be able to identify them in their teens. We should also be able to do the same with people who get malignancies. They are different people. We have to face it, now it is all the fault of cigarettes. We need to get some large-scale programs going along these lines. We must find out biochemically how people get these diseases--and why they do.

Shinn: Gil and I differ on this point. In the courtroom it is no defense to say people are different. This isn't enough....
Roemer:....But, sooner or later, we must know the truth. Maybe we should start now to accept the risk....
Panzer: The only sub-group identified now are the smokers....
Kornegay: Technically, would the source of the research funding complicate your problem?
Shinn: It's not all one way or the other. But the closer you get to the research to the main defendant the worse it is. In other words, "the more risky the project, the more need to have it done by someone else."
Kastenbaum: We have nothing at this time to recommend that we divert funds to. But we are going to have to make a decision on a project, or projects, to take the place of the AMA. If it is not done now, it will have to be done next year when the contract terminates.
Roemer: What we need is cohesive, directed research....
Wade: How about some of the projects we have in hand now. Where do we stand on Harvard, for instance?
Huebner: Protocol now at 300 pages. They are not out to embarrass or destroy the industry. They believe they can save it. They think that after they publish one or two papers the whole smoking and health question will be reopened....

Further along in the meeting, the participants discuss researchers at the University of Nebraska who could cast doubt on the smoking-pulmonary disease link, and the public relations benefits of "conclusive proof that smoking is not harmful to mothers...."

TOBACCO ADVERTISING AND PROMOTION

The AMA has long advocated that physicians make their offices free of tobacco advertising. *JAMA* published a list of magazines that did not accept tobacco advertising in the mid-1990s, but that list has not been updated recently. Building on the campaign a decade ago by Doctors Ought to Care, the Medical Society of the State of Maryland (MedChi) has begun a new list of tobacco-free publications, called the Tobacco-Free Periodicals Project. The list is regularly updated, and can be accessed at: www.medchi.org/grants/tobaccoads/main.asp, or www.smokefreemd.org/magazines.htm.

The world's largest tobacco companies agreed in 2001 to a global ban on the advertising of cigarettes on TV and radio. New marketing standards, agreed upon between Philip Morris, British American Tobacco (BAT) and Japan Tobacco, will also end tobacco sponsorship of big sporting events, such as soccer and Formula One racing worldwide. The three tobacco groups have agreed to pull advertising off television and to scrap youth-orientated advertising. The plan was announced as a countermeasure to the World Health Organization's proposed Framework Convention on Tobacco Control. The standards will take effect by the end of 2002 and will supposedly affect cigarette marketing everywhere and in every medium, including billboards, broadcasting sponsorship and packaging. Papastratos, the Greek tobacco company, Thai Tobacco Monopoly and two Latin American companies, CITSA and Grupo Iberamericano de Fomento, have also signed up.

The tobacco industry guidelines, predictably, are fairly weak standards, less stringent than existing laws in many developed nations. The new standards bar depiction of people appearing to be younger than 25 years of age and suggestions that smoking enhances athletic, professional or sexual success or popularity. Under the standards, outdoor billboards would be limited in size and kept at least 100 meters from schools. The standards further call for restrictions against television, radio and Internet adds "unless and until technology exists to verify that access is restricted to adult viewers and to countries where such electronic advertising is permitted." The guidelines prohibit product placement in movies, television and other media intended for the general public. They also call for "reasonable" efforts to make sure youths cannot have access to cigarettes in vending machines.

A new report, "How the Tobacco Industry Built Its Relationship With Hollywood," uses previously secret tobacco industry documents to substantiate the decades-long entanglement between Big Tobacco and the movies, and moviemakers. "While tobacco companies publicly swore to end paid product placement in 1989, tobacco use in movies was more extensive in the 1990s than the previous three decades and remains high today, even though overall tobacco use has dropped dramatically in the United States," said Stan Glantz, a University of California cardiologist who authored the report. It appeared in the Spring 2002 issue of *Tobacco Control*. The report offers copious examples of the tobacco industry's paid product placements in the 1970s and '80s - Phillip Morris alone is credited with 191 placements in films including "Grease," "DieHard," "Field of Dreams," and "The Muppet Movie." The most damning piece of evidence in the study is a Phillip Morris marketing plan written in 1989 that suggests the overt role the company had in cinema product placement: "We believe that most of the strong, positive

images for cigarettes and smoking are created by cinema and television. We have seen the heroes smoking in "Wall Street," "Crocodile Dundee," and "Roger Rabbit"; Mickey Rourke, Mel Gibson and Goldie Hawn are forever seen, both on and off the screen, with a lighted cigarette. It is reasonable to assume that films and personalities have more influence on consumers than a static poster....If branded cigarette advertising is to take full advantage of these images, it has to do more than simply achieve package recognition--it has to feed off and exploit the image source."

The report also offers examples of film companies' seeking out tobacco companies and offering product placements in return for money. In one such example, Twentieth Century Fox Licensing and Merchandising Corp. sought deals with several tobacco companies in 1984. "Tobacco use in movies, which was falling through the 1970s and 1980s, increased significantly after 1990," according to the report. More specifically, Glantz says, movie leads these days are four times more likely to smoke than their real-life counterparts. Whereas the lead characters who smoke often are wealthy and successful, "people who smoke in the real world tend to be poor, poorly educated people."

Despite Big Tobacco's recent attempts to portray itself as reformed, a report released early in 2002 by the Campaign for Tobacco Free Kids reveals some of the outrageous marketing practices that these companies continue to engage in worldwide. The report, "How Do You Sell Death," presents photos of Big Tobacco's advertising in a visually compelling way. Using pictures and stories to illustrate tobacco industry advertising around the world, this publication can be used by educators and activists to expose the many ways that the industry gets around national advertising restrictions to sell its deadly products. These include:

- using the Winston brand to promote the broadcast of an Evander Holyfield fight in Malaysia;
- using the imagery of the Statue of Liberty in a newspaper ad in Poland;
- hosting street raves in Switzerland featuring dancers dressed in skimpy Camel-and Winston-branded outfits;
- sponsoring a Salem concert by the Irish pop group The Corrs in Malaysia's National Stadium;
- sponsoring the Miss Niger fashion show;
- putting up Philip Morris billboards to promote the Prague zoo;
- opening up "Camel Adventure" and "Marlboro Classics" clothing stores in Thailand and the Czech Republic;
- giving out free cigarettes in countries such as Uganda, Sri Lanka and Japan; and
- hosting Internet sites that lure young people with images of fashion and music.

The report is available on the web at www.tobaccofreekids.org/campaign/global/FCTCreport2.pdf.

Despite restrictions imposed on some tobacco advertising, young people are frequently exposed to high levels of tobacco promotion in retail stores, according to a new Robert Wood Johnson Foundation-supported study released by the CDC (published in the March 7, 2002 *MMWR*). The study found that more than 90% of retail stores that sell tobacco products had some form of tobacco advertising, including interior and exterior advertisements; self-service pack placement; multi-pack discounts; tobacco vending machines; and tobacco-branded functional objects such as shopping carts or counter mats.

Overall, the report concludes that convenience, convenience/gas, and liquor stores were most likely to have "tobacco-friendly" environments where patrons would be highly exposed to tobacco advertisement, promotions, and tobacco branded objects in the stores. Previous research indicates that 75% of teenagers shop at convenience or convenience/gas stores once a week or more.

- An estimated 80% of retailers had interior tobacco advertisements with 22.8% of stores having high levels of such ads.
- Exterior tobacco advertisements were observed in 58.9% of stores with 40.4% of stores having high levels of ads.
- Only 4.1% had tobacco health warning signs.
- Low height ads (ads placed less than 3 1/2 feet above the floor) were observed in 42.9% of stores.
- Self-service cigarette pack placement was observed in 36.4% of stores.
- Multi-pack discounts were present in 25.2% of stores.
- 68.5% of stores had at least one tobacco-branded functional object (such as shopping baskets or counter change mats).

Other forms of promotion have been designed to reach the market segment just over age 18 years. Glantz and colleagues described the tobacco industry's use of bars and nightclubs to encourage smoking among young adults in a paper published in the March 2002 issue of the *American Journal of Public Health*. An analysis of tobacco industry documents showed that tobacco industry bar and nightclub promotions in the 1980s and 1990s included aggressive advertising, tobacco brand-sponsored activities, and distribution of samples. Financial incentives for club owners and staff were used to encourage smoking through peer influence. These bar and nightclub events are often featured in establishments close to college campuses, and are highly advertised in alternative weekly newspapers in large urban areas. Increased use of these strategies occurred concurrently with an increase in smoking among persons aged 18 through 24 years. The tobacco industry's bar and nightclub promotions are not yet politically controversial and are not regulated by the 1998 Master Settlement Agreement (MSA) between the industry and the states.

In a front-page story in the February 4, 2002, issue of *Advertising Age*, the magazine describes a move by Philip Morris to cancel its magazine advertising in the United States. The company has announced that it is cutting its print ad budget significantly, and some think this means total withdrawal from this medium for the company. The nation's leader in market share may not see the need to continue to advertise in magazines, since it has been subject to criticism from the health care community over the years for its aggressive use of youth-oriented publications. Having pulled back from many of these controversial placements, the decision may have been that the return from magazines was not worth the cost--and as the market leader, Philip Morris can afford to use its advertising budget in other ways, such as increasing its promotion of the music scene in bars and other venues that attract young professionals and college students. R.J. Reynolds Tobacco Co. (RJR) and the other major US tobacco companies have not indicated that they will stop using magazine advertising.

Philip Morris accounted for $114.7 million of the $267 million spent by tobacco companies on magazine ads in 2001, with *Time*, *Family Circle*, *Woman's Day*, *Playboy*, and *Ladies Home Journal* at the top of the Philip Morris magazine list. Philip Morris' magazine spending dropped 50% from 1999 to 2001. Overall, the *Advertising Age* story reports, tobacco companies accounted for 2.3% of all "measured media spending" in 1970, and only 0.5% in 2000. In 1981, cigarettes were the #1 revenue category for magazines, and now the product ranks #21.

In an editorial in the March 2002 *Tobacco Reporter* (a tobacco industry trade journal), a Brown & Williamson executive claims that Philip Morris is not being altogether honest in announcing its support last year for regulations that would eliminate self-service displays for cigarettes. By removing these displays, the editorial charges, Philip Morris has a hidden agenda to reduce the visibility of competitor brands. B&W and other brands lose because Philip Morris "uses merchandising contracts that force retailers to provide optimal behind-the-counter positioning for its brands and restrict the marketing opportunities for competitors, in order for the retailer to receive promotional and discount payments."

Researchers at the University of Chicago published a review of magazine advertisements that suggests tobacco companies are continuing to direct cigarette ads at youth, a practice that violates the 1998 settlement agreement between the major US tobacco companies and 46 states. The MSA specifically bans youth-targeted advertising, but Drs. Paul Chung and Craig Garfield said their study indicates that the tobacco companies have learned how to "appear to comply" with the MSA, while continuing to target underage smokers. The tobacco companies are using a standard offered by the FDA, which defined a youth-oriented magazine as one which has more than 2 million readers under age 18--*People* and *Sports Illustrated* are in this category--or one in which more than 15% of readers are age 18 or younger, such as *Allure* or *Hot Rod*. Using the FDA definition, tobacco companies could still target magazines with fewer than 2 million youth readers or magazines that fall below the 15% threshold. The researchers concluded that eliminating youth-targeted tobacco ads might be impossible without a complete ban on print advertising. (Philip Morris has pulled all its ads from *Sports Illustrated* and most other youth-oriented magazines, and is likely to be dropping all its Marlboro ads from print media. See above.) The study is in the March/April 2002 issue of *Health Affairs*.

Michael Schumacher, the 32-year-old reigning world champion of Formula One auto racing, is the world's highest-paid athlete. His salary and endorsement package, according to *Forbes*, of $59 million a year, which puts him ahead of Tiger Woods, Shaquille O'Neal, Kobe Bryant, Michael Jordan, and other elite athletes. Schumacher is also the sport's best test driver, working with Ferrari's engineers to hone the car's handling to a razor's edge. An estimated 350 million people in 150 countries watch every Formula One race on television. Formula One relies heavily on tobacco money. Schumacher's car is a rolling billboard for Marlboro, which uses racing to sidestep Europe's strict cigarette ad laws, and which provides Philip Morris with prime TV exposure. His star power has helped Formula

One's major promoter, Bernie Ecclestone, become the third richest man in Great Britain, worth a cool $3 billion. Ecclestone gave handsomely to Tony Blair's election campaign, and the sport received special exemptions in Britain's otherwise all-encompassing tobacco advertising ban.

Siegel reports on tobacco industry sponsorship of road racing in the July 2001 issue of the *American Journal of Public Health*, showing that from 1997 to 1999, tobacco companies received television exposure worth $410 million. Despite a ban on televised advertising, the tobacco companies have used racing as a prime means of subverting the ban. During the study period, 169 hours of television time was achieved through sponsorship of racing events (the Winston Cup series, etc.) and race cars themselves (Marlboro, Kool, and others). Siegel estimates that over 17 million people attended racing events in 1999 alone, with an average of 2.4 million home viewers of each event. The sponsorships appear to be a clear violation of the 1971 ban on televised tobacco advertising. The MSA allows each company one brand-name sponsorship of a racing event or tour each year. Siegel estimates that even if strictly enforced, this arrangement represents over 70% of the 1999 television viewing totals.

In a bid to comply with the 1998 tobacco settlement, RJR announced in July 2001 that its sole auto sponsorship event will be stock car racing's Winston Cup Series. The Winston Cup has been the championship trophy of NASCAR's premier series since 1971, with the company's support growing from $100,000 the first year to more than $13 million in 2001. Since 1971, when driver Junior Johnson helped bring the parties together, RJR has contributed more than $112 million in NASCAR purse, bonus and points-fund money. RJR will abandon its relationship with the NHRA Drag Racing Series. RJR had to reduce its sponsorship to a single cigarette brand by the end of the year to comply with the tobacco settlement. Winston's brand share among NASCAR Winston Cup attendees and fans is five times that of its national share of cigarette sales.

Philip Morris is expanding its Western look to women. For the first time, the company is using women as cowgirls in German movie ads. The company states that "the values Marlboro stands for, such as freedom and adventure, self confidence and self-determination are today just as true for women as they are for men." The company does not mention lung cancer and addiction as virtues of Marlboro use, naturally.

In Australia, Philip Morris was exposed in September 2001as being behind another event and relationship marketing strategy aimed at marketing Alpine cigarettes to young women. Other sponsors in the fashion/dance event had no idea PM was behind the marketing exercise and have withdrawn their support. The strategy aims to develop a database of suitable people from the target demographic (young women) and encourage them to attend cool events that heavily feature Alpine cigarettes. They also aim to get leverage from other brands that co-sponsor the events. These other brands are also brands that are popular with the target market. This expose follows a similar event in Australia last year involving Philip Morris and Alpine, and events marketing.

BAT has also been implicated in development of a "stealth" web site in Britain designed to lure young, fashion-conscious targets to retail and music events that would feature BAT products as centerpieces. Neither tobacco products nor BAT were identified as being part of the web site or event sponsorship. The scam was exposed by the tobacco control group, Action on Smoking and Health - United Kingdom.

Glantz and colleagues examined changes in tobacco promotions in the alternative press in San Francisco and Philadelphia from 1994 to 1999. A random sample of alternative newspapers was analyzed, and a content analysis was conducted. Between 1994 and 1999, tobacco advertisements increased from 8 to 337 in San Francisco and from 8 to 351 in Philadelphia. Product advertisements represented only 45% to 50% of the total; the remaining advertisements were entertainment-focused promotions, mostly bar-club and event promotions. The authors conclude that the tobacco industry has increased its use of bars and clubs as promotional venues and has used the alternative press to reach the young adults who frequent these establishments. This increased targeting of young adults may be associated with an increase in smoking among this group (*Am J Public Health* 2002 Jan;92[1]:75-78). (Similar anecdotal findings have been commonly reported in Chicago and elsewhere, especially promoting tobacco industry-sponsored entertainment around colleges.)

A study was conducted to test the hypothesis that greater exposure to smoking in films is associated with trying smoking among adolescents. A cross-sectional survey was made of 4919 Vermont and New Hampshire schoolchildren aged 9-15 years, and an assessment of occurrence of smoking in 601 films. Exposure to smoking in films varied widely: median 91 (49-152) occurrences. The prevalence of ever trying smoking increased with higher categories of exposure: 4.9% among students who saw 0-50 occurrences of smoking, 13.7% for 51-100 occurrences, 22.1% for 101-150, and 31.3% for >150. The association remained significant after adjustment for age; sex; school

performance; school; parents' education; smoking by friend, sibling, or parent; and receptivity to tobacco promotions. The adjusted odds ratios of ever trying smoking for students in the higher categories of exposure, compared with students exposed to 0-50 occurrences of smoking in films, were 1.7 (95% confidence interval 1.2 to 2.4), 2.4 (1.7 to 3.4), and 2.7 (2.0 to 3.8). These odds ratios were not substantially affected by adjustment for parenting style or for personality traits of the adolescent. In this sample of adolescents there was a strong, direct, and independent association between seeing tobacco use in films and trying cigarettes, a finding that supports the hypothesis that smoking in films has a role in the initiation of smoking in adolescents. (*BMJ* 2001 Dec 15;323). (Glantz has also written extensively on this subject, and has a web site devoted to the issue: www.smokefreemovies.ucsf.edu.)

In an online interview with Phillipe Boucher, tobacco advertising expert Rick Pollay of Canada discusses some of what he has learned over many years of studying tobacco ads:

Q: What did you learn from the study of those ads? What should they teach us about the strategies used by the tobacco industry?

RP: I've learned a great deal about how tactics change (a) when targeting different types of audiences (men vs. women, starters vs. concerned addicts); (b) when new technologies are introduced (e.g., filters, "light" products, "superslims", etc); (c) and when the industry members adopt new policies as a result of regulation, news events, or collusions (e.g., getting off TV, responding to the health scare of the 1950s and ceasing the use of explicit health claims that were "part of the problem").

Q: 8000 ads [in one of Pollay's tobacco ad collections], it's a lot of pictures. Are some more equal than others? What ad icons or ad campaigns do you think stand out?

RP: This is a very tough question. Many campaigns are notable for different things they illustrate, such as Marlboro's shift from being "mild as May" to using the cowboy as an icon of independence. On an artistic level, and for its role modeling, my favorite campaign is that of the Viceroy ads of the late 1950s wherein "intelligent people" were smoking--rocket scientists, astronomers, anthropologists, newspaper editors, etc. The art work was painstakingly detailed original art instead of the photography that is so common today.

Advertising Age and several other media outlets reported in August 2001 that Philip Morris, British American Tobacco and Japan Tobacco are working together to develop standard guidelines for how they market their products around the world. The following statement is excerpted from a reaction issued by the Center for Tobacco Free Kids:

> "The marketing standards being discussed do not deserve to be taken seriously and are especially inadequate in comparison to the total ban on tobacco advertising and marketing being proposed by many nations. They even fall short of the weak voluntary restrictions that tobacco companies have been willing to accept in the United States and other countries. For example, the tobacco companies propose to cease advertising in publications with greater than 25% youth readership, when in fact several companies have already stopped advertising in US publications with greater than 15% youth readership. The restrictions on outdoor advertising fall far short of what is required in the United States, and the provisions governing television advertising represent a stunning reversal of the long accepted prohibition of all television tobacco advertising. Furthermore, these standards would not affect some of the largest categories of industry marketing, such as promotional allowances for shelf space and product placement, discounts, giveaways and point-of-purchase advertising.
>
> "It is no coincidence that the industry's latest public relations initiative is being launched as the world's nations negotiate the first international tobacco treaty, the Framework Convention on Tobacco Control, and a growing number of countries around the world take action to regulate the manufacture, marketing and sale of tobacco products. The tobacco industry's latest PR effort is aimed at blocking the effective action we need."

Despite promises to stop targeting adolescents in magazine advertisements, tobacco companies continue to encourage young people to smoke, researchers reported in an article in *The New England Journal of Medicine* (2001;345:504-511, accompanying editorial pp. 535-537). Siegel and colleagues analyzed the amount of money the four largest tobacco companies spent between 1995 and 2000 on advertisements for "youth brand" cigarettes in 38 magazines designed for both young people and adults. The percentage of the advertising budget set aside for youth

advertising increased slightly to about 28% in 2000 from about 24% in 1995. And advertisements for cigarettes smoked by more than 5% of smokers in high school--which are considered ‘‘youth brands’’--reached more than 80% of young people in the United States in the last year. In an accompanying editorial, Dr. David A. Kessler of Yale University School of Medicine and former FDA Commissioner, and Matthew L. Myers, of the National Center for Tobacco-Free Kids, argue that Congress could also make a difference. They suggest that Congress provide funding for a national education campaign and also grant the FDA regulatory power over the tobacco industry.

In their article, Siegel and co-author Charles King of Harvard Business School note that some tobacco companies have honored the agreement more than others. Philip Morris decided to stop advertising in youth-oriented magazines beginning in September 2000, and Brown & Williamson also cut back on advertisements in these magazines. The two other major tobacco companies, RJR and Lorillard, have not made any changes in advertising.

In a related story, *Advertising Age* reports in its August 20, 2001 issue that some publishers have offered tobacco companies a modified subscriber list of customers verified as over 21 years. *Sports Illustrated*, *Entertainment Weekly*, and *Rolling Stone* have offered Brown & Williamson targeted subscription list for its ads. The tobacco company will pay about as much as for an ad in the magazine’s entire subscription list, even though the ads would appear in only about half the copies. In the article, it is reported that for January to June 2001, tobacco ad pages declined 45.8%. While Philip Morris has pulled its ads out of 50 youth-oriented publications, RJR has cut only six magazines, including *Spin* and *Vibe*, and Brown & Williamson has taken its cigarette ads out of about a dozen magazines.

Philip Morris, the second-largest advertiser in the United States, reduced ad spending in the first half of 2001 by 16% to $863 million from $1.03 billion, as compared with the previous year, according to Competitive Media, a firm that tracks ad spending.

LEGAL ISSUES

The US Supreme Court ruled 5-4 that a Massachusetts regulation on outdoor advertising of tobacco products is unconstitutional. The regulation would have kept tobacco ads from being displayed within 1000 feet of schools and playgrounds, including at convenience stores. The Court ruled that these regulations violated the First Amendment as it applies to commercial speech, and that parts of it were preempted by the Federal Cigarette Labeling and Advertising Act. The AMA and others in the health community argued in an amicus brief that the regulation should stand, pointing out among other things that the regulations merely restricted where tobacco advertising could be placed, and was not a ban based on health, which the federal law forbids.

Several press reports were filed in mid-March 2002 about a pretrial document filed in federal court in which the Justice Department said it might seek severe restrictions on the marketing of cigarettes if it wins its lawsuit against the nation’s tobacco companies. The document was filed in December 2001 and confirmed by the Justice Department and company lawyers. Both sides said it was part of the early jousting in the lawsuit. Staff at the Justice Department said it also signified the Bush administration’s commitment to the lawsuit, originally filed in 1999. Since President Bush succeeded Clinton in the White House there has been much speculation about whether the new administration would abandon the suit and seek a settlement with the companies. Negotiations between the Attorney General and the tobacco companies broke down last year. Some of the government’s tobacco control measures proposed in the document included:

- Prohibiting promotions in which companies give products to frequent users of a brand.
- A ban on use of terms such as “light” or “low-tar.”
- Disclosure of all ingredients and additives.
- Elimination of cigarette advertising in stores.
- Use of graphic warning labels that fill at least 50% of the space on cigarette packs and print ads.
- A ban on lobbying against ordinances directed at secondhand smoke.
- An end to the estimated $3.5 billion the industry spends each year on point-of-purchase advertising and promotions, including in-store signage and display racks.
- Restriction of cigarette ads to black-and-white print format.
- Creation of a foundation to develop, test and promote less hazardous cigarettes, funded by cigarette makers.
- Stiff penalties to tobacco companies if underage smoking fails to decline by target amounts. The targets include a 60% reduction in 10 years, with the companies liable for at least $80 million for each percentage point short of the goal.

In October 2001, Philip Morris and other US tobacco companies were ordered by a federal appeals court to disclose the ingredients used in making their cigarettes to Massachusetts officials. The 2-1 panel decision by the 1st US Circuit Court of Appeals reversed a lower court's ruling that the disclosures would be an "uncompensated taking," and violate the commerce clause of the US Constitution. The companies said the information, including weight, measure, and count, are trade secrets. The appeals court said informing smokers of potentially harmful ingredients is more important than exposing a company's trade secrets. The AMA had joined the state in its appeal process.

More than five years after Brown & Williamson was found liable in the tobacco suit brought by Grady Carter in Florida, the appeals process has finally stopped, and the company must pay $1.1 million in damages plus Mr. Carter's legal fees. The US Supreme Court declined to hear the case. Big Tobacco faces over 1600 individual plaintiff actions nationwide.

Philip Morris attorneys urged California judge Charles W. McCoy to slash a $3 billion punitive damage award to a cancer-stricken smoker and to grant a retrial. The arguments formed a two-pronged attack by the tobacco giant on a June 6 decision by a Los Angeles County Superior Court jury that awarded Richard Boeken, 56, compensatory damages of $5.5 million and $3 billion in punitive damages. The verdict was the largest in an individual lawsuit against a tobacco company. Boeken, a smoker for 40 years, has lung cancer. The former oil and securities dealer claimed in his lawsuit against Philip Morris that he was the victim of a tobacco industry campaign that portrayed smoking as "cool," but concealed its dangers. Philip Morris' attorneys urged McCoy to grant a motion to reduce the punitive damages to no more than $25 million. "The award of $3 billion in an individual case...raises profound issues in our system of justice," Kenneth Starr, attorney for Philip Morris, told the judge. Starr also argued that because the tobacco industry expects to be facing many similar decisions in the future, a smaller award is justified since the company could not afford to pay $3 billion to every plaintiff. The former independent counsel investigating President Clinton had previously defended the tobacco industry in a successful move to dismiss the Castano class action suit. Philip Morris' lawyers also argued for a new trial, primarily because McCoy refused to allow the company to present evidence of Boeken's past criminal convictions, information the jury might have used to decide his credibility. The judge decided to reduce the award to $100 million, still the largest punitive damage award to an individual smoker in tobacco litigation history. He refused to grant a new trial, and described the company's behavior as "reprehensible in every sense of the word, both legal and moral." Philip Morris will appeal.

The widow of a lung cancer victim in Scotland has been given permission to sue a tobacco giant over her husband's death. Judges at the Court of Session in Edinburgh decided that she has a legitimate case against Imperial Tobacco after an eight-year legal battle. The case, due to be heard in June 2002, is the first of its kind in Europe and if successful is likely to lead to thousands of similar civil actions against tobacco manufacturers. She is claiming damages of £500,000 from the firm, saying it did not warn her husband of the dangers of smoking. Her husband smoked 60 cigarettes a day, and died in 1993 at the age of 48, a year after he was diagnosed with lung cancer.

Under an agreement in February 2002 between the state Attorneys General and Walgreen's, the nationwide drug store chain and provider of health care products, has agreed to improve its efforts to prohibit underage customers from buying tobacco products. The company will review and amend its standards for hiring, educating and training new and existing employees who sell tobacco products. Walgreen's will check photo ID for all customers wishing to purchase tobacco products who appear to be under 27 years old. It will continue to use cash registers that prompt the cashier to enter specific information from the customer's ID while making a tobacco sale. In addition, the company has agreed to conduct random performance checks with no notification to the clerks selling tobacco. It also will use an outside consultant to conduct further performance checks. Several state Attorneys General had brought legal action against the company for multiple infractions of youth access laws across the country.

RJR violated terms of the MSA by advertising year-round at two Arizona auto race tracks, an Arizona judge ruled in November 2001. Judge Colleen McNally of Maricopa County Superior Court ruled that RJR violated advertising limits imposed by the settlement between 46 states and major tobacco companies. The ruling came in a lawsuit filed March 19 by the Arizona attorney general's office.

A March 2001 lawsuit filed by the Arizona attorney general's office said RJR left outdoor advertisements up year-round at Phoenix International Raceway and Firebird International Raceway in Chandler, Arizona. Those events last just a few days each year and the settlement required that ads be placed no more than 90 days before the first day and removed within ten days after the last day's event, the state's lawsuit said. RJR argued that it could leave the ads up year-round because it actually was advertising for each racing series' entire season.

Lorillard Tobacco has filed suit against the American Legacy Foundation, claiming that it violated the "vilification" clause of the MSA in Legacy's "truth" campaign of counter-advertising. Lorillard was offended by an ad that suggested the company put dog urine in its cigarettes (a reference to urea, often added to tobacco to control pH). The AMA and other health groups strongly defended Legacy's campaign.

In Japan, a lawsuit filed in 1998 by several sick smokers continues to drag along. Japan Tobacco, the object of the suit, denies that the health risks of tobacco use have been proven, or that nicotine is addictive. "If nicotine is so addictive, why can people still quit?" a company spokesman asked, citing the country's population of smokers, which has decreased by some 1% annually for the past five years. "Tobacco has served as a handy item for easy relaxation among Japanese people for centuries," he said. "Why can't we call tobacco itself a part of our culture?"

Philip Morris and other cigarette companies won the final round in lawsuits by Guatemala, Nicaragua and Ukraine, as the US Supreme Court turned aside an appeal by the three nations in October 2001. The suits sought to recover the costs of treating millions of sick smokers under the national health care programs in those countries. A federal appeals court in Washington threw out the complaints in May 2001. American judges have uniformly rejected tobacco lawsuits by foreign governments, generally concluding that any losses suffered by public treasuries are too remote to the alleged wrongdoing to be addressed by a court.

Philip Morris threatened to sue a Toronto AIDS charity over an ad that promotes condom use. The ad shows two gay cowboys who say, "Welcome to Condom Country." Philip Morris claimed this ad copies its "Marlboro Country" slogan too closely. The suit was later dropped, with the tobacco giant proclaiming that it wanted to do everything it could to help stop AIDS. (Particularly ironic since smoking-related diseases are particularly high in persons with AIDS and other conditions that weaken the immune system.)

Under new Canadian tobacco products information regulations, tobacco companies must display six toxic emissions warnings on the sides of cigarette packs. These include:

- Formaldehyde, classed as a probable human carcinogen by the Environmental Protection Agency (EPA)
- Hydrogen cyanide
- Benzene, listed as a Class 1 (known human) carcinogen by EPA
- Nicotine induces dependence and affects cardiovascular and endocrine systems
- Carbon monoxide reduces capacity of red blood cells to carry oxygen to tissues
- Tar contains hundreds of chemicals, some classified as hazardous waste

A group of American Indian tribes do not have the legal right to sue the tobacco companies for a share of the $206 billion settlement the industry reached with 46 states, a federal appeals court decided in July 2001. In a suit filed in 1999, 20 tribes had sought more than $1 billion from the tobacco companies, arguing that they were illegally excluded from the 1998 landmark settlement in which the industry agreed to pay the states for smoking-related health care costs. The US Court of Appeals in San Francisco tossed out the lawsuit, finding that the tribes did not have any right to sue because they had not been harmed by the settlement agreement.

In early September 2001, federal courts dismissed two other suits brought by Native American tribes against tobacco companies. The courts found that the suits, which sought damages for the health costs of tobacco use, were filed not on behalf of the tribes but individuals, and that the tribes were "too remotely connected" to the alleged injuries to bring suit.

On May 23, 2001, attorney Johnnie Cochran filed a suit against the major tobacco companies alleging that they conspired to hide the health effects of tobacco use and market their products to kids. The suit asks that the industry "disgorge profits received as a result of the conspiracy" and to fund an educational ad campaign.

The European Commission has lost a legal battle against Philip Morris and RJR, which it had accused of helping smuggle cigarettes into Europe. A US District Court judge dismissed the case July 18, 2001. The European Commission launched the action after claiming that the firms were involved in selling contraband cigarettes, costing it millions of dollars in lost tax. It wanted financial compensation and action to force a change of policy. Judge Nicholas Garaufis said the European Commission "cannot show that it has suffered any injury as a result of defendants' illegal acts. The EC's budget cannot, as a matter of law, be diminished as a result of the smuggling activities alleged in the EC complaint. For this reason, the EC lacks standing to bring suit,...and the EC complaint must be dismissed." Individual European governments do have the right to bring action against the tobacco

companies, however, and the EC itself vowed to reconsider its own options. A few days after the suit was dismissed, it was revealed that Philip Morris had been in discussions with the EU to settle the suit out of court. On August 7, 2001, the EU and several member nations filed a redirected suit based in part on the first defeat. Its new complaint was written to take the judge's first ruling into account. The second suit was also dismissed on a technicality, based on a hundred-year old law forbidding the US to rule on matters related to tax revenues lost by a foreign government.

US Smokeless Tobacco (UST) Company won a suit in California Superior Court in Sacramento County, overturning the recent action of the California State Board of Equalization (SBE) that resulted in unprecedented increases in the state excise tax on smokeless tobacco products, including its Copenhagen and Skoal brands of moist snuff. In previous years, smokeless tobacco was taxed at the same rate as other tobacco products. For the tax year ending June 30, 2001, all tobacco products were taxed at 54.89 % of the wholesale cost. State taxes on tobacco vary widely, with California's former tax rate already one of the highest. In June 2001, the board voted to untie the price of smokeless tobacco and other tobacco products. The taxes, which took effect July 1, 2001, run from 131 % of wholesale cost for higher-priced snuff to 490 % of wholesale cost for chewing tobacco. The price of Skoal, a higher-end brand of moist snuff sold by UST, climbed to as much as $8.50 per can, from $5 a can before the tax increase.

Two similar class actions against the tobacco industry went to trial the first week of September 2001 in Louisiana and West Virginia. State courts were asked to decide whether the industry must pay for medical checkups and tests for early detection of disease in groups of smokers and former smokers in the two states. In Louisiana, the case also asks the industry to pay for cessation coverage. The West Virginia suit was dismissed, but the Louisiana suit is still pending.

Other class actions in the courts include a suit on behalf of "low-tar" smokers in Illinois, and a class action in California alleging that the tobacco industry, by way of deceptive advertising and marketing activities in California during the class period, misled the smoking public on the health risks of smoking to "seduce and induce people to smoke." The California plaintiffs seek to recover all profits from the Defendants' sales of cigarettes during the class period, and an order stopping these practices.

POLITICS

The Presidential election in 2000 has the tobacco industry feeling certain that it is approaching a new era in governmental response to the issues surrounding tobacco use, regulation, and trade matters. An editorial in the July 2001 issue of *Tobacco Reporter* put it this way, "The victory of pro-business interests in the recent US elections has given the tobacco industry the confidence to invest again [in replacing obsolete equipment, increasing production facilities, and constructing new manufacturing plants]."

On September 28, 2001, President Bush quietly issued an Executive Order that either retained or eliminated initiatives from the previous Administration. Among the items cut was Executive Order 13168, establishing the "President's Commission on Improving Economic Opportunity in Communities Dependent on Tobacco Production While Protecting Public Health." This Commission had investigated the dual issues of public health and tobacco farming, and issued a report calling for strong FDA regulation of tobacco products, among other things.

Washington state briefly had the highest cigarette tax in the nation starting January 1, 2002. Initiative 773, passing easily, added a 60-cent-a-pack tax, taking Washington's cigarette tax to $1.425 per pack. Name brands such as Marlboro will cost more than $5 a pack. The election's outcome shows that voters are willing to increase taxes to improve access to health care and to protect kids from tobacco, according to tax supporters. In an unprecedented move, Big Tobacco stayed on the sidelines, allowing itself to be significantly outspent by proponents, including anti-tobacco organizations and health-maintenance organizations. Besides boosting the price of cigarettes, I-773 also will increase the wholesale tax on all other tobacco products, including cigars, snuff and chew. That is predicted to spur a roughly 30% increase in the retail prices. The largest part of the $130 million/year that the tax will generate is earmarked for the state's Basic Health Plan to provide health care services for low-income children and adults. About 10% will go to prevent tobacco use and to fund other programs for improving the health of low-income people.

New York state eclipsed Washington, increasing its tax from $1.39 to $1.50/pack in 2002--about 20 other states are considering tax increases to fill holes in state budgets.

Connecticut raised its tax 61 cents, and Utah's went up by 18 cents in the spring of 2002. These election-year tax increases point to the popularity of tobacco excise taxes, despite political nervousness about enacting them.

The Center for Tobacco Free Kids web site (www.tobaccofreekids.org) has a state-by-state breakdown of tobacco taxes and efforts by states to increase them.

Harvard's School of Public Health issued a press release on tobacco funding on January 25, 2002: "Faculty members at the Harvard School of Public Health have voted to reject research funding from tobacco manufacturers and their subsidiaries. Due to an incongruity with the public health mission, such funds had not been accepted at the School as a general practice for a number of years. Harvard's vote puts their current practice into official policy and remains consistent with the university's 13-year-old policy of not holding stock in tobacco companies."

HEALTH EFFECTS OF TOBACCO USE

The *Wisconsin Medical Journal* issued an excellent tobacco "theme" issue in August 2001. It may be viewed online at www.wiscmed.org.

In a study reported in the July 2001 *Pediatrics*, it was found that pediatric residents who had intensive tobacco control education as part of their training became highly involved with patients and their parents around tobacco control issues. Families of these residents, on 3-year follow up, were more likely to have a "smoke free" home. Comprehensive training on tobacco had a positive and powerful effect on the tobacco intervention behavior of pediatric residents. Such intervention on tobacco by pediatric residents may have a significant impact on patients and their parents. This shows the potential for tobacco control education in medical education, and the need to include it in both undergraduate and residency training programs.

Swedish investigators report in the *Journal of Clinical Periodontology*, July 2001, that smokers exhibit a significantly lower hemorrhagic responsiveness than nonsmokers. This was more evident in those undergoing periodontal procedures than in dental hospital patients in general. A dose-response effect was typically evident in the periodontal patient population. Accounting for the periodontal disease severity, however, the effect of smoking was also found in the general patient population. The authors conclude that smoking is associated with a clinically suppressed hemorrhagic responsiveness of the periodontium.

Stanford University researchers discovered that nicotine can trigger angiogenesis. The report was published in *Nature Medicine*. Angiogenesis has been implicated in local growth of tumors and arterial plaques. The authors suggest that even nicotine replacement therapy should be short-term, since nicotine may have health consequences of its own. In response, Prof. Neal Benowitz, a leading nicotine researcher, notes that the mechanisms of nicotine intake (the mice were injected with nicotine, or drank it) among the experimental mice used in the study are not at all similar to nicotine replacement therapy (NRT) and that humans may not have the same response under real-life conditions. He also notes that use of NRT is much preferred to smoking, in any case, since the miniscule risk (if any) from the doses of nicotine received during smoking cessation are greatly overshadowed by the known health hazards of continuing to smoke.

A new study sheds light on the so-called "smokers' paradox"--the fact that a smoker is not only more likely than a nonsmoker to suffer a heart attack, but also more likely to survive it. The answer, research published in the February 2002 issue of *Nicotine and Tobacco Research* suggests, is mainly that the smoker is much younger at the time of the attack. Previous studies have established that smokers with acute heart attacks are younger than nonsmokers, tend to have fewer illnesses and exhibit fewer cardiac risk factors. The current study attempted to confirm and finally explain the smokers' paradox by examining the largest group of heart attack patients to date, more than 250,000 cases. Of the 297,458 patients included, 24% were smoking at the time of their heart attack, while 76% had either quit smoking or had never smoked. Analysis of patient data revealed that smokers were only half as likely as nonsmokers to die while hospitalized. The smokers were, on average, 14 years younger at the time of the heart attack. The researchers observed other differences between the two groups, including a lower incidence of disease associated with high cardiac risk, such as diabetes or angina, among the smokers, and differences in the types of heart attacks suffered. The researchers found that the age difference between smokers and nonsmokers accounts for almost all the observed difference in mortality rates.

The rate of myocardial infarctions in women increased by 36% during the 1980s and early 1990s, a time when heart attacks among men declined by 8%, according to findings of a Mayo Clinic study published in the March 5 issue of the *Annals of Internal Medicine*. The increase in smoking among women was one of the major factors cited for the growing number of heart attacks in women.

French scientists studied women undergoing in vitro fertilization, finding that women who smoke more than 10 cigarettes a day have only a 15% chance of successful implantation, compared with about 23% for non-smokers.

An article in *Nature Genetics* (2001;28:355-60) elucidates the mechanism for early menopause among women who smoke. The authors have shown that polycyclic aromatic hydrocarbons (PAH) in cigarette smoke bind to the aromatic hydrocarbon receptor (Ahr) in oocytes in the ovary. This binding activates a gene called Bax to transcribe protein products that lead to cell death of the oocyte by apoptosis (self-destruction of the cell). Since the rate of death of egg cells determines how long the ovary will function, egg cell death may explain why women who smoke reach menopause 2-3 years earlier than nonsmokers and why women who smoke have a higher incidence of infertility.

In the August 2001 edition of the *American Journal of Epidemiology*, a Danish study reports that women who smoke while pregnant nearly double the risk of stillbirth. The authors examined the association between exposure to tobacco smoke in utero and the risk of stillbirth and infant death in a cohort of 25,102 singleton children of pregnant women scheduled to deliver from September 1989 to August 1996. Exposure to tobacco smoke in utero was associated with an increased risk of stillbirth (odds ratio=2.0, 95% confidence interval: 1.4, 2.9), and infant mortality was almost doubled in children born to women who had smoked during pregnancy compared with children of nonsmokers (odds ratio=1.8, 95% confidence interval: 1.3, 2.6). Among children of women who stopped smoking during the first trimester, stillbirth and infant mortality was comparable with that in children of women who had been nonsmokers from the beginning of pregnancy. Approximately 25% of all stillbirths and 20% of all infant deaths in a population with 30% pregnant smokers could be avoided if all pregnant smokers stopped smoking by the sixteenth week of gestation.

A recent study was undertaken to determine (1) whether reducing tobacco exposure during pregnancy increases the birth weight of term infants; and (2) the relative effects of early- and late-pregnancy exposure to tobacco on infant birth weight. Data were obtained from the Smoking Cessation in Pregnancy project, conducted in public clinics in three states (Colorado, Maryland, and Missouri) between 1987 and 1991. Self-reported cigarette use and urine cotinine concentration were collected from 1,583 pregnant smokers at study enrollment and in the third trimester. General linear models were used to generate mean adjusted birth weights for women who reduced their tobacco exposure by 50% or more and for those who did not change their exposure. Reducing cigarette use was associated with an increase in mean adjusted birth weight of only 32 g, which was not significant (p=0.33). As third-trimester cigarette use increased, birth weight declined sharply but leveled off at more than eight cigarettes per day. Findings were similar when urine cotinine concentration was used. Women who smoke during pregnancy may need to reduce to low levels of exposure (less than eight cigarettes per day) to improve infant birth weight (*American Journal of Epidemiology* 2001;154 (8): 694-701).

Many women do not know about the health dangers of smoking, according to a British study released in September 2001. The Smoking Cessation Action in Primary Care, (Scape) surveyed 1,757 men and women who were smokers or ex-smokers. Figures show that 14-year-old girls are twice as likely to smoke as their male peers. And last year, lung cancer overtook breast cancer as the biggest killer of women in Britain (it has had that distinction in the United States since 1986). But the Scape study showed 8% of women did not believe smoking was linked to increased risk of lung cancer. Two-thirds did not think smoking increased the risk of Sudden Infant Death Syndrome (SIDS). A quarter did not know smoking increases the risk of heart disease, and two-thirds did not believe smoking increases the risk of miscarriage. Other survey findings:

- 89% were unaware smoking is associated with cervical cancer
- 42% did not believe it increased the risk of stroke
- 88% did not believe it increased the risk of osteoporosis
- 30% did not think smokers had an increased risk of developing throat and mouth cancer
- Only 10% wanted to stop because they were worried about the effects on pregnancy or their children
- 29% did not think smokers' children were at increased risk of developing asthma

A Hong Kong study shows that male smokers may not respond to Viagra as well as nonsmokers. Of more than 5400 men in the study, 926 did not respond to Viagra--and 90% of the non-respondents were smokers. Most of the non-responding smokers puffed 1/2 to 1 pack per day, and had smoked for over 10 years.

In the August 18, 2001, issue of the *British Medical Journal*, a study finds that the current 33% rate of smoking-related deaths in Hong King will likely be followed by similar death rates in mainland China within 20 years. The study looked at all deaths in Hong Kong in 1998 and examined tobacco use (among other risk factors) for the preceding 10 years among the deceased. Tobacco use killed about 2,350 of the 7,590 men ages 35-69. Widespread smoking in mainland China lagged behind that in Hong Kong by about 20 years. The authors write, "Two-thirds of all young men in China (but as yet, few young women) become smokers. Half the smokers who persist will eventually be killed [by cigarette smoking]. On present smoking patterns, about one-third of all the young men in China will be eventually killed by tobacco."

DiFranza reports in the journal *Tobacco Control* that teens may become addicted to nicotine more quickly than adults. Addiction can develop among youth within a month, even without daily smoking. It had previously been thought that it took kids two years or so to progress from experimentation to becoming a confirmed smoker (*Tob Control* 2000 Sep;9[3]:313-9).

The polycyclic aromatic hydrocarbons (PAHs) found in tobacco smoke and elsewhere induce oocyte death by activating a preexisting apoptotic pathway rather than through some nonspecific toxic effect, according to a report published in the July 2001 *Nature Genetics*. Cigarette smoking has been linked to early menopause for several years, and animal studies have shown that PAHs induce oocyte death, but until now, the mechanisms involved were unclear. Dr. Jonathan Tilly, from Massachusetts General Hospital in Boston and colleagues found that treating female mice with PAH compounds led to oocyte expression of Bax, a gene previously shown to initiate apoptosis. Further analysis revealed that the PAHs bind to an oocyte surface receptor known as the aromatic hydrocarbon receptor, which then enters the nucleus to stimulate Bax expression. Mice that were engineered to lack the Bax gene or the Ahr gene did not show oocyte death when exposed to PAHs, the researchers noted.

To gauge the importance of the findings for humans, the researchers grafted human ovarian tissue under the skin of mice. Once again, a striking Bax-driven increase in degenerating oocytes was noted after treatment with the PAH compounds. "Women who smoke undergo menopause earlier, and we've correlated this with exposure to a class of chemicals in tobacco smoke that accelerate the death of egg cells in the ovaries," said Tilly. "We need to get people away from thinking that toxic chemicals cause general harm. Here we have mapped how a chemical, through several discrete steps, influences specific genetic events that lead to cell death."

Because of the prevalence of PAHs in tobacco smoke, these data strongly support the hypothesis that the early onset of menopause in women smokers is at least partly due to PAH-induced egg cell death. This work has defined the actual molecular mechanism that triggers inappropriate death of eggs after exposure to PAHs.

Tobacco smoke has been known to cause cancer for many years, and one mechanism that has been identified is genetic malfunctioning of the p53 gene, which keeps unrestrained cell growth in check. A new report in the September 2001 *Cancer Research* found further evidence consistent with the hypothesis that chemical carcinogens such as benzo-pyrenes in cigarette smoke cause G:C to T:A transversions at p53 codons 157, 248, and 249 and that nontumorous lung tissues from smokers with lung cancer carry a high p53 mutational load at these codons.

Canadian researchers analyzed the effects of smoking cigarettes only and of smoking cigars, or pipes, or both, with or without cigarettes, on the risk of prostate cancer. Overall, the associations between smoking cigarettes and prostate cancer were weak and compatible with no effect; the associations with cigar and pipe smoking were stronger. Among men with high body mass index, however, the researchers found appreciable associations between cigarette smoking and prostate cancer risk. A history of ever smoking daily was associated with an odds ratio of 2.31 (95% confidence interval=1.09-4.89). Risk increased with the amount smoked per day and with the duration of smoking. Taken together, the findings of increased risk associated with cigar and pipe smoking and the findings of increased risk associated with cigarette smoking among obese men suggest that tobacco smoking may be a risk factor for prostate cancer (*Epidemiology* 2001;12(5):546-51).

Researchers in Miami explored whether cigar smoking affects flow-mediated vasodilation in healthy, nonsmoking young adults. Nonsmoking young adult cardiology trainees and staff between the ages of 20 and 45 years were randomly assigned to a cigar smoking group (n=15) or a control group (n=14). The main outcome measures were

the difference in percent diameter increase in the brachial artery after reactive hyperemia and sublingual nitroglycerin between members of the cigar smoking and control groups at baseline, measured after cigar smoking, and at 5 hours. A 2.5% increase in brachial artery diameter with hyperemia after cigar smoking was observed, compared with a 9.4% increase in the control group. The researchers conclude that these data are compatible with the possibility that cigar smoking may have an acute effect on endothelium-dependent, flow-mediated brachial artery dilation and do not support the possibility of an immediate effect on endothelium-independent vasodilation. Taken together, these results suggest that cigars are not an innocuous alternative to cigarette smoking (*Am Heart J* 2002;143:83-6).

To determine whether cigarette smoking is an independent risk factor among men with low levels of serum cholesterol, data on 25-year coronary, cardiovascular, and all-cause mortality for 8,816 middle-aged men screened between 1967 and 1973 by the Chicago Heart Association Detection Project in Industry were examined. Relative risks of coronary heart disease and cardiovascular disease mortality associated with smoking for two groups with favorable levels of serum total cholesterol, that is, less than 180 and 180-199 mg/dl, were of the same magnitude as those for men with elevated serum cholesterol, that is, 200-239 and 240 mg/dl. In the two lower strata of cholesterol, the absolute risk and absolute excess risk of mortality for current smokers at baseline were substantially higher compared with men who never smoked, with all-cause death rates of 423.0 and 428.0 per 1,000 and absolute excess rates of 209.8 and 225.7 per 1,000. These translate to estimated shorter life expectancies of 5.3 and 5.7 years, respectively (*Am J Epidemiol* 2002;155[4]: 354-360).

Although the association between smoking and increased risk of coronary heart disease (CHD) is well established in the general population, this relationship is less well-defined among individuals with diabetes. Using data from the Nurses Health Study, researchers found a dose-response relationship between current smoking status and risk of CHD among diabetic women. Compared with never smokers, the relative risks (RRs) for CHD were 1.21 for past smokers, 1.66 for current smokers of 1 to 14 cigarettes per day, and 2.68 for current smokers of 15 or more cigarettes per day in multivariate analyses ($P<.001$ for trend). The multivariate RR of CHD among diabetic women who had stopped smoking for more than 10 years was similar to that among diabetic women who were never smokers (RR, 1.01; 95% CI, 0.73-1.38). In secondary analyses involving diabetic and nondiabetic women, the multivariate-adjusted RR of CHD for those with diabetes who currently smoked (15 cigarettes per day) compared with those who never smoked was 7.67 (95% CI, 5.88-10.01). The authors conclude that **c**igarette smoking is strongly associated with an increased risk of CHD among women with type 2 diabetes mellitus, and that quitting smoking seems to decrease this excess risk substantially (*Arch Intern Med* 2002;162:273-279).

Although cigarette smoking is a major risk factor for acute myocardial infarction (MI), cigarette tar yield has not been clearly demonstrated to affect MI risk. A case-control study of first MI in smokers aged 30 through 65 years was conducted among 68 hospitals in an 8-county area during a 28-month period. After adjustment using multivariable logistic regression, the odds ratios (ORs) for subjects smoking medium and high compared with low-tar-yield cigarettes were 1.86 and 2.21, respectively. The adjusted OR increased as tar per day intake increased ($P<.001$ for the trend). There was a similar trend of increasing ORs as tar per day increased in smokers of lower-yield cigarettes ($P<.001$ for the trend) and when low-yield cigarette smokers were excluded ($P<.001$ for the trend). The authors conclude that smoking higher-yield cigarettes is associated with an increased risk of MI, and there is a dose-response relationship between total tar consumption per day and MI (*Arch Intern Med* 2002;162:300-306).

A study on the effect of smoking on renal allograft loss was published in the journal *Transplantation* (2001;71:1752-57). A cohort study of 645 transplant recipients showed that pretransplant smoking was significantly associated with reduced graft survival. Smokers had kidney graft survival of 84% at 1 year, 65% at 5 years, and 48% at 10 years compared with 88%, 78%, and 62% survival at comparable times for nonsmokers. Smoking was associated with an RR of 2.3 for graft loss. Smoking cessation should be strongly urged for patients who are considering renal transplantation.

In the August 2001 *Archives of Internal Medicine* (2001;161:983-988) a new study looks again at the risk of smoking and hip fracture among postmenopausal women. This Swedish study examined 1328 cases and 3312 controls. Current smokers had an increased risk of hip fracture (RR=1.66), with duration of smoking more important than the amount smoked. Former smokers had a small increased risk (RR=1.15).

A study in the July 2001 *Journal of Occupational and Environmental Medicine* reported that 10% of employees with injury claims account for about half of total workers' compensation costs. In a four-year study at Xerox, employees' risk factors were evaluated based on their health profiles. Factors considered included smoking, alcohol consumption, physical activity and inactivity, blood pressure, cholesterol levels, stress, safety belt use, and job and life satisfaction. Injury claims were assessed in relation to risk status: low-risk employees, zero to two risks; medium-risk employees, three to four risks; and high-risk employees, five or more risks. One of the most costly individual health risks at Xerox was smoking. The workers' compensation cost for a smoker averaged $2,189 compared to $176 for a nonsmoker.

An investigation of the effect of lower respiratory infections (LRI) on patients with lung disease who continue to smoke was reported in the August 2001 issue of the *American Journal of Respiratory and Critical Care Medicine*. In the year during which a LRI occurred, FEV(1) did not change in sustained quitters, but decreased significantly in smokers (p=0.0001), with some recovery the following year if no LRI occurred. Over 5 years, LRI had a significant effect on rate of decline of FEV(1) only in smokers. In smokers averaging one LRI/yr. over 5 years there were additional declines in FEV(1) of 7 ml /yr. (p=0.001). Smokers with more than one LRI/yr. had greater declines. Chronic bronchitis was associated with increased frequencies of LRI, but did not affect their influence on lung function. Smoking and LRI had an interactive effect on FEV(1) in people with mild COPD, and in smokers frequent LRI may influence the long-term course of the disease.

The Obstructive Lung Disease in Northern Sweden Studies (OLIN), presented in October 2001 at the 11th Annual European Respiratory Society Congress in Berlin, showed that pulmonary function declines rapidly in ex-smokers who resume cigarette use. In the 10-year study, researchers analyzed lung function and smoking habits among 1,116 men and women aged 35 to 68 years. Participants were divided into five groups: those who never smoked; those who stopped smoking 10 years before the study's start; those who stopped smoking during the 10-year observation period; ex-smokers who re-started during the observation period; and those who smoked throughout. The study did not include those smokers who "took breaks" for less than a year. Among smokers, those who re-started after at least one year of abstinence showed the greatest annual decline in lung function--even slightly higher than people who smoked throughout the 10 years. It is still unclear how many years this rapid decline in lung function might continue and whether the lung function then stabilizes to the level of smokers who never quit. One other study, from Arizona in the mid-1990s, had previously shown that ex-smokers who start again experience a faster decline in lung function than those smokers who never quit.

Cigarette smoking has been demonstrated to increase the risk of subarachnoid hemorrhage (SAH). Whether smoking cessation decreases this risk is unclear. A case-control study to examine the effect of smoking, cessation, and other known risk factors for cerebrovascular disease on the risk of SAH was reported in August 2001 (*Neurosurgery* 2001;49: 607-613). The investigators reviewed the medical records of all patients with a diagnosis of SAH (n=323) admitted to Johns Hopkins between January 1990 and June 1997. Controls matched for age, sex, and ethnicity (n=969) were selected from a nationally representative sample of the Third National Health and Nutrition Examination Survey. The researchers determined the independent association between smoking (current and previous) and various cerebrovascular risk factors and SAH. In the multivariate analysis, both previous smoking (OR, 4.5) and current smoking (OR, 5.2) were significantly associated with SAH. The risk factors for 290 patients with aneurysmal SAH were similar and included hypertension (OR, 2.4) previous smoking (OR, 4.1) and current smoking (OR, 5.4). The authors conclude that hypertension and cigarette smoking increase the risk for development of SAH, as found in previous studies. However, the increased risk persists even after smoking cessation, which suggests the importance of early cessation.

Permanent smoking cessation reduces loss of pulmonary function. Less is known in the long term about individuals who give up smoking temporarily or quitters with lower initial pulmonary function. A study in *Thorax* (September 2001) examined the association between smoking, decline in pulmonary function, and mortality. Over 1000 Finnish smokers were followed for more than 30 years. During the first 15 years, adjusted decline in forced expiratory volume in 0.75 seconds ($FEV_{0.75}$) was 46.4 ml/year in never smokers, 49.3 ml/year in past smokers, 55.5 ml/year in permanent quitters, 55.5 ml/year in intermittent quitters, and 66.0 ml/year in continuous smokers ($p<0.001$ for trend). Quitters across the entire range of baseline $FEV_{0.75}$ had a slower decline in $FEV_{0.75}$ than continuous smokers. Among both continuing smokers and never smokers, nonsurvivors had a significantly ($p<0.001$) more rapid decline in $FEV_{0.75}$ than survivors. Never smokers, past smokers, and quitters had significantly lower total mortality than

continuous smokers, partly because of their slower decline in $FEV_{0.75}$. These results highlight the positive effect of smoking cessation, even intermittent cessation, on decline in pulmonary function. Accelerated decline in pulmonary function was found to be a risk factor for total mortality. The beneficial effect of smoking cessation on mortality may partly be mediated through a reduced decline in pulmonary function.

Issues concerning smoking and depression have been reported in past Annual Tobacco Reports, with different conclusions on whether smoking is a possible causal factor in depression, or whether depressed person smoke to "self-medicate" with nicotine. A new study (*Aust N Z J Psychiatry* 2001 Jun;35:329-35) examined associations between depression and cigarette smoking. Researchers failed to find any difference between smokers and nonsmokers in history or severity of depression. Cigarette smokers were distinguished principally by greater exposure to aversive experiences in childhood; disordered personality function; and greater use of illicit drugs, anxiolytics and alcohol. Logistic regression identified dysfunctional personality "domains" physical violence in childhood, long-term anxiolytic use and illicit drug use, as the most significant predictor set. The authors conclude that cigarette smoking and depression may be linked by shared early deprivational variables, rather than cigarette smoking causing depression or vice-versa.

On the other hand, in another look at the smoking-depression relationship, researchers at the University of Mississippi Medical Center examined postmortem samples of the locus ceruleus from the brains of seven people who had been heavy smokers and nine who had been non-smokers; all had been mentally healthy. They found that the brains of long-term smokers had neurochemical abnormalities similar to the brains of animals treated with antidepressant drugs (*Archives of General Psychiatry* 2001;58:821-7). Specifically, the brains of longtime smokers had significantly fewer alpha-2 adrenoceptors and significantly less of the enzyme tyrosine hydroxylase, which helps to manufacture noradrenaline and dopamine. The findings suggest that cigarette smoking may have effects on the human brain similar to those of antidepressant drugs, and this may explain the high rate of smoking among depressed people and their resistance to quitting.

In November 2001, the National Cancer Institute (NCI) released the 13th in its "Smoking and Tobacco Control Monograph" series. Titled "Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine," the publication concludes that:

- There has not been a public health benefit from changes in cigarette design and manufacturing over the last 50 years.
- There appears to be complete compensation for nicotine delivery among brand switchers, reflecting more intensive smoking of low-yield cigarettes.
- Low-yield cigarettes have not prevented the sustained increase in lung cancer in older smokers.
- Many smokers use low-yield products as an alternative to smoking cessation, and believe that the products are less risky. Tobacco company advertising and marketing of low-yield products seems to promote initiation and impede cessation.
- The Federal Trade Commission (FTC) measurements of tar and nicotine do not provide meaningful information for smokers on the amount of these substances actually delivered while smoking, or from smoking different brands.

The 14th in the NCI series, released in March 2002, dealt with "Changing Adolescent Smoking Prevalence." Its main conclusions:

- Smoking prevalence among adolescents increased during much of the 1990s, but has recently begun to decline. Female adolescents, Hispanic, and African-American adolescents experienced a lower smoking prevalence than other subgroups.
- The increase in the 1990s was accompanied by an increase in reports of friend's smoking, and this may indicate that teens are beginning to view smoking as normative behavior.
- Evidence on the relationship between tobacco advertising and promotion and youth smoking suggests that tobacco industry marketing practices are causal factors in youth smoking initiation.
- Tobacco control interventions such as aggressive counter-marketing, increases in tobacco taxes, and other strong tobacco control policies at the "macro" level are effective in reducing smoking among youth.

PASSIVE SMOKING

A Canadian study provides some of the most compelling scientific evidence yet for a total ban on workplace smoking, including bars and restaurants. The research, published in the *International Journal of Cancer* in July 2001, found that that a nonsmoking woman who lives with a smoker has a 21% higher risk of developing lung cancer over her adult lifetime. But if the woman lived with a smoking parent as a child, her risk jumps 63 % above that of someone who has always lived in a smoke-free home. A woman who has always lived in a smoke-free home but works where smoking is permitted sees her risk of developing lung cancer jump by 27%. That risk climbs steadily over time, and increases based on the number of smokers in the workplace. The new research found that when the number of "occupational smoker years" (the number of smokers in the workplace multiplied by the worker's years of service) reaches 26, the risk of lung cancer has doubled. That could mean two smoking co-workers over 13 years or five smoking co-workers over five years. It could also mean 26 customers daily for a year in a bar. When researchers looked at the upper third of workers--those exposed to the most second-hand smoke--they found the lung cancer risk was more than tripled.

The effects of workplace passive smoke exposure on lung function was examined in a Scottish study, published in the journal *Occupational and Environmental Medicine* (2001;58:563-568). Three hundred one never smokers were the subject of pulmonary function testing, correlated with exposure to Environmental Tobacco Smoke (ETS) at work and home. Compared with unexposed subjects, those with the highest work exposures had a 254 ml reduction in FEV-1, and a 273 ml reduction in FVC after adjustment for confounders. Case-control analysis also showed a significant exposure-relation between ETS exposure at work and lung function. This nearly 10% drop in pulmonary function was statistically significant ($p<.05$) and is yet another clear indication for smoke-free workplace policies.

Another look at passive smoking and endothelial dysfunction was published in the July 25, 2001, issue of *JAMA*. The Japanese study found substantially reduced coronary flow velocity reserve as measured by echocardiographic examinations in healthy nonsmokers subjected to passive smoke for a duration of only 30 minutes (the study was conducted in the hospital "smoking room"). This provides direct evidence of the harmful effects of passive smoking on coronary circulation in nonsmokers. In an accompanying editorial, Glantz and Parmley remind us that passive smoking increases the risk of cardiac morbidity and mortality by about 30%, about one-third of the effect of active smoking. They suggest that the underlying biochemical and cellular processes saturate at the low doses received by persons exposed to passive smoke. This reinforces the need to expand protection from the hazards imposed by secondhand smoke to all persons, including the home, workplaces, restaurants, bars, and other recreational venues.

An increased risk for myocardial infarction (MI) related to ETS exposure has previously been reported, but several aspects of the association are still uncertain. Swedish researchers running the Stockholm Heart Epidemiology Program (SHEEP) investigated the MI risk associated with ETS exposure among 334 nonfatal never-smoking MI cases and 677 population controls, 45 to 70 years of age, in Stockholm County. A mail questionnaire with a telephone follow-up provided information on ETS exposure and other potential risk factors for MI. After adjustment for age, gender, hospital catchment area, body mass index, socioeconomic status, job strain, hypertension, diet, and diabetes mellitus, the odds ratio for MI was 1.58 (95% confidence interval=0.97-2.56) for an average daily exposure of $\geq$20 cigarettes from spousal smoking. Combined exposure from spouse and work showed an increasing odds ratio for MI, up to 1.55 (95% confidence interval=1.02-2.34) in the highest category of weighted duration, more than 90 "hour-years" of exposure (1 "hour-year"=365 hours, or 1 hour per day for 1 year). More recent exposure appeared to convey a higher risk. The data confirm an increased risk of MI from exposure to ETS and suggest that intensity of spousal exposure, combined exposure from spouse and work, and time since last exposure are important (*Epidemiology* 2001;12[5]:558-64).

Using ultrasonography, Italian researchers studied the effects of passive smoking on endothelium-dependent arterial dilation in 18 healthy subjects. They measured the brachial-artery diameter in a smoke-free environment and in the same environment polluted by 30 to 35 ppm carbon monoxide reached by the combustion of 15 to 20 cigarettes within 30 minutes. Passive smoking induced a statistically significant increase of blood carbon monoxide in the subjects under study, associated with an acute impairment of endothelium-dependent dilatation, and suggesting early endothelial damage. Passive smoking is associated with dose-related impairment of endothelium-dependent dilatation. The study was reported at the European Society of Cardiology meeting in September 2001.

In another presentation at the European Cardiology Conference, Greek scientists found a significant dose-response association with passive smoke exposure. Relative risks of 1.23 and 1.52 for heart disease were found for nonsmokers who were exposed to the smoke of 6 to 20 cigarettes per day and those who were exposed to the smoke of 21 or more cigarettes per day, as compared with nonsmokers not exposed to smoke ($p<0.05$ for linear trend).

Researchers measured lung tissue concentrations of nicotine and cotinine in SIDS (n=44) and non-SIDS cases (n=29) stratified according to household smoking status. When all the SIDS and non-SIDS cases were compared regardless of smoking status, there was a significantly higher nicotine concentration in the SIDS cases than in the non-SIDS cases, (P=.0001). Upon stratifying for smoking status, there was a nonsignificant trend toward more nicotine in SIDS versus non-SIDS lungs that had come from a reported smoking environment. In the nonsmoking group, there were significantly higher nicotine concentrations in SIDS than non-SIDS cases (P=.001). The researchers concluded that children who died from SIDS tended to have higher concentrations of nicotine in their lungs than control children, regardless of whether smoking was reported. These results are based on an objective, biochemical test rather than history, and they further support the relationship between environmental tobacco smoke and the risk of SIDS (*J Pediatr* 2002;140:205-9).

The Canadian capital of Ottawa initiated on August 1, 2001, one of that country's toughest public smoking bans, outlawing smoking in workplaces, restaurants, bars, pubs, sports arenas, nightclubs, bingo halls and taxis. Ottawa police have set up a special unit to patrol bars and restaurants to ensure that no one is smoking. Beginning in September 2001, owners of establishments who allow patrons to light up can be fined up to C$5,000 for repeat offenses. Around 40 other Canadian cities and towns have already imposed smoking bans but Ottawa's is particularly tough. Unlike other municipalities, it does not allow bars and restaurants to build separate ventilated smoking rooms. It does, however, permit smoking on outdoor patios. Bar owners, who feared the ban could help drive them out of business, went to court to have the new laws thrown out. A judge ruled on August 31, 2001, that the city has the right to enact and implement its law, ending the appeals by business groups.

Several Minnesota colleges will have all smoke-free dormitories in the fall of 2002, including Minnesota State University (Mankato and Moorehead), and St. Cloud State University. Duke University also announced in 2002 that its residence halls will become smoke-free. The University of Connecticut announced plans in the spring of 2002 to make its dorms all smoke-free by the end of 2003.

In the largest study of its kind, researchers published the first detailed examination of trends in workplace smoking restrictions for each of the 50 states and the District of Columbia. The study, published in the August 2001 issue of the Journal of Occupational and Environmental Medicine, found that while more than 80% of workers in states such as Maryland and Utah reported that their workplace is smoke-free, workers in most states report far lower rates of workplace protection. The study findings are based on interviews with over 270,000 private sector workers who were questioned about the existence of official workplace smoking rules by the US Census Bureau for the NCI.

Some key findings:

- Nationally, 68.6% of all indoor workers reported working under a smoke-free policy in 1999 compared to 46% in 1993.
- The five states with the highest rates of smoke-free workplace coverage in 1999 were: Utah (83.9%), Maryland (81.2%), California (76.9%), Massachusetts (76.8%), and Vermont (76.6%).
- The five lowest ranked states were: Nevada (48.7%), Kentucky (55.9%), Indiana (58.1%), South Dakota (59.7%), and Michigan (60.7%).
- In 1993 only two states, Washington and Utah, had 60% of their workforce reporting a smoke-free policy; 47 states and the District have now reached this level of coverage.
- Major tobacco producing states have also seen significant progress. Only 31% of workers in North Carolina reported a smoke-free policy in 1993; by 1999, 61% were smoke-free. Other tobacco-producing states and the percent of workers that were smoke-free in 1999 are: Virginia (70.0%), Georgia (66.5%), South Carolina (64.1%), and Kentucky (55.9%).

November 6th, 2001, was a good day for tobacco control advocates:

- Final vote in Alamosa, Colorado - 63.9% of Alamosa voters adopted a clean indoor ordinance that will prohibit smoking in all public places except bars.
- Final vote in Montrose, Colorado - 59.6% voted against the repeal of the city's smoke-free ordinance.

- Voters in Duluth, Minnesota voted to maintain both the city's original clean indoor air ordinance from June 2000 and provisions enacted in June 2001 to strengthen the ordinance. The outcome of the first ballot question, the original clean indoor air ordinance, was an overwhelming victory by Duluth's smoke-free advocates. On the second ballot question, the clean indoor air coalition won a hard-fought contest to preserve the amendments that made the ordinance a stronger, more comprehensive clean indoor air policy by almost a 53% margin.

The Honolulu City Council has banned smoking in all restaurants and most restaurant bars on the island of Oahu starting July 1, 2002. Smoking will be prohibited in the remainder of restaurant bars starting July 1, 2003. Stand-alone bars and nightclubs are exempt.

A new meta-analysis of the relationship between passive smoking and lung cancer was published in the *Australia/New Zealand Journal of Public Health* (2001 Jun;25[3]:203-11). The authors found that the pooled relative risk (RR) for never-smoking women exposed to ETS from spouses, compared with unexposed never-smoking women was 1.29 (95% CI 1.17-1.43). Sequential cumulative meta-analysed results for each year from 1981 were calculated: since 1992 the RR has been greater than 1.25. For Western industrialized countries the RR for never-smoking women exposed to ETS compared with unexposed never-smoking women was 1.21 (95% CI 1.10-1.33). Previously published international spousal meta-analyses have all produced statistically significant RRs greater than 1.17.

In the *Journal of Epidemiology and Community Health* (August 2001;55[8]:588-94), Chapman reports on tobacco industry efforts to discredit research on passive smoking. Searches of tobacco industry documents in both the Minnesota and Guilford (England) depositories found that the industry built up networks of scientists sympathetic to its position that ETS is an insignificant health risk. Industry lawyers had a large role in determining what science would be pursued. The industry funded independent organizations to produce research that appeared separate from the industry and would boost its credibility. Industry-sponsored symposia were used to publish non-peer reviewed research. Unfavorable research conducted or proposed by industry scientists was prevented from becoming public. The author concludes that tobacco industry documents illustrate a deliberate strategy to use scientific consultants to discredit the science on ETS.

A fledgling movement to make US hotels smoke-free got a boost when Woodfin Suite Hotels, owner of 18 hotels in 11 states, said its six California properties will go smoke-free starting September 1, 2001. The announcement followed a similar move by Howard Johnson International Inc., which said in June 2001 that its hotel on Pocahontas Trail in Williamsburg, Virginia would become the chain's first smoke-free property. And on August 1, 2001, Apple Core Hotels turned its 80-room Comfort Inn Midtown in New York City's Theater District into a no-smoking property. The New York hotel may have been the country's first no-smoking hotel (apart from the country's many smoke-free bed-and-breakfast spots). Apple Core Chief Operating Officer Vijay Dandapani said his company decided to take the no-smoking plunge because of customer demand. The executive director of Woodfin Hotels says that it that plans to extend the program to its remaining hotels if reaction is positive.

A review of about 1.5 million pages (about 3.75%) of the Minnesota Tobacco Document Depository revealed a concerted tobacco industry campaign against policies that address ETS. The study, published in the September 2001 issue of the *American Journal of Public Health*, shows that for decades, the tobacco industry fought the legitimacy of science showing ETS to cause disease, using disinformation, funding studies to discount true scientific research, and mounting a major public relations campaign to discount the hazards imposed by exposure to passive smoke.

Childhood exposure to ETS is associated with an increased prevalence of asthma among adult nonsmokers. According to a Swedish study published in the September 2001 issue of *Chest*, ETS also increases the chance that exposed children will smoke in adulthood. Among never-smokers with childhood exposure to ETS, the prevalence of physician-diagnosed adult asthma was 7.6% versus 5.9% among those non-exposed. In never-smokers without a family history of asthma, the prevalence of physician-diagnosed asthma in subjects reporting childhood ETS was 6.8% versus 3.8% among non-exposed. People with childhood exposure to ETS were more likely to smoke as adults. The prevalence of ever-smokers (smoked at one time) was 54.5% among ETS-exposed versus 33.8% in non-exposed subjects. The study found that people exposed to ETS during childhood were more susceptible to developing asthma, and that they were also more likely to experience breathing difficulties from exercise and when exposed to cold air. The impact on children exposed to ETS is attributed to the fact that their airways are smaller and children breathe more rapidly than adults. In addition, their respiratory and immune systems are not fully developed and they typically spend more time at home, where the exposure to ETS is considerable if their parents smoke.

Another examination of childhood exposure to ETS, focusing on children's pulmonary function, was carried out in rural China. The analysis included 1,718 children 8 to 15 years of age whose mothers were never-smokers. When compared with children of never-smoking fathers, children of smoking fathers had small, but detectable deficits in FEV_1 and FVC. When children of smoking fathers were subdivided into two subgroups based on the number of cigarettes the father smoked per day, exposure to 30 or more cigarettes/day had the largest deficits in both FEV_1 and FVC. This monotonic exposure-response relationship remained in all strata when the analysis was further stratified by children's sex and asthma status. The data also suggested that the relationship was greatest among nonasthmatic girls. The researchers conclude that there is a monotonic exposure-response relationship between paternal smoking and decline of pulmonary function in children in this rural Chinese population. The study was released in the October 2001 *American Journal of Respiratory and Critical Care Medicine*.

While surveys show that adults, including smokers, agree that smoking should be restricted in homes of smokers with children, only 12.5% of such homes are actually smoke-free. One study examined factors associated with home smoking restriction among inner-city smokers. Home smoking restriction was reported by 38.2% of all smokers. On multivariate analysis, home smoking restriction was more likely with the presence of a child and a nonsmoking adult partner in the home. Conclusions: The presence of children and of nonsmoking adults is associated with the practice of smoking restriction in the homes of inner-city smokers. These findings suggest that inner-city smokers are concerned about health effects of ETS on children. Health Care professionals should target nonsmoking adult members of households with children and smokers about home smoking restriction and emphasize the health effects of ETS on children as a motivation for smoking parents to limit exposure and to quit smoking (*Pediatrics* 2002 Feb;109[2]:244-9). (The AMA and the EPA have been collaborating on a campaign to raise awareness of ETS exposure in the home for several years, and have jointly produced public service announcements about this issue.)

SMOKING CESSATION

In the March 2002 issue of *Neuron*, researchers revealed an extraordinary discovery that explains how the brain is "rewarded" by exposure to nicotine, and why success at smoking cessation is so difficult. A single nicotine exposure increases dopamine levels in the mesolimbic reward system for hours. The authors showed in experiments on rat brains that persistent modulation of both GABAergic and glutamatergic synaptic transmission by nicotine can contribute to the sustained increase in dopamine neuron excitability. Nicotine enhances GABAergic transmission transiently, which is followed by a persistent depression of these inhibitory inputs due to nAChR desensitization. Simultaneously, nicotine enhances glutamatergic transmission through nAChRs that desensitize less than those on GABA neurons. Therefore, nicotine does not just stimulate the brain's "reward" center, it also shuts down the system that limits how long those rewards last. "It would be difficult to design a better drug to promote addiction to this horrible habit," said Daniel McGehee, a neurobiologist at the University of Chicago. "It takes only a few exposures to create a lasting memory of the rewards of smoking, which are reinforced by each cigarette smoked," he said. Nicotine hijacks the reward system by attaching to receptors on nerve cells and triggering the release of dopamine, a neurotransmitter that causes pleasant feelings. Nicotine also attaches to another receptor that triggers the release of a chemical called GABA, which stops dopamine. The receptors keep releasing GABA until they run out and they cannot produce more for up to an hour after being exposed to nicotine. Without GABA, the body cannot stop the pleasure signal caused by nicotine.

In an article on preparedness for clinical practice (*JAMA* 2001;286:1027-1034), a national survey of resident physicians in their last year of training found that 96% of residents in internal medicine, family practice, and obstetrics/gynecology rated their preparedness to counsel patients about smoking cessation as "very prepared" or "somewhat prepared." Overall, smoking cessation counseling was the behavioral issue about which they were most comfortable.

In the March 8, 2002, issue of the *British Medical Journal*, the activist group Action on Smoking and Health released a survey that looks at what Britons think about their smoking, and their inappropriate expectations related to cessation. The survey of a representative national sample of 893 smokers shows that most are disenchanted with smoking and claim that they would not smoke if they had the opportunity to make the decision again. When asked: "If you had your time again would you start smoking?" 83% of current smokers replied that they would not (79% men, 87% women). Those aged 45 to 64 were most regretful, 90% saying that they would not smoke "given their time again." This may reflect the increasing distress of smokers reaching the age at which the major smoking-related

diseases are becoming noticeable in themselves and among their peers. Given the supposedly carefree and rebellious image attributed to teenagers and young adults, young people were also very disenchanted with smoking: 78% of those aged 16 to 24 declared that they would not smoke if they had it to do over.

The survey also tested expectations about stopping smoking in the future, asking "Looking ahead, do you think you will still be smoking in 1 year's time, or will you have given up?" Those who responded that they would still be smoking were asked the same question looking ahead to 2, 5, 10, and 20 years time. The responses show that the smokers had inappropriate expectations about the timing of successfully stopping and the experience of recent history, particularly in the near term, with 53% expecting to stop within two years, while in reality only 6% manage to do so. Women were more likely than men to think that they would stop smoking within one year (45% v 34%), and younger smokers were more optimistic than older smokers (47% of those aged 16-24 v 15% of those aged over 64). Poorer smokers were less likely to think they would have given up within one year (33% among the poorest v 47% among the most affluent).

An article in the November 2001 issue of *Preventive Medicine* describes "The Pediatric Residency Training Director Tobacco Survey," mailed to all pediatric residency training directors in the United States. The survey assessed the nature of training and supervision on tobacco, barriers to training, and factors that influence the inclusion of tobacco in pediatric residency training. The survey found that relatively few programs offered training/supervision on tobacco on a formal basis. Training directors were reluctant to treat parents who smoke, were skeptical about third party payer reimbursement, and did not believe that office-based interventions for treating tobacco use among patients were effective. Key barriers to training were competing priorities, lack of training resources, and lack of faculty with expertise on tobacco. The authors conclude that while residency training is an excellent time to train future pediatricians to intervene on tobacco, too few pediatric training programs have taken up this charge. Much needs to be done to correct this situation and to prepare future pediatricians to meet the tobacco challenge.

A newly patented form of nicotine may soon be added to the list of products available to those who need the drug. Known as "nicotine water," the product is tasteless, but could be sold in various flavors. It might be marketed as a substitute for smoking (on airplanes, in a business office, theater, etc.) and/or as a way to help smokers stop. A company brochure claims that the water-based nicotine is "preferred 9 to one over the patch and gum." A food supplement, it will not be subject to FDA review.

In a bizarre news report from the United Kingdom in October 2001, a man trying to stop smoking choked to death while using nicotine gum. Two pieces of the gum were found in his larynx at autopsy.

A British biotechnology company began clinical trials in September 2001 on a nicotine addiction vaccine. The product, manufactured by Xenova Group, would prevent the addictive cycle of cigarette smoking by stopping nicotine from crossing the blood-brain barrier. The nicotine molecule by itself is too small to generate an immune response, so the vaccine contains nicotine bound to an existing cholera vaccine. The combined molecule generates anti-nicotine antibodies in the bloodstream that in turn make the nicotine too big to pass the blood-brain barrier. Although the vaccine, called TA-NIC, is unlikely to completely block all the nicotine from entering the brain, it will slow it down, which is more important for preventing the nicotine "hit" smokers get. The manufacturers predicted that the vaccine would need to be given in four or possibly five intramuscular doses, with booster shots required, as the antibodies only last in the bloodstream for several months. This initial study of TA-NIC will assess its safety and tolerability at different doses, and researchers still have several years work ahead to prove the efficacy of the product.

Smoking among pregnant women is a particular concern because of the effect on both mother and fetus, and for the neonate exposed to passive smoke in the home. An attempt to deliver increased information on smoking in a pregnancy clinic in Finland has had salutary results. A controlled study was conducted to evaluate the effects of a low-intensity population-based smoking cessation program in maternity care clinics. In the intervention group, 58/306 women (19.0%) reported quitting smoking during pregnancy; in the control group the numbers were 22/152 (14.5%). The intervention group indicated that they received more information on adverse effects of smoking, studied the material more actively, and felt that material from maternity care influenced their smoking behavior more than the control group (*Eur J Public Health* 2001 Dec;11[4]:446-9).

Excerpts from the MMWR November 9, 2001: 50(44);979-982, "State Medicaid Coverage for Tobacco-Dependence Treatments - United States, 1998 and 2000"

"Health insurance coverage for tobacco dependence treatments has been shown to increase both quit attempts and quit rates among smokers. Coverage for tobacco dependence treatments under state Medicaid programs is growing. In 2000, over 32 million low-income Americans received their health insurance coverage through the Federal-State Medicaid program, and more than one-third of them (36%) smoked cigarettes. Thus, more than 11.5 million smokers were enrolled in the Medicaid program in 2000. Surveys of State Medicaid program coverage of tobacco dependence treatments were conducted in 1998 and 2000. In 1998, 25 states offered coverage for tobacco dependence treatments. Nine additional states began offering coverage in 2000, increasing the total number of states that offer any coverage to 34, and the proportion of the Medicaid population with any coverage to 73%.

"In 2000, a total of 33 states and DC offered some coverage for tobacco-dependence treatments; Oregon was the only state to offer all of the pharmacotherapy and counseling services recommended in the 2000 Public Health Service clinical practice guideline on treating tobacco use and dependence. In 2000, some pharmacotherapy coverage was offered by 31 states, an increase of 35% from 1998. Sixteen states offered coverage for all recommended pharmacotherapy treatments in 2000. In 1998, a total of 23 states offered some coverage for prescription drugs and 17 for over-the-counter drugs; in 2000, a total of 31 states offered coverage for prescription drugs and 23 for over-the-counter drugs. In 2000, a total of 13 states offered special tobacco-dependence treatment programs for pregnant women; in two states, counseling services were covered for pregnant women only. In 2000, two states covered some form of counseling services without coverage for any drug treatments. During 1998-2000, one state dropped Medicaid coverage for bupropion and one state stopped Medicaid coverage for counseling. In 2000, a total of 11 states covered at least one type of pharmacotherapy and one type of counseling. In 2000, a total of 17 state Medicaid programs reported no coverage for tobacco-dependence treatments."

An article in the *Archives of Pediatrics and Adolescent Medicine* (2001;155:597-602) looked at how well primary care physicians performed in screening and counseling services among youth who smoke. A group of pediatricians and family physicians in New York were surveyed about their practice patterns. While 91% of them reported asking most adolescents about smoking, only 32% asked about spit tobacco use. They reported assessing motivation for cessation among 81% of these smokers, but only set quit dates for 34%, and only 28% got follow-up visits connected with smoking. Family physicians were more likely than pediatricians to provide effective counseling interventions, and were more likely to be familiar with smoking cessation guidelines.

In an article published in *Thorax*, researchers in England and the United Sates report on a review of studies of smoking cessation efforts among hospitalized patients. Intensive intervention (inpatient contact plus follow up for at least 1 month) was associated with a significantly higher cessation rate compared with controls OR 1.82, 95% CI 1.49 to 2.22. Any contact during hospitalization followed by minimal follow up failed to detect a statistically significant effect on cessation rate. There was insufficient evidence to judge the effect of interventions delivered only during the hospital stay. Although the interventions increased quit rates irrespective of whether nicotine replacement therapy (NRT) was used, the results for NRT were compatible with other data indicating that it increases quit rates. There was no strong evidence that clinical diagnosis affected the likelihood of quitting. It seems prudent to use hospitalization as another "teachable moment" for smoking cessation, particularly when follow-up contact can be made.

How well do family physicians do at counseling their patients who smoke? In a study that used direct observation of patient encounters, tobacco use was discussed during 633 of 2963 encounters (21%; range among practices=0%-90%). Discussion of tobacco use was more common in practices that had standard forms for recording smoking status (26% vs. 16%; P=.01). Discussions about tobacco were more common during new patient visits but occurred less often with older patients and among physicians in practice more than 10 years. Of 244 smokers identified, physicians provided assistance with smoking cessation for 38% (range among practices=0%-100%). Bupropion and nicotine-replacement therapy were discussed with smokers in 31% and 17% of encounters, respectively. Although 68% of offices had smoking cessation materials for patients, few recorded tobacco use in the "vital signs" section of the patient history or assigned smoking-related tasks to non-physician personnel. The research was reported in the August 2001 *Journal of Family Practice*.

An open study in the August 2001 *Journal of Nicotine and Tobacco Research* examined the effect of smoking reduction and smoking cessation on established cardiovascular risk factors. Fifty-eight healthy adult smokers were provided with nicotine nasal spray (to be used ad libitum) and asked to stop smoking. The primary goal during the

first 8 weeks, however, was to reduce their daily smoking by at least 50%. Subjects were then followed for another 8 weeks; at this point, 33 participants had successfully stopped smoking. Cardiovascular risk factors including fibrinogen, hemoglobin, hematocrit, triglycerides, and cholesterol were measured at baseline and at 9 and 17 weeks. After 8 weeks of smoking reduction, the mean number of cigarettes smoked per day had decreased from 21.5 to 10.8. This was accompanied by significant improvements in fibrinogen, white blood cell count and the high-density/low-density lipoprotein (HDL/LDL) ratio. Following 8 weeks of abstinence from smoking, the mean white blood cell count was further reduced and there were also significant improvements in HDL and LDL. In conclusion, 8 weeks of smoking reduction resulted in clinically significant improvements in established cardiovascular risk factors. These improvements were even greater after an additional period of abstinence from smoking. (Following a year of abstinence from smoking, heart disease risk is cut by about 50%).

Young smokers in England ages 12 and older are to be given nicotine patches in a project designed to help youth stop smoking. Supported by Britain's two biggest cancer charities, a team of experts will be working with school-age smokers in Nottingham to investigate whether nicotine replacement therapy can be effective in helping them quit. If successful, the Cancer Research Campaign and Imperial Cancer Research Fund will likely recommend that the new program be rolled out in towns and cities across Britain and Scotland. The project began in mid-2001.

Increased cigarette excise taxes can substantially reduce smoking rates among all groups of pregnant women, even those with high smoking rates, reports a study released in the November issue of the *American Journal of Public Health*. It is the largest to date on the impact of higher taxes on smoking during pregnancy. The study reports that a increase of 55 cents per pack would cut smoking rates among pregnant women nationwide by about 22% on average, among all groups of pregnant women regardless of age, ethnicity, education, or marital status. This effect appears to be larger than the smoking rate decreases seen in the general population following cigarette tax increases. The study examined roughly 20 million births between 1989 and 1995 from the Natality Detail File, an annual, state-by-state birth census compiled by the National Center for Health Statistics. Of the 20 million cases examined, 16.5% of mothers reported having smoked during pregnancy. The researchers examined the smoking rates of pregnant women before and after a state raised their cigarette tax, and compared these changes to smoking rates in states that had no such change. Even among subgroups of pregnant women who smoked heavily, the study found large drops in smoking. For example, a 55-cent tax increase is estimated to reduce smoking for women under age 30, unmarried women, and lower-educated women by 11% to 15%. The groups most responsive to an increase in excise taxes were white, older, married, and highly-educated women, who would reduce smoking by 25% to 40% with the tax increase. The authors estimated that a 55-cent tax increase would reduce smoking rates among expectant teens by 16%. The lower smoking rates generated by higher taxes should help reduce the smoking-related complications among pregnant women and their infants, resulting in health care cost savings within a few months of the tax increase.

Nebraska's prison inmates will be offered nicotine patches in an effort to help them over the "cold turkey" break from cigarettes imposed by the state. All 12 prison facilities will be included in the state's ban on smoking on all state property. While smoking had not been permitted indoors in the state prisons for some time, the total ban on tobacco use began in February 2002.

STATISTICS AND FIGURES

Figures from the Maryland Department of Education released in October 2001 show that following last year's $0.30 per-pack cigarette price increase, as many as 20,000 youth have been prevented from smoking and the state has received an $80 million revenue boost.

The increase in tobacco use by college students over the past few years has been documented in articles by Wechsler and others. Recent survey data from Southern Illinois University's Core Institute contain data on tobacco use on college campuses. A huge sample size (up to 65,000 students) in over 150 campuses makes it a very thorough review.

	1995-96	1998	1999 (most recent data)
Use within past year	44.4%	49.5%	47.3%
30-day prevalence	34.2%	37.4%	35.5%

According to a report from the Federal Interagency Forum on Child and Family Statistics entitled "America's Children: Key National Indicators of Children's Well-Being 2001," smoking rates by children in grades eight through 12 peaked just before the MSA, and have been declining since then. Smoking rates for 12th graders declined from 25% in 1997 to 21% in 2000, according to the report. For 10th graders, the decline was from 18% in 1997 to 14% in 2000, and eighth graders saw a decline from a peak of 10% in 1996 to 7% in 2000.

Oregon put a school-based curriculum in place in 1999 as part of its tobacco control plan, funded by the MSA. In an *MMWR* report released August 10, 2001, the state reported significant decreased tobacco use among 8th graders in schools receiving the curriculum intervention, compared with schools without the intervention. Schools using the intervention, based on the CDC guidelines for school-based programs, dropped from 16.6% prevalence in 1999 to 13% in 2000, compared with a drop from 17% to 15.7% in control schools. The change was most marked in schools with "high implementation" of the program. The authors conclude that a school-based program based on CDC guidelines can be an effective part of a statewide, comprehensive program in tobacco control.

According to the World Bank, the number of children in affluent countries who start smoking every day is 14,000-15,000. The number of children in low and middle-income countries who start smoking every day is 68,000-84,000.

The year that tobacco use is expected to be the single biggest cause of death worldwide is 2030.

An NCAA survey (reported in June 2001) of more than 21,000 student athletes about their use of drugs and dietary supplements reveals that 22% smoke cigarettes. Of those who smoke, 7.9% are black, 25.8% Caucasian. Only 26% are daily smokers; about 45% say they smoke only socially, with friends. Seventy-five percent say they began smoking during high school or junior high. Use of spit tobacco declined to 17.4%, from 22.5% in 1997 and 27.6% in 1989. Its use remains high in some specific sports, however: 41% of baseball players, 29% of football players and 18 % of women skiers admit to using spit tobacco. About 53% use spit tobacco at least once a day.

Adult cigar use in California increased substantially between 1990 and 1996. To determine more recent trends, researchers examined cigar smoking prevalence from the 1990, 1996, and 1999 California Tobacco Surveys. Adult cigar use prevalence increased from 2.5% in 1990 to 4.9% in 1996, and declined to 4.4% in 1999. Nearly the entire decrease was accounted for by less use in adults who had never been cigarette smokers. Among current cigar smokers in 1999, 43.3% had not smoked a cigar in the last month; just 16.2% of never-cigarette smokers smoked three or more cigars in the past month; and 10.4% of former cigarette smokers the group with the highest level of cigar consumption reported daily use. Cigar use may have peaked in California around 1996; in 1999, the intensity of use was generally at modest levels. California's bans on smoking in bars and restaurants may limit cigar smoking while drinking, so that the observed patterns may or may not reflect those in the rest of the United States (*Am J Prev Med* 2001;21[4]:325-8).

The results from the year 2000 National Household Survey on Drug Abuse (NHSDA) were released in mid-October 2001. Findings from the 2000 NHSDA related to tobacco are summarized below.

- An estimated 65.5 million Americans reported current use of a tobacco product in 2000, a prevalence rate of 29.3% for the population aged 12 and older. Among this group, 55.7 million (24.9%) smoked cigarettes, 10.7 million (4.8%) smoked cigars, 7.6 million (3.4%) used smokeless tobacco, and 2.1 million (1.0%) smoked tobacco in pipes. Although the rate of cigarette use was lower in 2000 than in 1999, the difference between 25.8% to 24.9% is not statistically significant. However, the rate of past year use of cigarettes decreased significantly between 1999 and 2000, from 30.1% to 29.1%.

- There was a statistically significant decrease in current cigar use between 1999 and 2000, from 5.5% to 4.8% for the population aged 12 and older. Rates of use of smokeless tobacco and pipes were unchanged between 1999 and 2000.

- Among youth smokers aged 12 to 17 years in 2000, more than half (59.4 %) reported that they personally bought cigarettes at least once in the past month. Approximately one-third of youth smokers (33.8%) reported buying cigarettes at a store where the clerk hands out the cigarettes. Among youth smokers aged 12 and 13 years old, 45.8% reported that they personally bought cigarettes in the past month.

The "Monitoring the Future" survey is a well-respected survey on youth tobacco use. The report released in December 2001 is summarized below:

- Cigarette use by 8th and 10th graders declined in several categories between 2000 and 2001: Lifetime use decreased from 40.5% to 36.6% among 8th graders and from 55.1% to 52.8% among 10th graders; Past month use declined from 14.6% to 12.2% among 8th graders, and from 23.9% to 21.3% among 10th graders; Daily use in the past month declined from 7.4% to 5.5% among 8th graders and from 14.0% to 12.2% among 10th graders.

- Recent years have seen several declines in smoking by youth. Reductions in smoking between 1999 and 2000 involved students in all three grades and several categories of use; between 1998 and 1999 past month use declined among 8th graders; and between 1997 and 1998 cigarette use decreased among 10th and 12th graders.

- Use of bidis decreased among 8th and 10th graders. Past year use of these small, flavored cigarettes went from 3.9% to 2.7% among 8th graders and from 6.4% to 4.9% among 10th graders.

- Rates of smokeless tobacco use remained statistically unchanged between 2000 and 2001. In 2001, 4.0% of 8th graders, 6.9% of 10th graders, and 7.8% of 12th graders reported using smokeless tobacco in the past month.

A report, "Smoking During Pregnancy in the 1990s," from the CDC's National Center for Health Statistics was released in August 2001. It presented an analysis of the current patterns and trends in smoking during pregnancy by age, race and ethnic origin on a national basis as well as a state-by-state breakdown of smoking rates for each year and the percent change from 1990 to 1999. The full report is available at www.cdc.gov/nchs.

The rate of smoking during pregnancy dropped 33% between 1990 and 1999, so that in 1999 just over 12% of all women reported smoking during their pregnancies. The greatest success in reducing smoking was for women in their late twenties and early thirties, where there was more than a 40% drop since 1990. Teenagers were more likely than women of any other age to smoke while pregnant. After experiencing a dramatic 20% decline in the first part of the decade, smoking rates among pregnant teenagers-unlike women of all other ages--increased by 5% from 1994 to 1999. The highest rate in 1999 (19%) was for women 18-19 years of age.

Other highlights of the report show:

- Women of all race and ethnic groups were less likely to smoke during pregnancy in 1999 than they were in 1990.
- Of all groups, American Indian women still have the highest rate of smoking during pregnancy (20%) and had the smallest percent reduction.
- Smoking rates for non-Hispanic white expectant mothers was 16%; their rate dropped by 25%.
- Smoking rates for Asian/Pacific islander women were cut by 47% to a rate of 3% by 1999.
- Non-Hispanic white teens had the highest overall rate at 30%.
- About 2% of mothers with four or more years of college smoked during pregnancy, in contrast with 29% for those not completing high school.
- Declines were largest during the decade in the District of Columbia (77%), and Massachusetts and Arizona (both 50%).
- New York City, DC, Texas, Arizona, and Hawaii all had rates of smoking during pregnancy less than 8% in 1999.

The CDC analyzed self-reported data from the 1999 National Health Interview Survey (NHIS) about cigarette smoking among US adults. The report, released in the October 12, 2001, *MMWR*, summarizes the findings of this analysis, which indicate that, in 1999, approximately 23.5% of adults were current smokers, representing a modest decline in prevalence since 1993.

In 1999, an estimated 46.5 million adults (23.5%) were current smokers. Overall, 19.2% of adults were everyday smokers and 4.3% were some day smokers. The prevalence of smoking was higher among men (25.7%) than women (21.5%). Among racial/ethnic groups, Hispanics (18.1%) and Asians/Pacific Islanders (15.1%) had the lowest prevalence of cigarette use; American Indians/Alaska Natives had the highest prevalence (40.8%). Adults who had earned a General Educational Development diploma had the highest smoking prevalence (44.4%); persons

with masters, professional, and doctoral degrees had the lowest prevalence and met the 2010 objective (8.5%). Prevalence was highest among persons aged 18-24 years (27.9%) and 25-44 years (27.3%) and lowest among those aged ≥65 years (10.6%). The prevalence of smoking was highest among adults living below the poverty level (33.1%) compared with those living at or above the poverty level (23.4%), and lowest among those with unknown poverty status (20.2%). In 1999, an estimated 45.7 million adults (23.1%) were former smokers; 25.8 million were men and 19.9 million were women. Former smokers constituted 49.5% of persons who had ever smoked ≥100 cigarettes.

Researchers have noted previously that smoking is more common among blue-collar than white-collar workers. However, a new study (*American Journal of Industrial Medicine* 2001;40:233-239) breaks down these categories into 40 occupations and 44 industries. The authors examined data from a survey conducted by the National Center for Health Statistics over a 6-year period and included more than 20,000 adults, investigating their cigarette smoking status, occupation, industry, employment and gender. They found that 28% of the respondents smoked cigarettes from 1988 to 1994. The study also found that men smoke more often than women (32% versus 25%) and blacks smoke slightly more often than whites (31% versus 28%). But some occupations showed a disproportionate number of smokers. Nearly half of waiters, construction workers, mechanics, and movers smoked, while less than one fifth of teachers and sales representatives smoked. The investigators also found that 43% of unemployed people smoked, compared with 30% of employed people and 23% of those not in the labor force. Teachers seemed to be most successful at stopping smoking, perhaps partially due to schools' no-smoking policies. Twice as many teachers were former smokers than were current smokers.

Vocabulary enhancement for tobacco control: Misocapnist (Noun). Pronunciation: [mi-sah-'kæp-nist]. Definition: A smoke-hater. Usage: The word has only rarely been used in the past, but perhaps its time has come. The extreme opposite of "smoker," who is presumably a smoke-lover, is not captured in "nonsmoker." A nonsmoker merely eschews smoking; a misocapnist is someone who despises and fights it. The hatred itself of smoke is "misocapny." Suggested usage: "All the managerial misocapnists have decided to make the building smoke-free." Etymology: Greek misos "hatred" + kapnos "smoke."

LEGISLATION AND REGULATIONS

Smoking will be banned in all Berkeley County, West Virginia, restaurants, shopping malls, sporting arenas and other public places under an ordinance passed in July 2001 by the Berkeley County Board of Health. Violation of the ordinance is a misdemeanor and carries a fine of $200 to $1,000. Freestanding bars in which more than half of the sales revenue comes from alcohol are among the few places exempt from the law.

Reports from the National Council of State Legislatures (NCSL) and the General Accounting Office (GAO) (both released in August 2001) show that only a small fraction of the MSA dollars are being spent on tobacco control. The NCSL puts the figure at about 5% nationally, and the GAO estimates the tobacco control fraction at about 8%. The NCSL reported that 36.1% had been set aside for health care, 26% went to bolster endowments or state budget reserves, 9.5% was spent on schools or youth programs, 5% for tobacco prevention and 4.5% was put into research.

"They [state legislatures] act like this money just fell out of heaven or something," said Mike Moore, attorney general of Mississippi. "There's no connection between the way they're spending this money on highways or tax cuts or whatever the political whim of the day is, and the public health fight that we the attorneys general of this country fought."

On August 13, 2001, Canadian Health Minister Allan Rock announced legislation that will prevent cigarettes from being marketed under the terms "light" or "mild," and called such descriptions of cigarettes misleading advertising. Rock made the announcement at the annual meeting of the Canadian Medical Association in Quebec City. Health groups welcomed the decision. Dr. Peter Barrett with the Canadian Medical Association says they are "quite happy" about Rock's announcement. "We welcome that as a health initiative in this country," Barrett said. David Sweanor of the Ontario Non-Smokers' Rights Association said it's a good decision to stop what he calls a "massive consumer fraud." He said a majority of Canadian smokers buy "light" or "mild" cigarettes and believe they are making a safer choice. Both Canadian and international tobacco companies are expected to fight the proposal.

In New Jersey, two new tobacco-related ordinances of interest passed in August 2001. The state banned tobacco use on public school grounds, extending the indoor-smoking rule to all school property. And the town of West Orange banned smoking outdoors in all city parks, playgrounds, and other public outdoor recreational facilities.

A story in the September 24, 2001 *Wall Street Journal* and excerpted here points out that there are several problematic issues related to tobacco sales over the Internet:

"Visitors to BarbisButts.com can order a carton of Marlboros for $28.75--about a third less than in a bricks-and-mortar store in New York. Serious bargain hunters can buy cut-rate cigarettes with names such as Market and Niagara for as little as $10 a carton, or $1 a pack.

"The web site, decorated with a silvery profile of a buxom woman, says the company ships its wares from an Indian reservation near Salamanca in western New York State. Barbi's Butts promises that all information about customer orders will be kept 'strictly confidential'--which could make it easier for smokers to avoid paying state excise taxes on the cigarettes they buy.

"A survey by the Massachusetts Health Department found that more than 200 web sites sell cigarettes and other tobacco products. Some, like Barbi's Butts, are based on Indian reservations. Others are small retailers based in the United States and overseas. Collecting taxes on cigarettes sold online isn't easy. A federal law, the Jenkins Act, requires companies that ship cigarettes across state lines to report the names and addresses of buyers (other than licensed distributors) to state tax authorities. The law says companies must file those reports every month or risk being fined.

"But state tax collectors say that the law is widely flouted. Many web sites promise not to divulge the identity of purchasers and states generally haven't been aggressive about pursuing them since the amount of money involved is relatively small. 'Compliance is really hit or miss,' says Dennis Maciel, chief of the excise-tax division of California's tax department. He estimates that fewer than 10% of the out-of-state companies selling cigarettes through the mail to California residents are submitting Jenkins Act reports. California has moved to enforce excise-tax payments, pushing out-of-state companies to submit lists of their California customers and then sending the customers tax bills. Between 45% and 65% of the smokers contacted by the state have paid up since the program started, according to Mr. Maciel. He figures that California is missing out on at least $15 million a year in cigarette excise taxes on sales from out-of-state sources. The state takes in a total of about $1.2 billion annually from tobacco excise taxes, he said.

"Currently, the electronic sale of cigarettes is legal in the US. New York last year enacted a law banning the sale of cigarettes by mail order, telephone and the Internet. The law made it illegal for any company to sell cigarettes through these means to New York consumers; it also made it illegal for a shipper to deliver cigarettes to people in New York. The state Legislature said that such cigarette sales posed a "serious threat" to public health and the state economy. New York's cigarette excise tax is the highest in the nation, at $1.11 a pack.

"But British American Tobacco PLC's Brown & Williamson unit, the country's third-largest cigarette maker, and Santa Fe Natural Tobacco Co., the small New Mexico company that makes American Spirit cigarettes, sued in US District Court in Manhattan last year to overturn the law, saying it was an unconstitutional interference with interstate commerce. The judge hearing the case agreed and struck down the law earlier this year. In her June 2001 ruling, Judge Loretta A. Preska wrote that the New York law was protectionist and discriminatory because it favored local tobacco retailers over out-of-state competitors. She said there were plenty of measures the state could use to accomplish its goals short of an outright ban on the home delivery of cigarettes. Judge Preska said the state could require Internet retailers to verify the age of their customers before shipping cigarettes and move to collect whatever taxes are due.

"The state is appealing the ruling. A spokesman for New York Gov. George Pataki also says the governor will ask the state's congressional delegation to introduce federal legislation to regulate mail-order and Internet cigarette sales.

"Tax collection isn't the only headache states face when it comes to Internet cigarette sales. Enforcing age-restriction laws is also a problem. Kurt Ribisl, a professor at the University of North Carolina School of Public Health who studies online tobacco selling, says Internet shoppers should have to present the same kind of proof of age required to buy cigarettes in a regular store--a government-issued photo ID.

"Identification would need to be checked again when the cigarettes are actually delivered, he says, to ensure that they end up in the right hands. But policing such transactions wouldn't be easy, and making such a system work would require compliance not just by cigarette sellers but by delivery services.

"Michigan, Oregon, Washington and other states have taken steps to prevent online tobacco merchants from selling to kids. Rhode Island, for instance, has enacted a law requiring an adult to sign for delivery of any cigarettes shipped to customers in the state. Bills before the US Congress would also prohibit Internet cigarette sales to people under 18 years old.

"State action isn't enough, says Dr. Ribisl. 'Internet cigarette sales pose serious regulatory challenges,' he says. 'What we really need is some federal leadership.'

"So far, few kids are using the Internet as a way to get cigarettes. A study by the University of Michigan found that in 1999, fewer than 2% of teenagers who bought cigarettes did so through the mail. The American Legacy Foundation, an antitobacco organization in Washington, DC, that closely tracks tobacco use by children, has found that almost no kids are actually buying cigarettes online.

"In part, that's because there are usually a number of obstacles that discourage kids from online cigarette purchases. Generally, payment must be made by credit card. Often, there is a minimum order size. Kids also can't be sure that the cigarettes will be delivered at a time when the shipment won't be discovered by adults.

"The main thing keeping kids from buying online, however, according to Dr. Ribisl, is that prevention measures for offline purchases haven't been so great. It is easier for kids to get cigarettes from stores or friends. 'I don't think there's a big need for kids to turn to the Internet now,' he says. But, he warns, that is likely to change if enforcement of minimum-age laws at stores improves.

"Another concern is whether the web will turn into a way to evade restrictions on tobacco advertising. German company Reemtsma GmbH, for example, has a web site promoting its West brand of cigarettes. Visitors can view English-language television commercials that feature, among other things, a bikini-clad woman smoking. (Television advertising of cigarettes is illegal in the US.) The site also offers free e-mail to users, as well as video games including one with a Formula One car-racing theme--which some critics say could appeal to children.

"Major US tobacco companies have moved cautiously online. The only brand offered online by a US manufacturer is RJ Reynolds Tobacco Holdings Inc.'s Eclipse cigarette--which the company says may be less likely to cause cancer. The company says it uses strict controls to ensure that only people 21 years of age can purchase the cigarettes, which, rather than burn tobacco, primarily heat it using a carbon heating element embedded in the end of the cigarette and lit with a match. Brown & Williamson has said it eventually intends to start selling some of its smaller, less successful brands online, while Philip Morris Cos., the nation's largest cigarette maker, says it favors an outright ban on Internet tobacco sales. The company says it believes all cigarette sales should be conducted face-to-face so a purchaser's age can be verified."

The article quotes Dr. Gregory Connolly, director of the Massachusetts state tobacco-control program, who says that Internet sales of tobacco "could be devastating to the tobacco-control policies we've implemented over the past 20 years." Connolly advocates strict government regulation of such sales so that "public-health interests outweigh commercial interests. But many tobacco-control activists believe it is only a matter of time before cigarette companies start using the Internet as a way to gather information about smokers and potential customers and use it to market their brands." If a regular customer quits smoking and stops placing orders, for example, says Dr. Connolly, a cigarette company could theoretically try to lure them back with coupons or other enticements.

INTERNATIONAL ISSUES

The Royal College of Physicians (RCP) issued a call to the British government to ban tobacco advertising, sponsorship and promotion as it launched a new report in March 2002 highlighting the death toll of cigarettes. Forty years ago the RCP warned the government of that day about the dangers of tobacco-related death and disease by publishing its ground-breaking report, "Smoking and Health." Since that time more than five million premature

deaths have occurred in Britain as a result of smoking and many of the RCP's original policy recommendations have still not been implemented. Clive Bates, director of the British tobacco control group Action on Smoking and Health, said: "You can either see the last 40 years as a catastrophe with five million dead from smoking or a public health triumph with almost two million saved due to the reduction in smoking since 1962. Either way, we still need to see tobacco as a potent malign force in society filling the cardiac and cancer wards, draining away people's lives and soaking up National Health Service resources." The complete RCP report can be accessed on the Internet: www.rcplondon.ac.uk/pubs/books/ash.

A special review of international tobacco issues was published in the industry trade publication, *Tobacco Journal International*, in December 2001. The article indicates that the "big three" tobacco producers are Philip Morris, British American Tobacco, and Japan Tobacco. For the year 2000, their market share worldwide was:

	Billion cigarettes sold	Cigarette production (percentage of total world production)
Philip Morris	887.3 billion	16.5%
BAT	807.0 billion	15.0%
Japan Tobacco	447.9 billion	8.1%

Philip Morris is described as the "undisputed market leader" with the world's most popular brand (Marlboro), operating in 180 markets worldwide, with 50 factories either wholly or partly owned. Marlboro has a market volume greater than the next 7 competitive brands combined. In 2000, the company generated revenues of $22.7 billion domestically, and $26.4 internationally.

BAT has more than 300 brands in its stable, with 86 factories in 64 countries. It is described as the most aggressive in promoting local and regional brands, as well as building "global" ones (Benson & Hedges, Lucky Strike, Dunhill, Pall Mall, Kool). BAT is focusing on markets outside the US and European Union. In May 2001, BAT became the only major tobacco company to establish a joint venture in China, at Mianyang in the Sichuan province. This allows BAT to build a factory in China, the first such outside effort. It also has plans to build new factories in South Korea and Vietnam.

Japan Tobacco International, headquartered in Geneva, was created in 1985 by privatization of the state tobacco monopoly. When it bought the RJR international tobacco section in 1999, it became a major player in the world market. The company operates in 170 countries, and is particularly active in Russia, with a 20% market share. Its factory in St. Petersburg may be the world's largest. With over 190 brands, its 4 international brands are Mild Seven, Camel, Salem, and Winston. It is concentrating its efforts in Asia, Eastern Europe, and Russia.

Philip Morris began circulating a report in July 2001 claiming that the premature demise of smokers saved the Czech government between $23.8 million and $30.1 million in health care, pensions and housing for the elderly in 1999. The report also calculates the costs of smoking, such as the expense of caring for sick smokers and people made ill by second-hand smoke as well as income taxes lost when smokers die. Weighing the costs and benefits, the report concludes that in 1999 the government had a net gain of $147.1 million from smoking. Philip Morris said it received the report (which it had commissioned) from the Arthur D. Little consulting firm late in 2000 and handed it out after complaints from Czech officials that the tobacco industry was saddling the country with huge health-care expenses. Philip Morris manufactures about 80% of the cigarettes smoked in the Czech Republic.

The report was immediately criticized by American health economists and tobacco control organizations for scientific and economic flaws and its callous disregard for human life. The result was scores of editorials across the globe blasting the tobacco giant, and an "apology" from Philip Morris that ran in several papers.

Philip Morris began construction in July 2001 of a new $300 million cigarette manufacturing plant in the Philippines. It is to be fully on-line in 2003. The Philippine President attended the ribbon-cutting ceremony that kicked off the project; government spokesmen defended the presidential participation as promoting jobs, not smoking.

Philip Morris opened a cigarette plant in Romania to cut local sales costs, a local newspaper reported in September 2001. The factory, in which the company invested $100 million, employs 600 workers and will produce brands such as Marlboro, L&M, and Bond Street. Philip Morris had 24% of the Romanian cigarette market as of June 2001, the second largest share behind British American Tobacco, which had a 31% of the market, the paper said.

South Korea will now allow foreign tobacco companies to produce cigarettes in the country, subject to production and investment minimum standards. The South Korean government abolished the manufacturing monopoly of state-run Korea Tobacco & Ginseng Corp. and introduced import duties on July 1, 2001. BAT, the world's second largest tobacco group, has become the first foreign cigarette maker to enter South Korea's newly deregulated manufacturing market. BAT said on August 7, 2001, that it would invest just over a billion dollars in South Korea over 10 years, starting with an $82 million factory capable of producing 400 million packs a year. "We always wanted to put down roots, commit to society and to give something back to the Korean people," John Taylor, president of BAT Korea said in a news release about the new factory. Philip Morris and Japan Tobacco, the other two major forces in international tobacco markets, are considering building plants in South Korea as well.

South Korea is also the target of renewed US governmental trade pressure on tobacco, with the Bush administration's successful push for the tobacco tariff reduction, which will stimulate consumption of US brands.

Philip Morris plans to increase production in Indonesia in 2001 by 20%, to 60 million cigarettes per day. The increase comes from new machines made in Britain and Germany. The company expects that this will help raise its local market share from 2.2% to 3.4%.

Egyptian smokers spend an average of nearly 22% of their income on tobacco, the country's health minister said in March 2002. Egyptians spend five billion Egyptian pounds every year on tobacco, which for an individual smoker averages almost 22% of total income, the minister, Ismail Sallam, told the state-owned daily *Al-Ahram* paper. Egypt, home to nearly 68 million people, consumes about 85 billion cigarettes every year, according to figures for 2001, and that amount is growing by about 8% per year. The average Egyptian income is estimated by international organizations as about US $1,200 per year.

Norway dropped its overall tobacco consumption by 427 tons between 1999 and 2000, according to a report from the tobacco industry there. This includes all forms of tobacco, including cigarettes, chewing tobacco, and snuff.

Advertising of tobacco products on outdoor posters and billboards ended in Hungary on January 1, 2002, reinstating the total ban on tobacco advertising initially legislated in 1978, but selectively repealed in 1997 to permit advertising in print media, cinema and theatre, outdoor and point of sale advertising, as well as cultural event sponsorship. Subsequent legislation, the Act on Advertising, was passed by the Hungarian Parliament on December 19, 2000, and banned tobacco advertising in print media, movies and theatres beginning July, 2001, and in outdoor advertising starting January 1, 2002. The Hungarian legal framework for tobacco control is now one of the most progressive in the world.

The head of the US delegation to the Framework Convention on Tobacco Control (the WHO international tobacco control treaty, known as the FCTC) retired from the federal health service in early August 2001. Tom Novotny, MD, MPH, had led the US delegation for over 2 years. During the Geneva deliberations in May 2001, the United States weakened its stance on the FCTC. Dr. Novotny was clearly disturbed by the new US position, and confided privately to tobacco control advocates that he would resign. Health and Human Services officials denied that his retirement had anything to do with the FCTC. The AMA and other health groups have protested the Bush Administration's shift in international tobacco control policy.

Russia's Aeroflot airlines has long allowed smoking, and even sued the US government last year over US policy requiring international flights landing in this country to be nonsmoking. In an about-face, the company announced in November 2001 that it would become a smoke-free airline in March 2002. The company said that it was bowing to international demand and the fact that it was the lone holdout till allowing smoking among major airlines worldwide.

Tobacco companies are jeopardizing the health of Third World tobacco farmers who are required to use dangerous pesticides under exclusive contracts that hook them to company credits, according to a report released in February 2002 by a major development group. London-based Christian Aid concludes that the BAT controls the livelihoods of some 45,000 small-scale farmers through contracts that force them into farming methods relying on the use of highly toxic pesticides. The report, "Hooked on Tobacco," found that acute sickness, chronic illness, and suicide are common among Brazil's tobacco farmers and coincide with key moments in the tobacco-growing calendar when they suffer greater exposure to pesticides, especially organophosphates, which are prescribed in their contracts.

One farmer who contemplated suicide has instead decided to launch a lawsuit against the company in a bid to win compensation for an illness that left him severely debilitated and prone to severe bouts of depression. If he wins his case, "hundreds, perhaps thousands of other Brazilian tobacco farmers may follow suit," according to the report.

All the major transnational tobacco companies use similar practices in Brazil, according to the Campaign for Tobacco Free Kids report, "Golden Leaf, Barren Harvest." They sign contracts with thousands of small-scale farmers who agree to buy all their seeds, fertilizers, and pesticides from the company, administer them in the way prescribed by the company, and sell their harvest exclusively to the company, which then uses its own discretion to set leaf grade and price. The contracts are essentially rigged against the farmers, according to the Christian Aid study of Brazilian tobacco operations.

China has been admitted into the World Trade Organization (WTO). With the country's WTO membership, profound effects could occur in the international tobacco sector. With more than 300 million smokers, China is the world's largest tobacco market, representing one third of the entire world cigarette market. The production figures of the Chinese tobacco industry reflect the huge demand: In 1999, China National Tobacco Corporation (CNTC), the executive branch of the State Tobacco Monopoly Administration (STMA), manufactured 1,642.5 billion cigarettes; profits and taxes in the same year reached $11.96 billion and climbed to $12.7 billion in 2000. Almost 1,600 different brands are produced, most of them sold at provincial level.

Estimates from the March 2002 *Tobacco Reporter* show how much tariff rate reductions will be because of WTO membership:

Product	Tariff rate				
	At date of WTO entry	2002	2003	2004	2005
Cigarettes	49%	35%	25%	25%	25%
Cigarette making machinery	12%	10%	6.8%	5%	0%

Following the Chinese entry into the WTO, Zhou Ruizeng, a representative of the Chinese state tobacco monopoly, made these remarks to *Tobacco Reporter*:

> "Of course the market will have some changes. One of the biggest is the import duty on all tobacco products; all import duty for cigarettes, leaf and machinery will be reduced. The reduction of import duty means all foreign products will be more competitive. For example, the reduction of import duty on cigarettes will reduce the price....
>
> "The CNTC (China National Tobacco Corporation) is very clear on the issue of smoking and health--we admit smoking somehow affects human health. Therefore, the CNTC supports the activity of the WHO. We are willing to cooperate with them and to have constructive dialogue to make this issue acceptable to our society. At the same time, we will continue efforts to reduce the harmful effects. In the last 20 years, the CNTC has made steps in the right direction of being more responsible. For example, tar levels were 30 mg, and now they are at an average of 16 mg, which is nearly half. Also, less than 6 percent of cigarettes had filters; now more than 98 percent have filters. This is more than a thirty fold increase. In the meantime, the CNTC has made use of herbal medicine in cigarette blends to reduce harmful effects. People in the West do not know much about Chinese medicine. Chinese medicine is not for when you are ill; but it is good for health. So the idea is that we apply the extract of the herbal medicine into the cigarette blend to reduce the harmful effects and make use of the herbal medicine. The resulting cigarette will keep the flavor of the tobacco. This is one of the contributions of the Chinese."

Several very well-known international brands are sold throughout China, and exports are gathering momentum. Although some joint ventures exist, imported cigarettes have only played a minor role. Faced with the prospect of increased competition under the WTO, the Chinese government has started a far-reaching restructuring program within the country's tobacco industry. It is estimated that only around half of the existing 180 factories will survive. China is permitting BAT to establish a new joint venture company at Mianyang in the Sichuan province. For the first time, an international cigarette manufacturer has been assigned the right to use land for building a factory. In BAT's long history of involvement in China, this represents a significant breakthrough.

In Brazil, nine new picture-based warnings must be placed on cigarette packs beginning January 1, 2002. The warnings will cover 100% of the back of the pack, and will have text warnings that include several topics, including cancer, heart disease, impotence, addiction, and the effects of smoking on pregnancy. Words like "light" or "suave" will no longer be permitted on packs. A toll-free number for those wishing to quit will also be provided. The tobacco industry publication, *Tobacco Journal International*, calls the new law "a serious blow to the country's tobacco industry."

This year, the first Brazilian "smokers rights" association was founded in Sao Paulo. The Libertas association was created to "fight for smokers rights and against their discrimination." The new group intends to lobby against the growing number of clean indoor air laws in Brazil, and will offer legal aid to smokers who feel they have been the targets of discrimination. Their on-line shop offers, apparently, products that carry "pro-smoking" messages.

India's Supreme Court directed all states and centrally ruled territories, on November 2, 2001, to immediately issue orders banning smoking in public places and on public transport. Public places where smoking has been banned include hospitals, health institutes, public offices, public transport, court buildings, educational institutions, libraries, and auditoriums. However, hotels and amusement parks have been excluded from the ban.

The Guardian, a major British newspaper, reported in November 2001 that Japan Tobacco, which makes Camel, Winston and Mild Seven, has paid the pharmaceutical company Corixa for an exclusive lung cancer vaccine license. The report also claims the company has invested in two other pharmaceutical companies. News that a tobacco company could profit from a lung cancer vaccine angered doctors and health campaigners. Derek Yach, director of the non-communicable diseases cluster at the World Health Organization, told *The Guardian*, "We tackle lung cancer by breaking the addictive grip of the tobacco industry and taking action to help people quit smoking or never start. The last company that should control the rights to a lung cancer vaccine is one that makes huge profits from products that cause the disease." Clive Bates, of Action on Smoking and Health, a British tobacco control activist group, said, "What we have got is a company that wants to block the things that would prevent the diseases in the first place and profit from mopping up the mess that their products have created."

But Roy Tsuji, general manager of the media and investor relations division at Japan Tobacco, said the company was diversifying because of the limited prospects for growth in the tobacco sector. "The vast majority of people welcome efforts that help find drugs for various diseases," he responded.

From a press release by the Framework Convention Alliance (a group of nongovernmental organizations supporting the FCTC):

Tobacco products in developing countries are cheaper now than they were a decade ago, sometimes even cheaper than bread or rice, according to the WHO in a report released in February 2002. The WHO says lower tobacco product prices have grave consequences in countries that could soon see the greatest number of tobacco-related diseases and deaths. The new study can be found in the journal *Tobacco Control* 2002; 11(1), available at: www.tobaccocontrol.com.

The new study by the WHO looking at tobacco price trends between 1990 and 2000 in more than 80 countries indicates that, in for the most part, cigarettes have become more expensive in most developed countries and are more affordable than ever in many developing countries. More than 70% of the 8.4 million global tobacco deaths that are estimated to occur in 2020 will occur in developing countries. The WHO warns that cheaper tobacco products would will only fuel the tobacco epidemic further, leading to more consumption, disease and death in the future.

"Increasing the price of tobacco products remains one of the most effective methods of curbing the consumption of tobacco products and thereby reducing the global deaths caused by tobacco," said Dr. Derek Yach, WHO Executive Director of Noncommunicable Diseases and Mental Health. "Higher prices may assist non-users in continuing to keep away from tobacco and thus avoid addiction. It can also induce current smokers to consume less tobacco or even persuade them to quit, or prevent ex-users from starting again. Governments receive more revenue from increased taxation. It's a win-win situation," he added.

According to the World Bank, a price increase of 10% can reduce demand for tobacco products by about 4% in high-income countries and by about 8% in low-and middle-income countries. The Bank estimates that tax increases that would raise the real price of cigarettes by 10% worldwide would cause about 42 million smokers to quit and prevent a minimum of 10 million tobacco-related deaths.

The tobacco industry realizes the implications that higher taxes would have on their sales volume. It is not surprising that the tobacco industry vehemently opposes increases in tobacco taxes and does everything it can to prevent governments from increasing taxes. Secret industry documents obtained in US litigation, from Philip Morris and BAT, express the industry's concerns. "Of all the concerns, there is one--taxation--that alarms us the most. While marketing restrictions and public and passive smoking do depress volume, in our experience taxation depresses it much more severely. Our concern for taxation is, therefore, central to our thinking about smoking and health," reveals one Philip Morris International's document. "Increases in taxation, which reduce consumption, may mean the destruction of the vitality of the tobacco industry," said BAT in a 1992 internal document.

The WHO calls on governments not to be deflected from their primary mission to protect public health and to resist industry pressure in taxation and other measures that will help save lives.

The WHO also recommends earmarking a portion of government revenues gained from tobacco taxes to fund tobacco control activities such as cessation programs, counter-advertising or cancer research. Many countries such as Australia, Thailand, Egypt, Iran and several US states such as California already do so. Additional countries such as the United Kingdom, Saudi Arabia, and Qatar have indicated their intention to earmark a portion of tobacco taxes to fund tobacco-control activities. Additional recommendations made by the WHO include: regional cooperation to harmonize tobacco prices, which cuts down the incentive to smuggle; government actions to adjust cigarette prices with increases in the Consumer Price Index so that it keeps up with inflation; and a strong push for strong price and tax measures in on-going negotiations for a Framework Convention on Tobacco Control.

To update the evidence on the association between smoking and mortality, researchers analyzed data from a population-based prospective study in Japan. 19950 men and 21534 women aged 40-59 years who reported their smoking history and had no serious disease at baseline survey were followed. During 1990-1999, 1014 men and 500 women died. Twenty-two percent of deaths from all causes, 25% of all cancer, and 17% of all circulatory system disease deaths could be attributed to cigarette smoking in males, and 5%, 4%, and 11% in females, respectively. Cumulative dose as indicated by pack-years was clearly associated with cancer death (*Jpn J Cancer Res* 2002 Jan;93(1):6-14).

THE TOBACCO INDUSTRY

Table - Company volume and market share (US)

	Volume (billion)		Market share (percent)	
	2000	1999	2000	1999
Philip Morris	211.90	208.15	50.5	49.6
RJR	96.40	96.44	23.0	23.0
B&W	49.16	56.06	11.7	13.4
Lorillard	40.40	43.61	9.6	10.4
Commonwealth	7.53	4.52	1.8	1.1
Liggett	6.44	5.24	1.5	1.2
Others	7.97	5.28	1.9	1.3

The leading cigarette brand continues to be Marlboro, with 37.7% of the US market. No other brand hits double figures. Newport, the leading menthol brand, has 7.6% of the US market. Winston has only 4.8% of the market share, and Camel 5.4%. The discount brands Doral (6.2%) and Basic (5.1%) are also relatively strong.

Roll-your-own cigarettes, popular for years in Europe, accounted for an estimated 4 billion "sticks" smoked in the United States in 2000, the latest year for which data are available.

US Tobacco, the nation's largest manufacturer of spit tobacco products, is introducing a new blend of tobacco and mint leaves called "Revel." A "spitless" product, the sweet mix will be marketed as an alternative to smoking, and will not require the user to spit.

Both Vector Tobacco and Brown & Williamson rolled out "reduced carcinogen" cigarettes in November 2001. Vector's nationally-marketed offering is called "Omni," a product that claims to have less polycyclic aromatic hydrocarbons (PAHs), nitrosamines and catechols, three major carcinogens in tobacco smoke. Vector uses a "catalytic" approach to removing the chemicals, with palladium and other elements. Omni is promoted as having "great taste" with less risk, at least by inference. The ads have a second warning in addition to the standard Surgeon General wording, which says, "Smoking is addictive and dangerous to your health. Reductions in carcinogens (PAHs, nitrosamines, and catechols) have NOT been proven to result in a safer cigarette. This product produces tar, carbon monoxide, and other harmful by-products."

Brown & Williamson began test-marketing in Indianapolis with "Advance." This product claims that differences in curing reduce the tobacco-specific nitrosamines, and the use of a 3-stage filter with an "ion exchange" mechanism further reduces "toxins across several categories." A package insert in its "Advance Lights" shows a long list of toxins in smoke and the alleged reductions in Advance compared with "average levels." The insert also says that "There is not enough medical information to know if Advance with less toxins will lower health risks."

At almost the same time (November 2001) the Star Tobacco Co. sent out a memo by Federal Express to "members of the public health and tobacco control communities" announcing its new smokeless tobacco product, "Ariva." Although the company claims that new curing methods remove much, if not all, the tobacco-specific nitrosamines from the product, Star says in the memo that it will "not make any reduced-toxin claims about Ariva at this time." It will be test-marketed in Dallas and Richmond. In the information packet, Star also calls for "comprehensive regulation of all aspects of the manufacturing, labeling, marketing, and sale of all tobacco products."

A March 2002 Newsday story reports that Vector Tobacco will unveil a nicotine-free cigarette, called "Quest," in the third quarter of this year, with a $40 million ad campaign. The cigarette will be manufactured at a plant near Roxboro, NC, from tobacco grown in Pennsylvania, Illinois, Mississippi and Louisiana. About two-thirds of the crop was grown on Amish and Mennonite farms in Pennsylvania. Agriculture Department tests found very small amounts of nicotine in the Vector tobacco--about 400 to 1,000 parts per million. Conventional tobacco has 20,000 to 30,000 parts per million.

The state-run Chinese tobacco industry is using a chemical called "Puleye" in some cigarettes. Puleye is a liquid that Chinese scientists claim will inhibit some of the carcinogens in tobacco smoke, by protecting genes from mutations induced by smoke exposure. The chemical was developed by a Chinese medications expert. No reports of animal or human testing of the new cigarettes were mentioned in the report, published in a tobacco industry trade journal in September 2001.

An international tobacco industry symposium held in Hong Kong in October 2001 featured several interesting topics, including:

- "Social Responsibility in an International Environment," by Steve Parish, SVP at Philip Morris
- "A Research-based Approach to Tobacco Control," by John Luik (a Canadian "scientist" on the payroll of the industry
- "Litigation: Will the Rest of the World Follow the US Example?," by Tim Lindon, associate general counsel, Philip Morris
- "The Effect of More Dramatic Health Warnings on Cigarette Packs" (speakers from BAT and Rothman's Tobacco companies)
- "Nitrosamines--What's the Cure? What other chemicals need to be eliminated early on?" (no speaker identified)
- "Less Hazardous Products," by Gio Gori (former National Cancer Institute staff, now industry apologist)
- "Can tobacco production survive WHO's Framework Convention on Tobacco Control?"

Philip Morris announced in November 2001 that it plans to change its name to "Altria," in a move that many believe is designed to shift attention from its tobacco business and the resultant imagery of disease, corporate misdeeds, and selling products that kill when used as intended. The company said it was intended to clarify the difference between the tobacco businesses (which will evidently still be under the PM name) and the parent company, which also owns Kraft Foods, Miller Brewing, and other businesses. SatireWire.com produced a wonderful spoof of the tobacco giant's move:

> Just days after Philip Morris declared it will change its name to the Altria Group, lung cancer today announced it will change its name to Philip Morris. According to lung cancer officials, the chance to snap up a brand that is more widely associated with lung cancer than lung cancer itself was too enticing to pass up. The 'lung cancer' brand certainly evokes something powerful and terrible, but that brand essence is palpable only in English-speaking markets," explained lung cancer marketing/communications director Reginald Hacking-Coughlin. "In terms of global markets, it lacks universality. That is, if you're in Spain, you cannot just say lung cancer, you have to say cáncer de pulmón. In Germany, it's lungenkrebs. 'Philip Morris,' by contrast, ensures instant, worldwide comprehension. It needs no translation. When you hear 'Philip Morris,' you think lung cancer, no matter if you speak English or German or Cantonese."
>
> Lung cancer analysts, who estimate the market value of the Philip Morris brand at more than $1 billion, applauded the disease's move, and conceded they were mystified by the cigarette maker's adoption of "Altria," which comes from the Latin altus, meaning "high." (Philip Morris currently insists it will still use the name to identify its tobacco subsidiaries; lung cancer is expected to fight for full use of the name in court.) "Philip Morris, the parent company, has spent more than a century building up phenomenal brand equity. That they would voluntarily relinquish it for the first pretty pseudo-word to come along is unfathomable," said Janet Spittingblack-Phlegm. At least one expert with an even worse name, however, theorized that the corporation, which includes subdivisions such as Kraft Foods and Miller Brewing, may have chosen Altria for more than its pretty sound.
>
> "I wonder if they decided to change names precisely because people do associate it with cigarettes and lung cancer," said Richard Sooty-Bits-of-Lung-On-A-Handkerchief of Salomon Smith Barney. "It could very well be that, far from embracing that well-earned image, they want to distance themselves from it."
>
> One issue most agree on is that changing names can be an expensive marketing proposition. Last year, for instance, Andersen Consulting had to spend an estimated $175 million to rebrand itself as Accenture. Hacking-Coughlin, however, insisted the change to Philip Morris will require very little outlay. "For a time, patients will have to get used to hearing 'We suspect you have "Philip Morris" instead of 'We suspect you have lung cancer,'" he said. "But in terms of comprehension, I think they will instantly understand what they're being told."

Philip Morris also changed leaders in 2002. Louis Camilleri, age 47, took over from Geoffrey Bible in January.

Investigators from North Carolina have attempted to estimate the number and geographic location of web sites selling cigarettes in the United States, and to examine their sales and marketing practices. A comprehensive search of over 1800 sites on the Internet were examined to identify 88 Internet cigarette vendors. Internet cigarette vendors were located in 23 states. Nearly half (n=43) were located in New York state, and many were in tobacco-producing states with low cigarette excise taxes. Indian reservations housed 49 of the 88 sites. Only 28.4% of sites featured the US Surgeon General's health warnings and 81.8% featured minimum age of sale warnings. Nearly all sites (96.6%) sold premium or value brand cigarettes, 21.6% sold duty-free Marlboros, and 8.0% sold bidis. About one third featured special promotional programs. The authors conclude that Internet cigarette vendors present new regulatory and enforcement challenges for tobacco control advocates because of the difficulty in regulating Internet content and because many vendors are on Indian reservations. (This also has negative implications for excise tax increases as a population-based method of reducing the prevalence of smoking, since many of these sites, particularly on Indian reservations, levy no sales tax. Youth access to these sites is another regulatory issue that should be addressed.) (*Tobacco Control* 2001 Dec;10[4]:352-9).

From Anne Landsman's Tobacco Document Searches

This 1987 Philip Morris draft planning document outlines how PM planned to influence tobacco control activities in European and Middle Eastern countries. It reveals that their efforts have had great effect:

<u>Corporate Affairs Plan Regional Overview</u>

It remain a key priority to use the Corporate Affairs Function to promote and defend vigorously our business interests. As set forth in our 1987 long range plan, our success in doing so relies on one or a combination of the following factors: human resources, argumentations and market intelligence, credibility and political clout, and the assistance of PMI and PM USA.

- The fundamental issues
  - Primary: "Turning the other cheek" on this issue undermines our credibility, our political effectiveness and limits smokers' confidence.
  - Secondary (ETS): Uncertainties about the new USA strategy need early resolution.
  - Addiction
  - Paternalistic authorities and limits on freedom of choice
- Laws and regulations
  - Tax levels and structures along with price controls.
  - Product legislation and testing
  - Marketing freedoms
  - Smoking restrictions
- Smoking acceptability trends amongst smokers and nonsmokers.

While significant progress against plans has been achieved, it is also apparent at this stage in the development of the Corporate Affairs program that certain weaknesses still exist. A majority priority will be to address these weaknesses in a concerted manner. They include:

- Building human resources
  - We are recruiting a Corporate Affairs Manager for Turkey, specialist in communications and lobbying for the Scandinavia/Finland area, a communications specialist for Switzerland and a lobbyist for the GCC (Gulf Cooperative Council Countries)....
  - Together with R&D/S&T (Research & Development/Science and Technology) we will expand our dialogue and working relationships in priority markets with the officials who govern product guidelines and testing.
  - We will recruit consultants with political credibility, experts in welfare economics and ETS whitecoats [note: a project in which scientists were recruited to spread misinformation about ETS and health] in Scandinavia/Finland and Switzerland, and supplement Dr. Almoran outside of Saudi Arabia in the GCC.
- Strengthening arguments and communicating our messages.
  - Major issues which require better argumentation include the primary [health] issue, maximum constituent levels, addiction, and Smoking and Islam. The effort to develop these will be led by the Industry Issues Manager.
  - Achieving our objectives for these issues and others will depend on the effectiveness of our ability to communicate Philip Morris' views directly, via coalitions and through third party spokesmen. We will measure our success and track shifts in public opinion, including inter-alia extending the General Consumers Surveys....

<u>Area & Market Specific Plans, Gulf Cooperation Council Countries</u>

Philip Morris and the industry are positively impacting the government decisions of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE through the creative use of market specific studies, position papers, well briefed distributors who lobby, media owners and consultants such as Dr. Abdullah Alomran. These actions have defeated initiatives such as an advertising ban in Kuwait and have delayed and amended proposals such as the tax increase. But we will need to expand our resources and commitment in order to win on key issues including the tax level/structure and product legislation....

3. Lobby against further restrictions on marketing freedoms.
   - Work closely with the Kuwaiti media owners to maintain the effective opposition to the anti-tobacco proposal of the minister of Health, Dr. Al-Wadi, who is seeking to ban advertising and sports sponsorship, and to mandate severe smoking restrictions. In cooperation with the organizations which are supported through sports sponsorships, publicize the benefits via the Pan Arab and Kuwait media.
   - Creatively market throughout the GCC the Children's Research Unit study on juvenile smoking initiation which has been completed during 1987 in Kuwait.
   - Together with Radius/Leo Burnett and Tihama, build and strengthen GCC chapters of the International Advertisers Association as a coalition which can fight for market freedoms. Where possible Philip Morris will join and participate in the national Chambers of Commerce and we will support our Distributors activities in these chambers....
5. Work to develop a system by which Philip Morris can measure trends on the issue of Smoking and Islam. Identify Islamic religious leaders who oppose interpretations of the Quran which would ban the use of tobacco and encourage support for these leaders.

6. Recruit a consultant who can help us monitor and influence the Alexandria-based WHO office which helps prepare GCC health plans.

In an interview in the January 2002 *Tobacco Journal International*, Brown & Williamson's new 43-year-old chief, Susan Ivey, shared her thoughts about how to succeed in the tobacco industry. Among other things, she includes the following habits for success: "Take personal responsibility. Be honest and a person of high integrity and business ethics." She said this about the need for "social responsibility" in the tobacco industry. "Tobacco products carry real risks for those who choose to smoke, though more than one billion adults [no mention of kids] worldwide choose to do so. We agree that there is an important need to reduce the health impact of tobacco use and we want to do our part as a responsible company by working with governments and regulators to address the fundamental issues. We support sensible regulation as one part of the policy mix to reduce the health impact of tobacco use." She also predicted a new, more productive future for the tobacco industry. "I think we are entering a new period in the United States, as increasing numbers of leaders and the public come to understand that much more progress can be achieved in a spirit of cooperation than in confrontation."

In December 2001, RJR purchased the independent Santa Fe Natural Tobacco Company. Its brand, "Natural American Spirit," is described as a "micro-brew" of the tobacco industry. The Native American mystique and "natural" production of the product make this an interesting acquisition for RJR.

The spring 2002 *Tobacco Control* is a "theme" issue related to new information gleaned from searches of the tobacco industry document archives. Below are several of the abstracts from the special issue, reprinted with permission. Full text of the issue is available free from the British Medical Association (the journal's publisher) at: www.tc.bmjjournals.com/content/vol11/suppl_1/

Marketing to America's youth: evidence from corporate documents
K.M. Cummings, C.P. Morley, J.K. Horan, C.Steger and N.-R. Leavell
Objective: To evaluate the claim that the tobacco industry does not market its products to youth.
Design: The data for this study come from tobacco industry documents collected from the tobacco industry's document web sites, presently linked at www.tobaccoarchives.com. The web sites were searched using "request for production" (RFP) codes, specified keyword searches, and serendipitous terms identified in document citations found with RFP and keyword searches.
Results: Industry documents show that the cigarette manufacturers carefully monitored the smoking habits of teenagers over the past several decades. Candid quotes from industry executives refer to youth as a source of sales and as fundamental to the survival of the tobacco industry. The documents reveal that the features of cigarette brands (that is, use of filters, low tar, bland taste, etc), packaging (that is, size, color and design), and advertising (that is, media placements and themes and imagery) were developed specifically to appeal to new smokers (that is, teenagers). Evidence also indicates that relevant youth oriented marketing documents may have been destroyed and that the language used in some of the more recent documents may have been sanitized to cover up efforts to market to youth.
Conclusions: The tobacco industry's internal documents reveal an undeniable interest in marketing cigarettes to underage smokers. The industry's marketing approaches run counter to and predicate methods for tobacco prevention: (1) keep the price of the product high; (2) keep product placements and advertising away from schools and other areas with a high volume of youth traffic; (3) make cigarette advertising (that is, themes and visual images) unappealing to youth; (4) make product packaging unappealing to youth; and (5) design the product so it is not easy to inhale.

The dark side of marketing seemingly "Light" cigarettes: successful images and failed fact
R W Pollay and T. Dewhirst
Objective: To understand the development, intent, and consequences of US tobacco industry advertising for low machine yield cigarettes.
Methods: Analysis of trade sources and internal US tobacco company documents now available on various web sites created by corporations, litigation, or public health bodies.
Results: When introducing low yield products, cigarette manufacturers were concerned about maintaining products with acceptable taste/flavor and feared consumers might become weaned from smoking. Several tactics were employed by cigarette manufacturers, leading consumers to perceive filtered and low machine yield brands as safer relative to other brands. Tactics include using cosmetic (that is, ineffective) filters, loosening filters over time, using medicinal menthol, using high tech imagery, using virtuous brand names and descriptors, adding a virtuous variant to a brand's product line, and generating misleading data on tar and nicotine yields.

Conclusions: Advertisements of filtered and low tar cigarettes were intended to reassure smokers concerned about the health risks of smoking, and to present the respective products as an alternative to quitting. Promotional efforts were successful in getting smokers to adopt filtered and low yield cigarette brands. Corporate documents demonstrate that cigarette manufacturers recognized the inherent deceptiveness of cigarette brands described as "Light"or "Ultra-Light" because of low machine measured yields.

Cigarettes with defective filters marketed for 40 years: what Philip Morris never told smokers
J.L. Pauly, A.B. Mepani, J.D. Lesses, K.M. Cummings and R.J. Streck
Background: More than 90% of the cigarettes sold worldwide have a filter. Nearly all filters consist of a rod of numerous (>12,000) plastic-like cellulose acetate fibers. During high speed cigarette manufacturing procedures, fragments of cellulose acetate that form the mouthpiece of a filter rod become separated from the filter at the end face. The cut surface of the filter of nearly all cigarettes has these fragments. In smoking a cigarette in the usual manner, some of these fragments are released during puffing. In addition to the cellulose acetate fragments, carbon particles are released also from some cigarette brands that have a charcoal filter. Cigarettes with filters that release cellulose acetate or carbon particles during normal smoking conditions are defective.
Objective: Specific goals were to review systematically the writings of tobacco companies to: (a) identify papers that would document the existence of defective filters; (b) characterize the extent of the defect; (c) establish when the defect became known; (d) determine whether the defect exists on cigarettes marketed currently; (e) assess the prevalence of the defect on cigarettes manufactured by different companies; (f) define whether the knowledge of the defect had been withheld by the tobacco company as confidential and not disclosed publicly; and (g) ascertain the feasibility of correcting or preventing the defect.
Methods: Document searches utilized databases of the scientific literature, medical journals, chemical abstracts, US Patents, Tobacco Abstracts, papers presented at tobacco meetings and court documents.
Results: Sixty one documents of Philip Morris, Inc were selected for study because they disclosed specifically the "fall-out" of cellulose acetate filter fibbers and, for cigarettes with charcoal filters, carbon particles from cigarette filters. The term "fall-out" was defined in 1985 laboratory protocols of Philip Morris, Inc. as "loose fibers (or particles) that are drawn out of the filter during puffing of the cigarette". As early as 1957, the health concern of inhaling cellulose acetate fibers released from cigarette filters was addressed by Philip Morris, Inc. A 1962 document reported the results of laboratory tests conducted by Phillip Morris, Inc. that compared the "fall-out" of cellulose acetate fibers from the filters of their cigarettes (Marlboro) and cigarettes of their competitor (Liggett & Meyers). A 1997 overview by Phillip Morris of documents addressing the "fallout of carbon particles and cellulose acetate fibers from filters" stated that they were "essentially routine reports" of cigarette filter assays, and referenced a "Filter Fallout" memo written in 1961--more than 40 years ago. Most likely these tests are being conducted presently as illustrated by a 1999 report that details the revisions of the "fall-out" protocol of Phillip Morris, Inc. and reports the results of tests that measured the discharge of cellulose acetate fibers and silica gel from beta cigarettes with a new type of filter. Our analysis of the "fall-out" tests results presented in the 61 "fall-out" documents showed that filter fibers and carbon particles were discharged from the filters of all types of cigarettes tested. These cigarette types (n=130) included both coded cigarettes and popular brand name cigarettes. No publications were found in the scientific literature of the "fall-out" studies. Thus, the results of the "fall-out" studies are thought to have been withheld as confidential to Philip Morris, Inc. We have identified also other companies that have tested recently cigarettes for defective filters. In addition, our searches have shown that simple, expedient, and inexpensive technologies for decontaminating cigarette filters of loose cellulose acetate fibers and particles from the cut surface of the filter have been developed and described in 1997 and 1998 US patents. What is more important is that these patents also define methods for preventing or reducing the broken plastic-like fibers that arise during cigarette making. Many US patents (n=607; 1957 to 2001) have been awarded for cigarette filters. Some of these inventions describe novel materials and unique filtration schemes that would eliminate or minimize the discharge of filter materials into mainstream smoke.
Conclusions: We have shown that: (a) the filter of today's cigarette is defective; (b) PhilipMorris, Inc. has known of this filter defect for more than 40 years; (c) the existence of this filter defect has been confirmed by others in independent studies; (d) many methods exist to prevent and correct the filter defect, but have not been implemented; and (e) results of investigations substantiating defective filters have been concealed from the smoker and the health community. The tobacco industry has been negligent in not performing toxicological examinations and other studies to assess the human health risks associated with regularly ingesting and inhaling non-degradable, toxin coated cellulose acetate fragments and carbon microparticles and possibly other components that are released from conventional cigarette filters during normal smoking. The rationale for harm assessment is supported by the results of consumer surveys that have shown that the ingestion or inhalation of cigarette filter fibers are a health concern to nearly all smokers.

Tax, price and cigarette smoking: evidence from the tobacco documents and implications for tobacco company marketing strategies
F.J. Chaloupka, K.M. Cummings, C.P. Morley and J.K. Horan
Objective: To examine tobacco company documents to determine what the companies knew about the impact of cigarette prices on smoking among youth, young adults, and adults, and to evaluate how this understanding affected their pricing and price related marketing strategies.
Methods: Data for this study come from tobacco industry documents contained in the Youth and Marketing database created by the Roswell Park Cancer Institute and available through roswell.tobaccodocuments.org, supplemented with documents obtained from www.tobaccodocuments.org.
Results: Tobacco company documents provide clear evidence on the impact of cigarette prices on cigarette smoking, describing how tax related and other price increases lead to significant reductions in smoking, particularly among young persons. This information was very important in developing the industry's pricing strategies, including the development of lower price branded generics and the pass through of cigarette excise tax increases, and in developing a variety of price related marketing efforts, including multi-pack discounts, couponing, and others.
Conclusions: Pricing and price related promotions are among the most important marketing tools employed by tobacco companies. Future tobacco control efforts that aim to raise prices and limit price related marketing efforts are likely to be important in achieving reductions in tobacco use and the public health toll caused by tobacco.

The cigarette pack as image: new evidence from tobacco industry documents
M. Wakefield, C.P. Morley, J.K. Horan and K.M. Cummings
Objectives: To gain an understanding of the role of pack design in tobacco marketing.
Methods: A search of tobacco company document sites using a list of specified search terms was undertaken during November 2000 to July 2001.
Results: Documents show that, especially in the context of tighter restrictions on conventional avenues for tobacco marketing, tobacco companies view cigarette packaging as an integral component of marketing strategy and a vehicle for (a) creating significant in-store presence at the point of purchase, and (b) communicating brand image. Market testing results indicate that such imagery is so strong as to influence smoker's taste ratings of the same cigarettes whenpackaged differently. Documents also reveal the careful balancing act that companies have employed in using pack design and color to communicate the impression of lower tar or milder cigarettes, while preserving perceived taste and "satisfaction". Systematic and extensive research is carried out by tobacco companies to ensure that cigarette packaging appeals to selected target groups, including young adults and women.
Conclusions: Cigarette pack design is an important communication device for cigarette brands and acts as an advertising medium. Many smokers are misled by pack design into thinking that cigarettes may be "safer". There is a need to consider regulation of cigarette packaging.

Failed promises of the cigarette industry and its effect on consumer misperceptions about the health risks of smoking
K.M.Cummings, C.P.Morley and A.Hyland
Background: In January 1954, US tobacco manufacturers jointly sponsored an advocacy advertisement entitled "A Frank Statement to Cigarette Smokers" which appeared in 448 newspapers in 258 cities reaching an estimated 43 245 000 Americans. The advertisement questioned research findings implicating smoking as a cause of cancer, promised consumers that their cigarettes were safe, and pledged to support impartial research to investigate allegations that smoking was harmful to human health.
Objective: To examine (1) the extent to which cigarette companies fulfilled the promises made to consumers in the 1954 "Frank Statement," and (2) the effect of these promises on consumer knowledge, beliefs, and smoking practices.
Methods: This study reviews statements made since 1954 by the tobacco companies individually and collectively through the Tobacco Institute and Tobacco Industry Research Committee/Council for Tobacco Research on the subject of smoking as a cause disease, and the industry's pledge to support and disclose the results of impartial research on smoking and health. Many of the industry documents evaluated in this study were obtained from a collection consisting of 116 documents entitled the "Statement of Defendants' Misrepresentations" prepared by attorneys representing the state of Connecticut in the Medicaid litigation against the tobacco industry in 1998. In addition, we searched for corroborating material from tobacco industry documents collected from the tobacco industry's document web sites. In order to contrast industry statements on smoking and health with what smokers' actually believed about smoking we reviewed reports of public polling data on smokers' knowledge and beliefs about smoking and disease gathered from tobacco industry sources and from surveys conducted by public health researchers.

Results: Analysis of public statements issued by the tobacco industry sources over the past five decades shows that the companies maintained the stance that smoking had not been proven to be injurious to health through 1999. The public statements of the tobacco industry are in sharp contrast to the private views expressed by many of their own scientists. The tobacco documents reveal that many scientists within the tobacco industry acknowledged as early as the 1950s that cigarette smoking was unsafe. The sincerity of the industry's promise to support research to find out if smoking was harmful to health and to disclose information about the health effects of smoking can also be questioned based upon the industry's own documents which reveal: (1) skepticism about the scientific value of the smoking and health research program established by the industry; and (2) evidence that research findings implicating smoking as a health problem were often not published or disclosed outside the industry. Industry documents also show that the companies knew that their own customers were misinformed about smoking and health issues.
Conclusion: It is clear that the cigarette companies failed to fulfill the promises made to consumers in the 1954 "Frank Statement" advertisement. The failure of cigarette manufacturers to honor these promises has resulted in a public that even today remains misinformed about the health risks of smoking.

21. REPORT OF THE ADVISORY COMMITTEE ON MEMBERSHIP - RELATIONSHIP BUILDING

Report 21 of the Board of Trustees was considered together with
Report 23 of the Board of Trustees and Resolutions 606, 611, and 615
see page 182

INTRODUCTION

Since its creation by the House of Delegates at the 2000 Annual Meeting through the Joint Report of the Task Force on Membership (TFM) and the Council on Long Range Planning and Development (Policy H-605.090, AMA Policy Database), the Advisory Committee on Membership (ACM) has been charged with the following responsibilities:

- Serving as the auditor of the relationship between the AMA and its members;
- Recommending any specific structure of an ongoing membership entity;
- Reflecting on membership decision influences;
- Analyzing membership research data and monitoring membership vital signs;
- Providing recommendations to the Board of Trustees on membership related issues;
- Identifying strategies to increase membership and reviewing membership programs and pilots; and
- Overseeing the development and evaluation of a comprehensive strategic membership communication plan.

Since its last Board of Trustees report at the 2001 Annual Meeting, the ACM has met five times and has had four conference calls and numerous electronic communications. This report summarizes the ACM's activities over the last twelve months and provides insight in its direction over the next twelve months.

INCREASING MEMBER VALUE

The ACM has been collecting and analyzing membership data to ensure that its activities as well as the AMA's are focused on the individual member and prospective member. The ACM strongly feels that the AMA needs to be a member-centered organization. The ACM has developed a number of membership activities to encourage one-to-one relationship building, to highlight the collective voice of organized medicine, and to increase member service and communications.

One-to-One Relationship Building

Knowing the AMA House of Delegates is an essential source of information on AMA activities, programs, and policies, the ACM created the ACM House of Delegates (HOD) Ambassador Program, which was approved by the Board of Trustees in June 2001. This program presents our AMA with the opportunity to reconnect with our leaders and provide the tools and education needed to help build the relationship with the grassroots physician and medical student.

The ACM developed HOD Outreach Cards that detail AMA's activities and initiatives at a glance. An educational workshop is scheduled for the 2002 Annual Meeting to equip the AMA House with a variety of communication tools and tactics enabling them to recruit and retain AMA members.

To prepare for the educational workshop, the ACM distributed a Communications Survey at the 2001 Interim Meeting that sought input from the House members on how they communicate AMA's activities, accomplishments, and value to their constituents. The survey showed that 29% of our delegates communicate with their constituents more than sixteen times per year and another 27% interact four to seven times per year. Presentations, meetings, and e-mail were the most common methods cited to communicate AMA's message. The HOD Ambassador Program aims to strengthen the one-to-one relationships between the House of Delegates and our grassroots members by providing effective educational programs and resources to our AMA leadership.

Member Communications

Relationships are crucial to our AMA. The sections and the special interest groups have a direct connection with their members that can improve membership activities if further targeted and enhanced. To encourage a continuing dialogue, the ACM has met with individual sections and governing councils over the last year and will continue to do so. This increased communication has led to recommendations allocating and utilizing funds for specific section activities that has impacted the individual member directly. For example, the section newsletters were recreated to include targeted messaging and to be more reader-friendly.

The ACM recognizes the critical importance of direct communications to members and sent a recommendation to the Board of Trustees emphasizing that a house organ is essential in communicating AMA's message to its members. The ACM will continue to stress member communications as a strategic priority of our AMA.

Pilot Programs

The ACM conducted an evaluation of the current membership pilot programs and identified that the pilot programs need to be consistent and goal specific to be successful. The ACM will build on the lessons learned from these programs as a guideline for future programs.

MEMBERSHIP PROCESSING

The ACM has been challenged continually with the accuracy, completeness and accessibility of AMA's membership database. To alleviate challenges for our members, the ACM has been educated on the system and believes an ongoing assessment of the membership management system is necessary to ensure our AMA is building a relationship with the individual member. The ACM will continue to monitor this process.

Delivery of Membership

Numerous concerns have been articulated about the delays of membership processing and the delivery of member benefits. This led to the House of Delegates adoption of an amended Resolution 617 (A-01), "Delays in AMA Student Membership Processing," which asked our AMA to perform an internal evaluation of membership processing. In addition, it asked that our AMA take steps to decrease delays and increase service to the members.

Our AMA has taken radical steps to reduce the delays in membership processing and to strengthen one of AMA's major initiatives, Customer Service. For example, the average length of time it took to post a medical student membership in the 2001 membership year was 46 days. In 2002, it was reduced to 48 hours.

Federation Membership Agreements

At the 2000 Annual Meeting, the House of Delegates adopted TFM Report 1, "Membership Processing" (Policy H-635.110). The policy states that any Federation component choosing to continue to bill and collect AMA dues must sign a binding primary partnership agreement with the AMA.

Due to the complexity of the policy and feedback from the Federation, it was not possible to fully execute the policy for the 2002 membership year. In June 2001, the Board of Trustees approved the Federation Membership Billing Program - Phase 1, which was a phased-in approach of the implementation of the policy. This approach was designed to be the foundation for the 2003 membership year.

This program was incorporated into the *2002 Partnership for Growth*, our AMA membership agreement with the state medical societies allowing them to recruit and retain AMA members. The Federation Membership Billing Program - Phase 1 was designed as a voluntary program. Fourteen states are participating in this program for the 2002 membership year.

Aware of the continued operational challenges, the ACM redesigned the *Partnership for Growth* for the 2003 membership year to provide the structure and the tools the Federation needs to strengthen membership through the Federation as well as compensate the societies for their efforts.

STRUCTURE

In compliance with the adopted recommendation from TFM Report 3-A-00, "Structure," the House conducted a forum at the 2000 Interim Meeting to debate and reach a consensus on the preferred AMA membership model. The discussions illuminated the need for a change, though there was not a consensus on which membership model was best for our AMA, our members, and prospective members. The ACM conducted the Follow-Up Survey on Membership Models to elicit the House of Delegates opinions on the models that were detailed in the Board of Trustees Report 27-I-00, "Discussion for Special Reference Committee on Membership." The results indicated a substantial preference for models that were individual-based versus organizational-based and which included voluntary versus involuntary membership. In addition, direct versus indirect relations were strongly preferred.

At the 2000 Interim Meeting, the Report of the Commission on Unity was adopted as amended by the House and the AMA Board of Trustees initiated steps to develop a detailed plan to transform our Federation. The Special Advisory Group Extraordinaire (SAGE) was established and five Work Groups were developed to discuss and make recommendations as it pertained to their work products. To avoid duplicating efforts in the membership arena, the ACM served as the foundation of the Membership Work Group. Two liaison members from the SAGE and an advisor representing the views of the county medical societies also were members of the Membership Work Group.

The Membership Work Group was charged with recommending the membership model for the Federation. Despite the SAGE's membership recommendation to transform our AMA to an organization of organizations within five years, the ACM strongly encourages that our AMA continue to offer the Voluntary Individual Membership Model to ensure a direct connection with the individual physician and medical student member. The Voluntary Individual Membership Model provides three key aspects of membership: portals of entry for the individual member to join the AMA, representation of the member, and management of the relationship between the individual member and the AMA.

CONCLUSION

The ACM will continue to work to ensure that our members receive value from our AMA. The ACM's agenda for the next twelve months will include:

- Conduct an assessment of all membership categories and related member benefits;
- Continue to enhance one-to-one membership activities that build a strong relationship with our members and the Federation;
- Strengthen interactions with the Sections and Special Interest Groups;
- Finalize the comprehensive strategic membership communication plan; and
- Depending on the actions of the House of Delegates at the 2002 Annual Meeting, recommend a smooth transition for membership.

APPENDIX - ADVISORY COMMITTEE ON MEMBERSHIP

Jack T. Evjy, MD, Chair
House of Delegates
Windham, New Hampshire

Bruce A. Scott, MD, Vice Chair
Board of Trustees
Louisville, Kentucky

Susan Hershberg Adelman, MD
Board of Trustees
Southfield, Michigan

John H. Armstrong, MD
House of Delegates
San Antonio, Texas

Albert L. Blumberg, MD
House of Delegates
Baltimore, Maryland

Todd A. Forman, MD
House of Delegates
Malibu, California

Marie G. Kuffner, MD
Council on Long Range Planning and Development
Los Angeles, California

Donald J. Palmisano, MD, JD
Board of Trustees
Metairie, Louisiana

Ruth D. Williams, MD
House of Delegates
Wheaton, Illinois

22. LEAPFROGGING THE MEDICAL STAFF (RESOLUTION 816, I-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 816 (I-01) AND REMAINDER OF REPORT FILED

INTRODUCTION

At the 2001 Interim Meeting, the House of Delegates considered Resolution 816, Leapfrogging the Medical Staff, submitted by the Organized Medical Staff Section (OMSS), and referred it to the Board of Trustees. This resolution asked the AMA to actively oppose efforts by third party and medical advisory groups, such as "The Leapfrog Group," to unilaterally influence hospitals and medical groups to modify clinical practice without specific advice and input by the medical staff organization of the hospital or medical group. It further asked AMA to advocate to all third party interests, such as The Leapfrog Group, that our AMA should be part of the discussion on proposed policy initiatives when they are developed.

BACKGROUND

During the previous two decades, a variety of business coalitions and other groups were organized to gather information on the ways in which health care was delivered in the United States. This information was largely used to develop strategies to alter the ways in which that care was delivered to produce savings to the purchasers of health care. The employer segment of our economy represented the vast majority of these health care purchasers. The strategies they used were often complementary to the new model used to coordinate the provision of health care services known as managed care. This model sought to reduce expenditures through a series of tactics aimed at creating greater efficiencies in the delivery of care. While new efficiencies did realize savings through lower utilization of services, physicians and patients were presented with an ever-increasing series of hurdles to secure needed patient services.

Today there are an unprecedented number of coalitions in the health care field looking for new sources of savings. Employers saw double-digit increases in health insurance premiums the last three years and continuing rapid rate increases are predicted for future years. Employers expect their health care costs to rise by an average of 12.7 percent this year, and some predict increases of more than 20 percent. Forty percent of large employers (more than 500 employees) indicate that they will require employees to pay a higher percentage of health care costs in the next year, and 34 percent will require higher co-pays and deductibles. Alarmed by these figures, a variety of new strategies are being used or advocated by different business coalitions to generate corporate health care savings for their coalition members, and the central theme that virtually all of these strategies address is improving the safety and quality of health care to generate these savings.

Employers have looked increasingly towards improving the quality of their own products and providing a safe environment for their employees as the keys to running a profitable enterprise. Businesses are seeking to apply what they learned in their own business to health care, which consumes an increasingly large portion of their cost of doing business. Employers have come to believe that higher quality health care will directly translate into lower overall health care costs. They further believe that healthy employees are happier and more productive employees. Conversely, a sick employee will be either very unproductive while ill or less productive while working at diminished capacity. Microsoft Corporation claims that each of its employees represents $700,000 in revenue per year so it is easy to see why highly productive employees are of such great interest to the company.

Quality health care and patient safety are two ideas that would seem to be widely embraced by all segments in the health care industry, and they are. Yet many physicians, nurses, hospital administrators, clinic managers and other individuals and organizations involved in the delivery of health care are troubled by the strategies and plans that coalitions are pursuing in the name of quality health care and patient safety. The reason for this dichotomy lies in determining what constitutes quality health care, who determines it, and the ways in which quality and safety standards are applied and utilized.

Physicians and other health care professionals express serious concerns over the use of data by coalitions and health plans to make clinical practice decisions and guidelines without the input or consent of physician groups, hospitals, medical staffs and/or organized medicine. Such determinations can be particularly damaging if they are improperly linked to the use of economic or practice incentives for particular care regimens and disincentives for other treatment options. In certain cases, performance measures can be used to evaluate the performance of physicians and health care institutions, but it is imperative that these measures be constructed and used in a scientifically valid manner. Physicians, health care institutions, and organized medicine should be integrally involved in overseeing the data collection and analysis used to formulate such guidelines.

The remainder of this report will begin by discussing current AMA policies regarding performance measures, patient safety and health care coalitions. This report will then take a detailed look at the current and planned activities of The Leapfrog Group and a more condensed summary of the initiatives of three other active business coalitions and their subsidiary or spin-off organizations. The report will conclude with recommendations for future AMA and Federation monitoring of and participation with business coalitions.

AMA POLICY

AMA has devoted a wealth of resources to quality, patient safety and data collection and analysis issues. As a founding member of the National Patient Safety Foundation and an active participant in the Physician Consortium for Performance Improvement, the National Quality Forum and the Practice Guidelines Partnership, AMA is one of

the most respected organizations in this field. AMA has addressed quality and patient safety issues in numerous ways and possesses scores of policies on these issues. Following is a listing and summarization of just a few of those policies that are most germane to this report on health care coalitions and their initiatives to generate savings through the implementation of programs using quality and patient safety standards: Policies H-160.988, H-320.949, H-406.993, H-406.994, H-406.996, H-406.997, H-406.998, H-410.976, H-450.961 and H-450.973 (AMA Policy Database).

Policy H-160.988 supports health care coalitions that include physician participation and place an emphasis on the quality of health care. Physicians are encouraged to take an active role in these coalitions. Policies H-406.994, H-406.998 and H-406.996 address the use of data to augment quality health care assessments. Physicians, medical staffs, and medical societies are urged to participate in the gathering and assessment of quality data. They address the proper use of the data and specify that they be severity-adjusted. Policy H-450.973 promotes the use of outcomes data and states that it should not be used as part of a punitive process. Policy 450.961 supports the active use of performance measures so long as physicians are involved in their formation, evaluation and refinement.

THE LEAPFROG GROUP

The Leapfrog Group (LG) was founded in 2000 by The Business Roundtable on the premise that better care, not cheaper care, will save money in the end. The group launched a national effort in November 2000 to educate employees, retirees, and their families about medical errors and the importance of hospital efforts in improving patient safety. LG's strategy of encouraging patients to choose hospitals according to quality is a departure from traditional managed care, which steers workers into networks with the lowest rates.

The LG is funded through the first three years by a grant from The Business Roundtable. Members are currently assessed no dues, but the LG has sought grants for some initiatives. The LG is committed to creating and disseminating incentives for improving health care quality and safety. All members are purchasers of health care and the role of organizations "in the health care field" is limited to that of an employer or representative of consumers. There are also organizations/coalitions of purchasers of health care included in its membership. Together, these private and public purchasers of health care, which include more than 90 Fortune 500 companies, represent more than 33 million Americans and more than $52 billion in annual health care expenditures.

LG is organized using a series of "Lily Pads" in lieu of committees. The Governance Lily Pad (a.k.a., Steering Committee) consists of the five founding organizational members of LG (Buyers Health Care Action Group, GE, General Motors, Pacific Business Group on Health, and Verizon). Other Lily Pads include The Regional Lily Pad, the Leaps and Measures Lily Pad, the Communications Lily Pad, and the Incentives and Rewards Lily Pad. The Primary spokesperson and executive decision-maker is the Bullfrog, Bruce Bradley, Director of Managed Care Plans, Health Care Initiatives, General Motors Corporation.

Some AMA Board of Trustees members met with the LG steering committee members in February 2002. A meeting was also held with Robert S. Galvin, MD, Director, Corporate Health Care and Medical Programs, GE, A founding member of LG, in July 2001. These meetings began an important dialogue between LG and organized medicine. LG is reaching out to a number of medical organizations.

Patient Safety Standards

The members of the LG, as well as the members of most health care coalitions throughout the country, firmly believe that improved health care quality will directly translate into lower health care costs in addition to a healthier, more productive workforce. LG is focusing its initial quality improvement measures on three criteria that LG believes will result in "forward leaps" in patient safety. LG would like to see these three patient safety standards implemented at all hospitals treating LG member companies' employees. These patient safety standards are required to meet the following five criteria to be included as a safety standard:

1. Implementation will result in major safety improvements.
2. Standard can easily be understood and appreciated by consumers.
3. Implementation is doable now.
4. Purchaser or health plan can easily determine if standard is in place.
5. Standard is memorable.

The following are the three Patient Safety Standards with an LG explanation of the reasons for adopting these as standards as well as concerns that have been raised by various groups regarding the use of these measures as standards at this time:

1. Computer Physician Order Entry (CPOE) Systems

   LG notes that more than one million serious drug errors occur each year in US hospitals at a cost of $17-29 billion. LG predicts that a functioning CPOE system will prevent from 50 percent to 80 percent of all serious drug errors. CPOE systems can eliminate errors caused by misreading or misinterpreting handwritten instructions. They can also intercept orders that might result in adverse drug reactions or that deviate from standard protocols. LG recommends that orders intercepted by the system be subject to an override only upon written orders from the prescribing physician.

   LG estimates that the cost of implementing such a system will vary from $500,000 to $15 million depending on the size of the hospital and the status of the current information system in place. Annual operating costs for the system should run from $200,000 to $2 million. These costs should be offset by annual savings of $180,000 - $900,000 from fewer medication errors and adverse drug events. Additional greater savings will be realized from medication substitutions, increased use of clinical pathways and gains in clinical efficiency. Although LG admits these savings will vary greatly from one institution to another and are difficult to quantify, they indicate that some hospitals with existing CPOE systems claim to be saving over $5 million per year.

   Critics of instituting mass installation of CPOE systems in hospitals usually focus on the cost of purchasing and implementing large commercial systems that may cost tens of millions of dollars. CPOE impacts clinicians and workflow substantially. Its complexity requires close integration with multiple systems, such as the laboratory and pharmacy systems. A UCSF-Stanford Evidence-based Practice Center (EPC) analysis of patient safety practices showed significant reduction in medication errors, but the reduction in preventable adverse drug events was relatively insignificant. Many believe that CPOE systems are promising, but the complexity and cost of installing and maintaining a system coupled with questionable efficacy in eliminating adverse drug events may not warrant its acceptance as a standard at this time.

2. Evidence Based Hospital Referral

   LG believes that for certain procedures and treatments, patients should be guided to hospitals and clinical teams that are more likely to produce better outcomes. LG has identified seven procedures/conditions that should be done at institutions performing/treating a minimum number of cases per year. Please note, that as geographic areas obtain risk-adjusted hospital outcomes data that are publicly reported, favorable risk-adjusted outcomes will replace the volume standards. Following is a listing of these procedures with their critical volume standards:

   - Coronary artery bypass >500/yr
   - Coronary angioplasty >400/yr
   - Abdominal aortic aneurysm repair >30/yr
   - Carotid endarterectomy >50/yr
   - Esophageal cancer surgery >7/yr
   - Expected birthweight under 1500 grams Regional neonatal ICU with average daily census >15
   - Surgery for major congenital anomalies Regional neonatal ICU with average daily census >15

   LG claims that acceptance of these standards would reduce mortality for these seven complex treatments by more than 10 percent. LG estimates that 60,000 lives would be saved annually. When setting the value of a human life at $50,000 per year, this totals an associated value of $9.7 billion. Because this estimate does not include the other total benefits such as quality of life and reduction in disabilities that would be realized, actual savings would be much greater.

Even critics agree that for a select number of high-risk surgical procedures, there is a correlation between volume and favorable outcomes. There is considerably more skepticism that data can show more favorable outcomes for the standards for obstetrical/prenatal care. The exact surgical procedures that are most favorably impacted by volume thresholds are debatable as are the volume indicators themselves. Many physicians are still uncomfortable with the premise that volume indicators can be used as a proxy for quality.

3. ICU Physician Staffing (IPS)

ICU care accounts for approximately 30 percent of acute hospital costs, and more than 500,000 patients in the US die in ICUs each year. LG cites evidence of a direct correlation between the level of training of ICU personnel and the quality of patient care. When ICUs are staffed by physicians credentialed in critical care medicine or when intensive care specialists are available to respond to 95 percent of pages within five minutes, the risk of patients dying is reduced by more than 10 percent.

LG standards for staffing medical and surgical ICUs require that a certified critical care physician manage all adult ICU patients. The ICU must be staffed during daytime hours, seven days a week, by an intensivist, whose duties are devoted exclusively to the ICU. At other times of the day ICU pages must be returned by an intensivist within five minutes, and a critical care physician or a certified non-physician "effector" can reach the ICU within five minutes. Please note, that in geographic areas where risk-adjusted ICU outcome data is publicly reported, favorable outcome data will replace the IPS standard. LG estimates that it will cost a hospital a minimum of $543,000 to meet these IPS standards.

These standards produce savings through reductions in inappropriate ICU admissions, elimination of unnecessary tests, shorter lengths of stay and fewer complications. LG estimates these savings to be $800,000 - $3.4 million per hospital per year. If nationally implemented, the IPS standards could save 53,850 lives at a dollar value of $5.3 billion each year.

Critics state that scientific evidence supporting LG's claims for improved patient safety using IPS standards is sparse and no data regarding long-term survival (6-12 months) is available. The most compelling problem facing hospitals wishing to implement the IPS standards is the shortage of board certified intensivists. The Society for Critical Care Medicine has agreed with this standard, and stated that there are insufficient intensivists to comply with this standard. Currently less than a quarter of all ICUs are staffed by board certified critical care physicians, and the Society expects the shortage to worsen significantly with the aging of the US population.

Pilot Project

Acute health care facilities in six regions or states (Atlanta, California, East Tennessee, Minnesota, St. Louis and Seattle/Tacoma/Everett) were strongly encouraged by LG and local business coalitions to complete a survey on LG's three patient safety standards. Health care institutions in these regions were instructed to log onto the LG web site and secure an ID and security code for the purpose of submitting data on their institution's relative compliance with the safety initiatives.

The survey data was collected and analyzed in conjunction with The Medstat Group. The results of the survey were given to the member companies of LG to share with their employees, and on January 17, 2002, these results were released to the public via a LG press conference. All hospitals in the six geographic regions (excluding children's hospitals that are not included in the current LG initiative) were included in the results. Hospitals that did not complete the survey were listed accordingly and distinguished from hospitals that completed the survey but indicated no progress towards implementing any of the three patient safety standards. All three standards for each hospital were addressed separately and each standard was given one of the following ratings:

- Fully implemented safety practice;
- Good progress in implementing safety practice;
- Good early stage effort in meeting safety standard;
- Willing to report publicly; did not meet criteria for good early stage effort; and
- Did not submit information.

497 urban hospitals were invited to complete this survey. 251 hospitals submitted responses and slightly more than half met at least one of the LG safety standards. A few hospitals responded even though they did not meet the "good early stage effort" criteria or better for any of the three standards. Some highlights include:

- Over 90 percent of the hospitals in the East Tennessee and Seattle/Tacoma/Everett regions completed the survey but only one hospital out of 31 in the St. Louis region responded.

- 2.4 percent of the responding hospitals were found to have CPOE systems in place and 31 percent indicated plans to have CPOE implemented by 2004.

- 11 percent of the responding hospitals have fully implemented IPS, and an additional 17 percent indicated plans to have intensivists on staff by 2004.

- Only 10 percent of the reporting hospitals met the volume standards for coronary bypass while a high of 30 percent of the hospitals met the standard for coronary angioplasty.

Complete results from the survey may be found on the LG web site at www.leapfroggroup.org. These results are also posted on the following additional web sites that contain information about their own products or initiatives:

- HealthGrades - HealthGrades is LG's technology partner in supporting HealthGrades own hospital data reports. HealthGrades includes the LG survey results as part of the hospital information it provides on the HealthGrades web site. This web site primarily consists of mortality rates for specific conditions using Medicare and other public data.

- DoctorQuality - DoctorQuality has information about individual physicians as well as hospitals, in addition to a number of products for consumers/patients to help them understand their health conditions. DoctorQuality uses data from public records as well as from LG, and encourages patients to submit ratings as well.

- Select Quality Care - This company offers a personalized web-based tool that enables employees or members to compare and select a hospital based on their individual needs. Its reports consist of side-by-side comparisons of the top hospitals for over 50 specific diagnoses. The comparisons are based on measures such as patient volume, mortality rates and unfavorable outcomes, as well as LG data.

- Subimo - Subimo's site educates patients about treatment options for more than 50 specific conditions and procedures and about where to get good care for these treatments. Users can input and prioritize their own preferences to obtain a customized report comparing the hospitals that best meet their criteria. Subimo's site also provides interactive explanations, interpretations of data and additional issues to consider. It includes federal, state, and other third party data and a complete medical encyclopedia in addition to the LG data.

- HealthScope (for California only) - HealthScope is an independent source of information for consumers regarding quality health care in California. Launched by the Pacific Business Group on Health in 1996, the site is designed to help consumers choose health care providers and health plans and to use quality information in decisions about their health.

LG plans to initiate phase two of this project by summer 2002 by asking hospitals in an additional 10-12 geographic regions to complete the LG survey.

Implementation Strategies

All purchasing members of LG have agreed to implement the following set of principles that will utilize the data collected from the hospitals:

1. **Inform and Educate Employees**. Purchasers will educate employees about the importance of comparing the performance of health care providers and assist them in understanding how to use such measures to make informed health care choices.

2. **Use Comparative Rating**. Purchasers will aggregate available validated performance information on their major providers of health care into comparative value ratings for all of their employees, retirees and family members. Wherever available, the performance measurement will come from nationally recognized sources such as NCQA, JCAHO, states and medical societies, in addition to the data collected by and made available through LG, to assure validity in performance comparisons.

3. **Use Substantial Incentives**. Purchasers will use two or all three of the following methods to reward delivery systems with higher value ratings and will annually increase their intensity until they prove sufficient to motivate widespread and substantial annual performance improvement among their major providers: patient volume; price; and public recognition.

4. **Focus on Discrete Forward Leaps in Patient Safety**. In implementing comparative rating and substantial incentives, purchasers will highlight a common set of discrete delivery system improvements likely to yield the largest safety gains ("safety leaps"). These will be earmarked for special visibility in purchasers' interaction with providers, insurers/administrators, and consumers.

5. **Hold Health Plans Accountable for Leapfrog Implementation**. In advancing these principles, purchasers who utilize health plans as their intermediaries may delegate responsibility to plans for applying the principles to their network providers. If so, purchasers would hold their health plans accountable via nationally standardized LG questions in health plan RFPs, heavily weighted scoring criteria, robust health plan performance incentives, and other methods of assuring health plan application of LG principles. Purchasers would intensify these incentives annually until their largest health plans fully meet their delegated responsibility for applying Principles 1-4 outlined above.

6. **Encourage the Support of Consultants and Brokers**. In selecting benefits consultants and brokers, purchasers will create strong incentives for them to incorporate LG principles (1) in their advice to other purchaser clients and (2) in their standard tools for assessing health plans and delivery systems.

Later this year LG will begin incentivising hospitals that participate in the survey process and adopt the three LG quality standards. LG is designating $2 million for bonuses to hospitals adopting these criteria. Empire BCBS, a LG provider member, is now giving compliant hospitals an additional 4 percent bonus on top of their normal reimbursement rates for care given to patients, who are employees of participating LG companies.

In January 2002, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accepted an invitation from LG to become a partner. This relationship means that LG will seek JCAHO's input on its patient safety initiatives. In the first major collaboration effort between the two parties, JCAHO has begun work with LG leaders to pursue the identification of a specific set of ICU-related outcome and process measures. Eventually, these measures may be used to supplement or even replace the current LG measures that recommend that hospitals have board-certified or board-eligible intensivists.

OTHER HEALTH CARE COALITIONS AND INITIATIVES

The **Central Florida Health Care Coalition** (CFHCC) has been in existence since 1984 representing 120 large employers located in Orange County (Orlando) and the surrounding counties, Osceola, Polk, Seminole and Brevard. CFHCC member companies employ 35 percent of the employees in this geographic area, which translates into 750,000 covered lives. Previous success in controlling costs in the inpatient setting helped drive a decision to find savings in the new decade by focusing on physician quality measures rather than hospital quality measures as the LG is doing.

CFHCC is in the process of collecting three sets of data on all of the physicians in the area in an attempt to determine the quality of medicine these physicians are practicing. The first set of data is physician inpatient data that is voluntarily being supplied by 26 hospitals in the area. The hospitals use Atlas, a clinical information management system developed by Mediqual Systems, a quality measurement company in Westborough, MA to analyze anonymous patient data from patients' records. The system adjusts the data for severity of illness and for the demographics of the hospital. Information that is collected and analyzed includes lab orders and results, radiology orders and results, transcribed dictation, medication records and patient demographics. The system is HIPAA compliant. The Atlas system uses this data to rate quality based on appropriateness of treatment, effectiveness of treatment and efficiency.

CFHCC is also capturing and analyzing data from the outpatient setting. This is currently a pilot project focusing on physicians, who treat employees of the Orlando Public Schools, Universal Orlando, and Walt Disney World. This represents about 250,000 covered lives. Specialties that are included in this pilot are family practice, internal medicine, gastroenterology, cardiology and OB/GYN. The data is gathered from outpatient claims data, which can be accessed from the employer.

CFHCC also wants to collect patient satisfaction data, but the pilot test was unsuccessful in producing reliable results. A new test is being fomulated.

While CFHCC continues to perfect the methodology to rate physicians on quality based on these inpatient, outpatient and patient satisfaction scores, it has also been working on a system to utilize this data to provide tiered compensation to physicians. Although it may be a few years before CFHCC feels its data for physician quality ratings is ready to use, CFHCC already has designed the basic structure to implement a physician tiered compensation program.

CFHCC proposes to use the three data sets to obtain a combined rating for each individual physician to rank him or her as silver, gold, or platinum. Physicians new to the area will automatically be ranked as gold. It is estimated that it will take at least six months for a physician to move from one ranking to another. Platinum physicians will receive the highest reimbursement rate and will receive additional compensation for treating patients with chronic illnesses. Gold physicians will receive lower reimbursement and silver physicians are scheduled to receive 65 percent of Medicare rates. Silver physicians will be allowed to balance bill under this plan. Patient co-pays will be lowest when seeing a platinum physician. Anticipated co-pays to see a silver physician are $35. Platinum physicians will have no managed care controls. They will be allowed to treat their patients as they see fit and be reimbursed for all services as long as those services are covered under the plan. Gold physicians will have some managed care controls and silver physicians will have more. Platinum and gold physicians will be required to take a one week mini-residency each year to keep their skills sharp. CFHCC views this as a benefit in that this mini-residency should satisfy the CME credits required by the State of Florida for licensure.

The **Integrated Healthcare Association** (IHA) is a California group of health plans, physician groups, health systems, academicians, purchasers, pharmaceutical companies, and consumer representatives. IHA formed a high-level working group in July 2000 to develop a statewide initiative for California that would pay physician groups for documented performance, "Pay for Performance." The fundamental principles of "Pay for Performance" are a common set of performance measures and significant health plan financial incentives based on that performance. The performance measures represent a balanced set of patient satisfaction, prevention, and chronic care management measures. The clinical measures currently reflect HEDIS markers in disease management (asthma, diabetes, and coronary artery disease) and prevention (breast cancer screening, cervical cancer screening, and childhood immunizations).

Six health plans, representing more than 8 million Californians, have agreed to launch the collaborative initiative: Aetna, Blue Cross of California, Blue Shield of California, CIGNA HealthCare of California, Health Net, and PacifiCare. Data will be a combination of lab, pharmacy, and administrative data, plus patient satisfaction data. An independent entity will validate the data and publish a consolidated public scorecard. Groups that do not score well initially can still benefit financially under the initiative by showing improvement from year to year.

Each participating health plan will make its own decisions about the source and amount of funding for performance-based payments to its delegated physician groups. IHA is urging health plans to offer significant bonus payments for maximum effect, but there is no minimum requirement. The system is expected to be fully operational by January 2003, but some plans will begin implemention in 2002.

The **Buyers Health Care Action Group** (BHCAG) is a coalition of Minnesota employers dedicated to health care reform through improved quality, increased competition and accountability, increased consumer knowledge and self-reliance, and enhanced efficiency of health care delivery. The BHCAG launched Choice Plus in 1997 to reshape Minnesota's health marketplace by developing the first-in-the-nation direct contracting program between employers and physicians. Patient Choice Healthcare was formed in May 2000 to take over program management of Choice Plus which had evolved into a defined-contribution, consumer choice program. Patient Choice Healthcare is also attempting to create consumer-driven, direct contracting systems between employers and physicians in Oregon and Colorado.

The Patient Choice delivery network is an alternative to the traditional provider networks, where health plans attempt to control costs by negotiating discounted rates with providers. The Patient Choice model encourages provider systems called "Care Systems" to compete for patients based on cost, quality, and patient satisfaction. Instead of negotiating fees, Patient Choice invites Care Systems to bid on health care services. The Care System bids are compared to one another and banded into cost groups (e.g., low, medium, high). Enrolling employees are then given information comparing cost, quality, and patient satisfaction, and they use that information to select a personal Care System.

In partnership with area health care systems, BHCAG also launched HealthFront, an organization aimed directly at engaging employees (and consumers in general) in initiatives that promote consumerism and quality health care. HealthFront, is a distinct non-profit organization whose governance is composed of employers, consumers, and health care providers. The HealthFront agenda is to increase consumerism in the Minnesota health care marketplace and, through the power of enlightened consumers, exert influence on quality of care. Already, HealthFront is laying the groundwork to promote innovation in areas of clinical quality improvement, patient safety, consumerism, and health care access.

CONCLUSION

The cost of health care and health insurance premiums continues to rise and increasing numbers of employers are joining or forming coalitions in an effort to develop strategies and initiatives to moderate these costs. Although the strategies to address these increasing costs are varied, most are based on employers' beliefs that improved quality of health care and patient safety will result in healthier and more productive employees and lower overall health care costs. While our AMA supports all initiatives that will result in improving the quality of health care and patient safety, there are some legitimate concerns about the methodologies planned or in use by some business coalitions.

Our AMA supports health care coalitions that include physician participation and that address quality and access to medical care. Our AMA also has a wealth of policy concerning the appropriate use of quality measures as a means to improve the quality of health care. Quality initiatives that use physician-specific, group practice-specific, or hospital-specific data in conjunction with quality measures and performance standards to determine reimbursement must take the utmost precautions to ensure the quality of the data and data analysis. In such cases physicians and hospitals should have the opportunity to review the data and respond to the interpretation of the data. Physicians should be involved in setting the quality standards, and the data should be severity adjusted.

Employer health care coalitions will continue to proliferate and expand their level of activity in the quality arena. This report has highlighted the initiatives of some of the larger and more active coalitions, but many other coalition initiatives addressing quality health care and patient safety are either in the process of being implemented or are in the planning stages.

The Board believes it is imperative that all health care coalitions include physicians, and preferably organized medicine, in their decision-making process. Organized medicine should work with these coalitions to ensure that they follow proper data collection and analysis methodologies. In cases where these coalitions are not seeking the counsel of physicians or are implementing or designing initiatives that have the potential to negatively impact quality and disrupt the patient/physician relationship, our AMA and the Federation of Medicine should actively seek to positively impact the nature of those initiatives.

RECOMMENDATIONS

The Board of Trustees recommends that the House of Delegates adopt the following recommendations in lieu of Resolution 816 (I-01), and that the rest of this report be filed:

1. That our American Medical Association continue to monitor the activities of business coalitions and other health care coalitions, including The Leapfrog Group, and keep physicians and the Federation of Medicine informed of the activities and new initiatives of these coalitions.

2. That our AMA continue to meet with and serve with vigilance on appropriate advisory committees to national business and other health care coalitions, including The Leapfrog Group, to establish a dialogue with these coalitions and provide physicians' unique clinical and patient-centered expertise in a manner consistent with AMA policy and sound quality and patient safety principles.

3. That our AMA encourage the other members of the Federation of Medicine to meet with and serve on appropriate advisory committees to business and other health care coalitions in their geographic area or field of medical specialization to establish a dialogue with these coalitions and provide physicians' unique clinical and patient-centered expertise in a manner consistent with sound quality and patient safety principles and keep the AMA informed of the results of these activities.

4. That our AMA continue to promote its policies regarding the proper collection and use of physician and hospital quality data.

5. That our AMA advocate that business and health care coalitions and other similar entities be reminded that the Joint Commission on Accreditation of Healthcare Organizations standards, as well as most state hospital licensure laws, require that the advice and approval of the hospital medical staff or medical groups must be sought before clinical practices are modified.

6. That our AMA actively address with business and health care coalitions, as well as with other similar entities, the problems of delivering quality care that are created by under-reimbursement of health care services by third party payors.

7. That our AMA exercise extreme caution when meeting with The Leapfrog Group and other business coalitions to avoid implied and unintended concurrence with the recommendations of such groups.

23. PHYSICIANS ENERGIZING THE PROFESSION: FINAL IMPLEMENTATION OF HOUSE ACTION ON COMMISSION ON UNITY REPORT (I-00)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RECOMMENDATIONS OF REPORT 21 OF THE BOARD OF TRUSTEES AND RESOLUTIONS 606, 611, AND 615 AND REMAINDER OF REPORT FILED

BACKGROUND

At the direction of the American Medical Association House of Delegates, the Board of Trustees initiated steps to fulfill its responsibilities outlined in the HOD's final actions at the 2000 Interim Meeting on the final report on the Commission on Unity (COU) Report, as amended. The recommendations as amended asked the Board to pursue the following actions:

1. The Commission on Unity's design for strengthening organized medicine shall be a conceptual starting point for transforming the current Federation.
2. The AMA Board of Trustees shall assume the leadership responsibility for working with the other Federation organizations and shall convene the leadership of the Federation organizations to determine if and how the design of the Commission on Unity can be achieved and provide a reality test of the design.
3. To assist the Board, a Special Advisory Group shall be appointed by the Chair of the Board of Trustees. It shall include broad representation of the Federation as well as the Chair and at least one other member of the Commission on Unity. The Federation representatives shall be selected from nominees submitted by the Federation organizations and the Chair of the Special Advisory Group shall be selected by the members of the Group.
4. The AMA Board of Trustees shall give the following areas high priority:
   (a) Determining what organization will become the Core organization;
   (b) Developing a process for involving Participating Organizations in the development of the annual advocacy and communication plan;
   (c) Developing a formalized process for consulting with Participating Organizations on key issues;
   (d) Describing the structure and functions of a Committee on Organizational Conduct and Cooperation and a dispute resolution process;
   (e) Describing how the Core Organization's business relationships with the Participating Organizations should be formalized and expanded; and
   (f) Identifying the best membership model for the success of the Commission's design.

5. The AMA Board shall submit a progress report at the 2001 Annual Meeting of the AMA House of Delegates. At the 2001 Interim Meeting, the Board shall provide a report that includes the detailed proposal for the final design, how the design could be achieved, a risk/benefit analysis, and a set of recommendations for consideration by the House.
6. The Board shall determine the likely cost associated with the completion of this work and a specific approach for obtaining financial support from the participating Federation organizations.

To date, the following actions have been accomplished:

1. The AMA Board of Trustees assumed leadership in organizing the work necessary to meet the HOD direction, recognizing that the Commission on Unity's design would be "a conceptual starting point for transforming the current Federation."
2. A meeting of a broad representation of the Federation (8 of 13 invited specialty societies, 10 of 13 invited state societies, a representative from a county society, and a representative from the group practice community) was convened in Orlando, Florida in February of 2001, to "determine if and how the design of the Commission on Unity can be achieved and to provide a reality test of the design." At this meeting, the Federation representatives said that the Commission on Unity design was not feasible. In developing this report, the Board of Trustees took under consideration the discussions at this meeting as well as numerous communications from the Federation. A copy of the report from this meeting can be found on the AMA web site, www.@ama-assn.org/go/annual2002.
3. From nominees submitted by the Federation organizations, the BOT Chair appointed a Special Advisory Group Extraordinaire (SAGE) of 30 physicians and staff leaders including the COU Chair and one additional COU member. Three individuals appointed to the SAGE did not participate in the entire process. The SAGE met in Washington, DC in March 2001, to discuss the results of the Federation Evaluation Meeting in Orlando. D. Ted Lewers, MD was elected Chair, and Mary Anne McCaffree, MD was elected Vice Chair.
4. The SAGE was advised of the "high areas of priority" that were identified by the HOD action on the COU's report and Work Groups were formed, with charges for Membership, Business Relationships and Products, Advocacy/Communications, Inter-Society Relations and Governance, and Finance. Each Work Group consisted of at least two members of the SAGE, a representative from a specialty society staff, a representative from a state society staff, a representative from a county society staff, and a representative from the AMA staff. The Membership Work Group was comprised of the Advisory Committee on Membership (ACM) as well as two members of the SAGE to serve in a liaison capacity and an advisor representing the views of the county societies. Meetings of the Work Groups took place several times during the summer, with their recommendations submitted for SAGE consideration at its September 2001 meeting; however, due to the events of September 11th, this meeting was postponed until December 2001.
5. The SAGE met again in January 2002, at which time it approved its final report and transmitted it to the Board.
6. At the Board's February Planning Retreat, the SAGE Report was presented. The SAGE Chair and Vice Chair presented the report to the Board followed by an extensive question and answer session and discussion of the report. This took the better part of a full day. At that time, the Board requested that the SAGE Report be distributed to the Federation so that the recommendations should be viewed by all stakeholders and comments were requested to be sent back to the Board for their review and input into the final report to the House.
7. The SAGE Report was sent out to the Federation on February 15th, with comments due back by April 1st. A copy of the SAGE report to the Board can be found on the AMA web site at www.@ama-assn.org/go/annual2002.
8. As of April 1, 2002 over 90 comments were received.
9. The AMA Board Chair formed a Task Force of the Board and AMA staff to review the comments received from the Federation, AMA Councils, Sections/Special Groups, members of the House of Delegates, and individual members. A draft report was prepared for review by the full AMA Board, during the week of April 15, 2002.

DISCUSSION

The AMA Board agrees with the SAGE Committee that this project has been under consideration by numerous committees of the House and Board since 1990. While this report may leave some questions unresolved, **the time for further study is over-- the time for action is now**.

We are presenting our recommendations as a vision for changing the Federation, including the AMA. The Board will continue to develop detailed business plans, financials, and implementation plans once the concepts have been approved by the House. We ask that House of Delegates view our recommendations as concepts that, if approved, will have details worked out, to include timelines, that will be brought back to the House for approval. We are aware that, if we are recommending additional activities, there must be a corresponding savings, or offset, from the current way of doing business.

The status quo of the Federation is no longer acceptable. Significant demographic and economic forces are dramatically impacting the practice of medicine and our associations. We must all be willing to do some things in a different way, and to that end, many of the changes, in both the short and long term, will affect everyone. These changes are the cornerstone for organized medicine to become more efficient, effective, and flexible.

As stated in the SAGE Report, the Board is acutely aware of the general lack of trust within the Federation. In order for trust to be enhanced, it must be earned. At the 2001 Interim Meeting, the House commissioned the Ad Hoc Committee on Governance to review the progress the Board has made on the governance recommendations of the House. In light of this ongoing review, the SAGE made no recommendations on Board governance activities. We also believe, as does the SAGE, **that an incremental approach is best served for implementation** of many of the recommendations we are making. In this way, we will be able to establish trust, verify the plan of action, make corrections as necessary, and verify the financial impact of our actions.

Relative to Recommendation 4(e) of the amended final Report of the Commission on Unity, the Board recognizes that there are opportunities to better harness the purchasing power of medical societies to bring lower cost products and services to a wider array of Federation members. The Board is also mindful of the antitrust constraints on the collective decision-making of medical societies regarding the offering of products and services. To that end, the Board would encourage the Federation to offer to each other the best affinity products and services. With care, antitrust concerns can be addressed.

Financials for the cost implications associated with the elimination of the Interim Meeting, instituting an Annual Advocacy Coordinating Forum, and decreasing the size of the House of Delegates are available from the Office of House of Delegates Affairs. Estimates are for both the AMA and the Federation.

The Board wishes to extend its sincere thanks to the members of the SAGE for their tireless efforts this past year. Also, the Board thanks the Federation, Sections/Special Groups, AMA Councils, the House of Delegates, and the individual physicians that took the time to review the SAGE Report and provide comments to the Board. These have proven to be invaluable in our deliberations.

Therefore, the Board presents a series of recommendations to energize organized medicine and the profession. The recommendations that follow are listed in bold, with clarifying/explanatory points after each recommendation. The recommendations are the only items that will be adopted, but the Board will use the explanatory points as a guide to aid in the implementation of the recommendations.

The Board recommends that the following recommendations be adopted and the remainder of the report be filed.

Note: For ease in use of the Proceedings, the recommendations are listed in two groups--first, the original recommendations as presented by the Board of Trustees, and second, the recommendations as amended and adopted by the House of Delegates. The following were the original recommendations presented by the Board of Trustees:

RECOMMENDATION 1: The House of Delegates reaffirm that our American Medical Association must continue to be the core organization of the Federation.

- Advocacy for the practice of medicine and the betterment of the public health based on sound scientific and ethical principles will be the focus of the AMA.
- To accomplish this, the AMA must be a more focused organization to include aggressively seeking new mutually beneficial partnerships and collaboration with organizations outside the AMA.
- The Board recognizes the need for a financially strong core organization (AMA). Therefore, it will be essential to measure the value of each product and service against the strategic initiatives of the AMA with an eye towards ensuring that AMA focuses its resources on the highest priorities.

RECOMMENDATION 2: The House of Delegates reaffirm that the House of Delegates of our AMA remains the policy setting entity as per the framework of the AMA Constitution and Bylaws.

- The current democratic process, which encourages broad participation, has served the profession well.
- The Board believes strongly that the House should continue to provide the policy base for the AMA's activities.
- The Board will implement the policy and continue to serve its fiduciary responsibilities for the AMA.

RECOMMENDATION 3: The House of Delegates retain the delegate allocation of 1:1,000 and survey the Federation to determine the desired delegate allocation.

- The Board recognizes the cost to the Federation associated with the number of delegates attending the House meetings.
- The Board is concerned that a more drastic reduction would impact the implementation of the new student delegate allocation in the House.
- The Board is concerned about the impact of a change in the delegate allocation on the smaller state and specialty society representation.

RECOMMENDATION 4: The House of Delegates eliminate the Interim Meeting beginning in 2004 and establish and implement a plan for ongoing two-way communication between the Board and AMA House of Delegates on AMA activities between annual meetings, with a report back by the 2003 Annual Meeting.

- The Board believes the business of the House can be conducted with one annual meeting and an established plan for an agenda to conduct any necessary business through teleconferencing, videoconferencing, and the internet.
- Informational reports and council reports would be posted for review and comment on the Web.
- A mechanism currently exists whereby the Board can call a meeting of House of Delegates for emergent issues or send out a call for input regarding such an issue.
- The Board will conduct its winter meeting outside of Chicago, to update all members.
- Regional town hall meetings will be held in the late Fall.

RECOMMENDATION 5: Our AMA establish individual member, two-way electronic communication vehicles that promote active grassroots discussion of timely issues; regular feedback for AMA leadership; and a needed voice for diverse ideas and initiatives from throughout the Federation.

RECOMMENDATION 6: Our AMA establish an Advocacy Coordinating Forum (ACF) to develop an annual advocacy plan:

Each year, the AMA would provide a forum for representatives of the Federation organizations to coordinate an Annual Advocacy Plan for the next year in an ACF meeting. This meeting would provide an opportunity to identify and discuss issues of importance, to agree on which issues and items to pursue, and to assign a priority to each issue. This would be a dynamic process. While there would be an annual meeting to set the year's agenda, it is expected that after the creation of the first agenda, changes in the following years would be more incremental, reflecting the pace of achieving Federation advocacy goals, while adding new issues, deleting others, and resetting priorities. This process would be refreshed throughout the year, with periodic communications throughout the year with the participants of the ACF.

A. All Presidents of component organizations of the AMA House of Delegates or their designee with authority to act on behalf of their association, their advocacy staff, and the leadership of the AMA Sections/Special Groups will be invited to participate in an annual ACF.

B. An initial Steering Committee will be formed to develop an implementation plan.

C. The Chair of the Steering Committee will be the President of the AMA for the initial meeting. Subsequent Chairs will be elected by the participants at the forum thereafter.

RECOMMENDATION 7: The ACF will recommend which organization(s) should provide advocacy leadership on a given issue. It is recommended that the following criteria be used to categorize and prioritize the agenda items and issues that are included in the Annual Advocacy Plan.

***Criterion 1: On selected issues that are agreeable to all Federation organizations, the AMA may take the lead*. Issues in this category must be carefully chosen so that minority positions by Federation organizations are unnecessary.**

***Criterion 2: On issues of common interest, but of narrow focus or lacking a consensus, Federation components may take the lead rather than the AMA*.**

RECOMMENDATION 8: The Board of Trustees recommends that the following model/framework be adopted for the annual advocacy coordinating process:

A. Development of advocacy input and ideas.

- ACF attendees are encouraged to submit/develop a list of important items that they would like to have included in the advocacy plan.
- These items will be submitted to the AMA advocacy staff prior to the ACF meeting.
- No effort is made by the AMA to limit or prioritize suggestions.
- The AMA member web site as well as the general AMA web site may be used to gather individual physician input.
- Organizations of the Federation should utilize their websites to solicit their individual member inputs.

B. Meeting of the ACF

- The context of the discussion should include issues such as the necessity of including an item in the advocacy agenda; the importance of the issue; the magnitude of the problem needing to be addressed; the support, opposition or lack of direct interest of the component organization and any opposition that could be expected within medicine.
- The advocacy staff will also offer information regarding advocacy/legislative developments, background information, etc. The intent is to meld the items and discussion into an agreed upon advocacy agenda.

C. Drafting of the Annual Advocacy Plan

- Following the conclusion of the Annual ACF meeting, advocacy staff will draft an advocacy plan based upon the ACF's deliberations and decisions.

D. Action By Component Organizations Participating in the ACF

- These component organizations will review and confirm their proposed level of participation in carrying out the Annual Advocacy Plan.

E. Updating and Rapid Response Mechanism

- This Annual Advocacy Plan will serve as the blueprint for the priorities and objectives for the coming year for the Federation; however, no plan can be all encompassing.
- As with any advocacy plan, changes in the environment and in the public and private sectors will confront the Federation throughout the year.
- Component organizations will communicate freely during the advocacy year.

RECOMMENDATION 9: The AMA be responsible for coordinating communications for strategically enhancing and strengthening the Annual Advocacy Plan as public policy.

- The AMA will coordinate the communication of the advocacy agenda through strategic national and grassroots campaigns, advocacy advertising, news media management in Washington DC, and appropriate speechwriting and messaging.

- The AMA will coordinate its effort with any/all appropriate Federation organizations. A coordinated strategic communication action plan will be developed, emphasizing the power of many is greater than the power of one.

RECOMMENDATION 10: The AMA develop and implement a communication vehicle, e.g., web-based, that will be dedicated to promoting the Annual Advocacy Plan.

- This advocacy communication vehicle will be directed to internal and external stakeholders.
- This advocacy communication vehicle will be disseminated on a periodic basis (e.g. biweekly, monthly) to provide necessary updates on activity relating to the Annual Advocacy Plan.

RECOMMENDATION 11: The AMA, in cooperation with the Federation, will strengthen two-way communication.

A. Individual meetings between AMA leadership and Federation organization leadership will be a priority.
B. The AMA and the Federation must strengthen their coordination on issues in order to minimize differences and enhance effectiveness.
C. The AMA will maintain an "on call" list of key Federation leaders that can be contacted when a rapid response issue arises.

RECOMMENDATION 12: Federation organizations will be encouraged to follow "The Statement of Collaborative Intent."

Principles--It is desirable that:

1. **Organizations in the Federation will collaborate in the development of joint programs and services that benefit patients and member physicians.**
2. **Organizations in the Federation will be supportive of membership at all levels of the Federation.**
3. **Organizations in the Federation will seek ways to enhance communications among physicians, between physicians and medical associations, and among organizations in the Federation.**
4. **Each organization in the Federation of Medicine will actively participate in the policy development process of the House of Delegates.**
5. **Organizations in the Federation have a right to express their policy positions.**
6. **Organizations in the Federation will support, whenever possible, the policies, advocacy positions, and strategies established by the Federation of Medicine.**
7. **Organizations in the Federation will support an environment of mutual trust and respect.**
8. **Organizations in the Federation will inform other organizations in the Federation in a timely manner whenever their major policies, positions, strategies, or public statements may be in conflict.**
9. **Organizations in the Federation will support the development and use of a mechanism to resolve disputes among member organizations.**
10. **Organizations in the Federation will actively work toward identification of ways in which participation in the Federation could benefit them.**

RECOMMENDATION 13: The AMA will maintain a list of facilitators/mediators that Federation disputants may use to address disputes.

- The AMA Office of General Counsel will establish a list of mediation firms that disputants may use at their cost.
- The Council on Ethical and Judicial Affairs (CEJA), as specified in current AMA Bylaws, will maintain its current jurisdiction to resolve disputes.
- Within the AMA, CEJA will continue to exercise judicial authority, with its decisions final. This authority involves interpretations of the Principles of Medical Ethics and the issuance of opinions.
- The Board believes that a dispute resolution process already exists through various mechanisms such as the House, meetings with the AMA Board, through the various AMA Councils, and through direct communications between state and specialty society leadership.

RECOMMENDATION 14: The AMA will focus on strengthening the voluntary individual membership model.

- In the spirit of collaboration, the AMA will continue to work with other components of the Federation to solicit membership. The AMA and each Federation organization recognizes it has an obligation to demonstrate value to its members.
- The AMA will work with other components of the Federation to eliminate barriers to membership.

The following are the recommendations as amended and adopted by the House of Delegates:

1. The House of Delegates reaffirm that our American Medical Association must continue to be the core organization of the Federation.

2. The House of Delegates reaffirm that the House of Delegates of our AMA remains the policy setting entity as per the framework of the AMA Constitution and Bylaws.

3. The House of Delegates retain the delegate allocation of 1:1,000 for the present time and reconsider the ratio at appropriate intervals as our AMA evolves.

4. Interim Meeting:

   (a) The business of the Interim Meeting of our House of Delegates shall be focused on advocacy and legislation.

   (b) A Resolution Committee of House members that is appointed by, and reports to, the Speakers shall be established to ensure that the emphasis of the Interim Meeting is placed on advocacy and legislation. Other issues may be considered at the Interim Meeting if the Resolution Committee determines that action is needed prior to the next House of Delegates meeting, or by majority affirmative vote at the opening session of the Interim Meeting of the House of Delegates.

5. Our AMA establish individual member, two-way electronic communication vehicles that promote active grassroots discussion of timely issues; regular feedback for AMA leadership; and a needed voice for diverse ideas and initiatives from throughout the Federation.

6. Creation of the Advocacy Coordinating Forum: Our AMA convene a meeting of state medical societies, national medical specialty societies, and other appropriate components of the Federation to determine the structure and process for an annual Advocacy Coordinating Forum (ACF). Each participating organization will determine who will participate in the meeting on their behalf. Each organization will be responsible for the expenses of their participants, including a registration fee if needed. The focus of the meeting will be on the advisability of an annual ACF, its implications, and what model/framework should be adopted. It is recommended that Recommendations 6 through 10 of the Board of Trustees Report 23 be utilized as a starting point for these discussions. The organizational meeting could be held in conjunction with the 2003 National Leadership Conference. The recommendations of the participants of the organizing meeting shall be reported back to the House of Delegates for its consideration and action at the 2003 Annual Meeting.

7. Our AMA, in cooperation with the Federation, will strengthen two-way communication.

   (a) Individual meetings between AMA leadership and Federation organization leadership will be a priority.
   (b) The AMA and the Federation must strengthen their coordination on issues in order to minimize differences and enhance effectiveness.
   (c) The AMA will maintain an “on call” list of key Federation leaders that can be contacted when a rapid response issue arises.

8. Federation organizations be encouraged to follow "The Statement of Collaborative Intent."

   Principles--It is desirable that:
   1. Organizations in the Federation will collaborate in the development of joint programs and services that benefit patients and member physicians.
   2. Organizations in the Federation will be supportive of membership at all levels of the Federation.
   3. Organizations in the Federation will seek ways to enhance communications among physicians, between physicians and medical associations, and among organizations in the Federation.
   4. Each organization in the Federation of Medicine will actively participate in the policy development process of the House of Delegates.
   5. Organizations in the Federation have a right to express their policy positions.
   6. Organizations in the Federation will support, whenever possible, the policies, advocacy positions, and strategies established by the Federation of Medicine.
   7. Organizations in the Federation will support an environment of mutual trust and respect.
   8. Organizations in the Federation will inform other organizations in the Federation in a timely manner whenever their major policies, positions, strategies, or public statements may be in conflict.
   9. Organizations in the Federation will support the development and use of a mechanism to resolve disputes among member organizations.
   10. Organizations in the Federation will actively work toward identification of ways in which participation in the Federation could benefit them.

9. The AMA Board of Trustees establish a National Collaboration Council (NCC) for the purpose of dispute resolution.

10. A Committee on Organization of Organizations (COO) be established by our AMA by convening and participating in a meeting(s) of interested state medical societies, national medical specialty societies, and other appropriate components of the Federation. The purpose of this Committee is to develop an implementable business plan for the orderly transition of our AMA to an organization of organizations. Each participating organization will determine who will participate in the meeting(s) on their behalf. Each organization will be responsible for the expenses of their participants. If the business plan is adopted by the AMA House of Delegates, our AMA will transition to an organization of organizations. The COO shall include representation from the Medical Student Section, the Resident and Fellow Section, and the Young Physicians Section.

    Elements of the business plan that must be described include, but are not limited to, the following issues:

    (a) Cost analysis of each participating organization's financial relationship to the Core (AMA).
    (b) Analysis of membership implications at all levels.
    (c) The future services, activities, and programs to be provided by a more focused AMA (such as CPT, RUC, advocacy, standard setting, publications, and ethics of the profession).
    (d) Implications of potential changes in governance within our AMA.

    The COO shall present its business plan to the House of Delegates at the 2003 Annual Meeting.

24. PHYSICIAN DISCRETION REGARDING THE INCLUSION OF ELECTRONIC COMMUNICATIONS IN THE MEDICAL RECORD

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, the House of Delegates referred Resolutions 703 and 707 to the Board of Trustees for decision. Resolution 703, introduced by the American Society of Addiction Medicine, and Resolution 707, introduced by the Pennsylvania Delegation, are identical, and call for the AMA to amend Policy H-478.997[1d] (AMA Policy Database) which addresses guidelines for patient-physician electronic mail.

Council on Medical Service Report 4-A-01, "Medical Care Online," modified Policy H-478.997[1d], which originally read as follows:

That the message may be included as part of the medical record, at the discretion of the physician.

As adopted by the House of Delegates, Council Report 4-A-01 modified Policy H-478.997[1d] so that it currently reads as follows:

> Whenever possible, electronic and/or paper copies of patient e-mails and corresponding responses will be retained as part of the patient's medical record.

Referred Resolutions 703 and 707 (I-01), seek to amend Policy H-478.997[1d] by addition and deletion to read as follows:

> At the physician's discretion~~Whenever possible~~, electronic and/or paper copies of patient e-mails and corresponding responses will be retained or summarized as part of the ~~patient's~~ medical record.

DISCUSSION

At the Reference Committee hearing, those testifying in support of Resolutions 703 and 707 (I-01) argued for a change in policy principally because patients may include personal information in an e-mail that may not be medically relevant, and that such information may be shared inadvertently with third parties. Those in opposition to the resolutions testified that there is no advantage to simply deleting e-mail messages, as even deleted messages are recoverable and legally discoverable; and that guidelines from both the American Medical Informatics Association and the eRisk Working Group for Healthcare, which represents Medem, a dozen of the nation's medical societies, and more than 30 professional liability insurance carriers, state that e-mail messages should be included as part of the medical record.

At its December 2001 meeting following the 2001 Interim Meeting, the AMA e-Medicine Advisory Committee (EMAC) discussed this issue. The EMAC, whose members include the author of Resolution 703 (I-01), as well as the Immediate Past Chair of the Council on Medical Service, developed the following "compromise" language for consideration by the Board of Trustees:

> Whenever possible and appropriate, physicians should retain electronic and/or paper copies of e-mail communications with patients.

Given that the Council on Medical Service developed the language currently contained in Policy H-478.997[1d], the Council similarly discussed this issue at its January 2002 meeting. The Council believes that the language developed by the EMAC is an improvement over that proposed in Resolutions 703 and 707 (I-01), and represents an acceptable compromise.

The Board of Trustees shares the view of the Council on Medical Service. Policy H-478.997[1d] provides appropriate guidance to physicians regarding the retention of their electronic communications with patients. Adoption of the language proposed in referred Resolutions 703 and 707 (I-01) would weaken such guidance to an unacceptable level. For example, summaries of e-mails may not accurately reflect the nature of the patient-physician communication. Accordingly, the Board believes that the modified language proposed by the EMAC strikes an appropriate balance between providing reasonable guidance to physicians, and providing adequate latitude regarding the retention of specific patient-physician electronic communications that may include personal information that is not medically relevant.

RECOMMENDATION

The Board of Trustees recommends that the following be adopted and that the remainder of the report be filed:

> That our American Medical Association amend Policy H-478.997[1d] by addition and deletion to read as follows:
>
> Whenever possible and appropriate, physicians should retain electronic and/or paper copies of e-mail communications with patients ~~patient e-mails and corresponding responses will be retained as part of the patient's medical record~~.

25. PEER REVIEW IMMUNITY

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, Board of Trustees Report 8, "Peer Review Immunity," was adopted as amended by the House of Delegates, and asked our American Medical Association to (1) monitor legal and regulatory challenges to peer review immunity and non-discoverability of peer review records/proceedings and continue to advocate for adherence to AMA policy, and (2) produce an additional report with recommendations that will protect patients and physicians in the event of misdirected or negligent peer review at the local level while retaining peer review immunity for the process.

This report recommends that (1) medical staffs adopt bylaws that provide for a peer review process that is consistent with Health Care Quality Improvement Act (HCQIA) criteria and AMA policy; (2) medical staffs consider bylaw provisions that include an option or alternative for external peer review when there is a reasonable allegation by the reviewed physician; and (3) if states believe that negligent or misdirected peer review is a problem, they consider legislative action establishing an administrative review panel to review physicians' claims of unfair peer review prior to judicial involvement.

AMA POLICY

Current AMA policy supports peer review activities by physicians and discourages involvement in a peer review process by physicians who are economic competitors of the involved physician. AMA policy also supports confidentiality protection of peer review documents and proceedings (Policies H 375.972, H 375.983, H 375.987, H 375.989, H375.990. H 375.992, H 375.993, H 375.997, AMA Policy Database).

BACKGROUND

Board of Trustees Report 8-I-01, "Peer Review Immunity," discussed the history and purpose of the Health Care Quality Improvement Act (HCQIA) and described in detail, the requirements that must be met in order to invoke immunity under the act. The limited immunity provided by HCQIA does not preclude all claims for damages against a peer review committee. The report specified those situations in which immunity would not apply, namely, (1) civil rights violations; (2) peer review which does not meet HCQIA criteria for fair process and notice; and (3) suits for injunctive relief.

The report also acknowledged the potential for abuse as well as the occasional personal agendas that may motivate peer review actions. It recommended that, among other things, medical staffs adopt/implement medical staff bylaws that are consistent with HCQIA and AMA policy.

DISCUSSION

Physicians sanctioned by a peer review panel face a daunting process if they challenge a peer review action and seek money damages. The time and expense involved in judicial proceedings is significant. Moreover, HCQIA generally enables a defendant to prevail in damage actions so long as the peer review committee has provided due process and notice to the physician under review.

HCQIA immunity provides protection for good faith peer reviewers but was not intended to protect illegitimate actions taken under the guise of furthering quality care. Congress did not want to see patient care undermined when privileges are unfairly terminated. Congress specifically recognized the potential abuse in the peer review process and limited immunity to actions that met the criteria articulated in the Act. Further, Congress did not place any barriers or impediments in the way of physicians who chose to file a complaint with federal antitrust agencies, bring matters to the attention of the state boards or licensing authorities, or file an action to enjoin the actions of a peer review committee or hospital. Physicians who feel that they have been the victim of unfair peer review have always had the opportunity to seek injunctive relief, for instance suits alleging violation of due process or suits alleging antitrust, so long as the claimant is not seeking money damages. HCQIA immunizes peer review participants from money damages; it does not insulate peer reviewers from suits. Physicians can also raise their concerns to the attention of the Department of Justice (DOJ) or the Federal Trade Commission (FTC) or the state board of medical examiners at no cost.

Current AMA policy recommends that hearing panels consist of members who are not in economic competition with the involved physician. Furthermore, When an objective fair peer review process is at risk due to participation of competitors, persons motivated by retaliation, discrimination, cronyism or other personal agendas, a mechanism for external review would provide physicians with some assurance of fairness. Medical staffs have discretion to establish procedures that provide for external peer review either as a standard bylaw provision or whenever there is a reasonable allegation that the peer review panel is biased. While one process may not necessarily be workable for all medical staffs, a variety of approaches can be established in bylaws which involve external peer reviewers. It should be noted, however, that even when HCQIA and state immunity is assured, it may be difficult for medical staffs to recruit physicians for external peer review. Some communities may have only one hospital and some physicians may still be reluctant to participate in professional matters of other medical staffs.

Private peer review organizations also exist to provide external peer review for medical staffs. These organizations provide independent physician evaluation to assist medical staff and committees and can provide board certified physicians in all specialties. Physicians who believe that peer review is the responsibility of medical staff members may meet utilization of these professional consultants with some resistance. The cost of using private peer review organizations is an issue which needs to be addressed and requires creative solutions on the part of both hospital and medical staff.

State medical societies or specialty societies may also be a resource in peer review by recommending physicians they know are willing to assist in peer review when requested by a party to peer review.

Because local external peer review may be unworkable in some communities, because local external peer review may not guarantee an objective and fair process, and because some medical staffs may be resistant to establishment of external review panels, a state remedy may be required.

Some states have legislated a process for judicial review of negative credentialing actions. Washington DC, Arizona, and Virginia, for example, have enacted laws establishing a process for judicial review of negative credentialing decisions. These laws give the courts parameters by which to determine whether a credentialing decision should be upheld.

Other states have created administrative review boards to hear the merits of physicians claims prior to court proceedings. In New York, an impartial panel of 14 persons appointed by the governor reviews the adverse decision. The panel may revise or uphold the decision of the hospital or it may make its own finding. After the panel's review, the physician may then file suit, although the panel's findings become evidence in any judicial proceeding. AMA staff has reviewed these programs and notes that some physicians are critical of a state-mandated review mechanism. Some physicians believe that state intervention encroaches on the medical professions' responsibility to monitor itself. Other physicians caution that more punitive recommendations than those of the original peer review committee may result.

Colorado established a committee to review claims of unreasonable anticompetitive conduct in connection with privilege or staff membership decisions. The committee may reverse, remand, or modify the action or dismiss the physician's complaint. Any allegation other than anticompetitive conduct may be filed directly with the court.

CONCLUSION

The potential for discriminating or anticompetitive peer review exists despite the integrity of the medical profession. However, immunity for peer reviewers must not be compromised. Peer review is essential for ensuring and improving quality patient care and immunity is essential to those physicians who participate in peer review.

In order to assure a fair process and avoid time-consuming and costly litigation by physicians who challenge the objectivity of the hearing panel, an opportunity for external review should exist at the local level. However, because of the assortment of bylaws in place in hospitals and possible resistance to incorporate alternatives for external review panels, state legislative action should be considered to offer redress to physicians when states believe that the peer review process is being undermined.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and the remainder of the report to be filed:

1. That our American Medical Association recommend that medical staffs adopt bylaws that provide for a peer review process that is consistent with Health Care Quality Improvement Act criteria and AMA policy.

2. That our AMA recommend that medical staffs include bylaw provisions that provide an option or alternative for external and impartial review when there is an allegation by a reviewed physician.

3. That our AMA recommend that if physicians believe that negligent or misdirected peer review is a problem, legislative action be considered at the state level to assure a fair due process proceeding for physicians subject to review.

4. That our AMA request that the Joint Commission on Accreditation of Healthcare Organizations require medical staff bylaws to include due process protections for peer review, including the option for external and impartial review.

5. That our AMA continue to monitor the legal and regulatory challenges to peer review immunity and non-discoverability of peer review records and proceedings, as well as consider legislative remedies, including the feasibility and impact of amending HCQIA to provide the option for external peer review for hospital medical staff physicians.

26. MEDICARE PAYMENT FOR PREVENTIVE EXAMINATIONS

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

BACKGROUND

At the 2001 Annual Meeting, the House of Delegates adopted Resolution 218, "Medicare Payment for Preventive Services." The resolution, introduced by the Young Physicians Section, calls for expanding Title 18 of the Social Security Act to include coverage for "most preventive services as a covered benefit," and further calls for the AMA to make payment for preventive services under the Medicare program a "legislative priority in the coming year."

Previously adopted American Medical Association policy is compatible with the YPS resolution, including:

- H-425.992 (AMA Policy Database) calls for "revision of current Medicare guidelines to include coverage of appropriate preventive medical services";
- H-165.880 seeks coverage for "certain types of well care examinations by health insurers, such as "mammography screening and periodic physician examinations"; and
- H-165-890 calls for "appropriate incentives for (Medicare) patients to seek and receive preventive services."

CONGRESSIONAL LEGISLATION

Currently there are two bills which mirror Resolution 218. On June 5, 2001, the "Medicare Wellness Act of 2001" was introduced in both the US House of Representatives and US Senate. H.R. 2058, introduced by Rep. Sander M. Levin (D-MI), has 35 cosponsors. S. 982, introduced by Senator Bob Graham (D-FL), has 12 cosponsors. The Senate bill has no Republican cosponsors.

The "Medicare Wellness Act" (MWA) would establish within the Department of Health and Human Services (HHS) a Working Group on Disease Self-Management and Health Promotion (Working Group) to develop policies and criteria for the Secretary to make grants to approved applicants to study specified approaches to further health promotion and disease prevention among Medicare beneficiaries under Title 18 of the Social Security Act (SSA). It directs the Secretary of HHS to conduct demonstration projects to promote disease self-management for conditions identified by the Working Group for target individuals.

The legislation would amend Title 18 to outline Medicare coverage of various specified preventive services, including: (1) therapy and counseling for cessation of tobacco use, and counseling for post-menopausal women; (2) screening for diminished visual acuity, and screening for hypertension; and (3) medical nutrition therapy services for Medicare beneficiaries with cardiovascular diseases, diabetes, or a renal disease. The bill would permit a waiver of coinsurance and deductibles for certain preventive services, such as: (1) diabetes outpatient self-management training services; (2) colorectal and prostate cancer screening tests; and (3) bone mass measurement.

Finally, the bill would direct the Secretary to: (1) integrate supplemental preventive health services with existing program integrity measures; and (2) conduct specified activities, including annual notices to Medicare beneficiaries, to promote use of preventive health benefits, items, and services. It further directs the Director of the Centers for Disease Control and Prevention to conduct a national prevention and awareness campaign among Medicare beneficiaries.

MEDICARE POLICY/LEGISLATIVE OUTLOOK

Unfortunately, due to the current political climate and the high costs associated with expansion of benefits under the Medicare program, the prospects of lobbying success on this issue before the end of the 2002 session of Congress seem unlikely.

First, as of January 1, 2002, Medicare implemented a 5.4 percent payment cut that applies to Medicare services provided by physicians and other health professionals, including, but not limited to, physician therapists, speech pathologists, optometrists, advanced practice nurses and podiatrists. This latest payment cut since the Medicare physician fee schedule was developed more than a decade ago and is the fourth cut over the last eleven years. Since 1991, Medicare payments to physicians have averaged only a 1.1 percent annual increase, or 13 percent less than the annual increase in practice costs, as measured by the Medicare Economic Index (MEI).

The current 5.4 percent cut is forcing many physicians to make difficult choices about their ability to continue accepting new Medicare patients, or even whether to retire or change to a career that does not involve patient care. If the pay cut is not immediately halted, it could soon become difficult to prevent serious access problems for elderly and disabled Medicare patients. Recent media reports already suggest that many physicians are simply refusing to see any new Medicare patients due to the severe reduction in reimbursements.

Even worse, under current law, physician payments are on an automatic pilot system that can reduce payments by as much as inflation minus 7 percent in a single year. The Centers for Medicare and Medicaid Services (CMS) projects that future cuts in physician payments will be: (1) -5.7 percent in 2003; (2) -5.7 percent in 2004; (3) -2.8 percent in 2005; and (4) -.01 percent in 2006. In 1993, Medicare conversion factor payments to physicians were $31.45. In 2005, payments, under current law, would be $31.29 in real dollars.

The AMA has been lobbying vigorously to halt the current-year cut, as well as eliminate future cuts. The AMA has been supporting the Medicare Payment Advisory Committee (MedPAC) recommendations as the best possible solution. However, both CMS and the Congressional Budget Office (CBO) estimate that a physician fix would cost about $126 billion over ten years. The AMA has also been working on suggestions which would bring down the overall costs. These include the following:

1. Remove Medicare-covered outpatient prescription drugs from the physician spending pool.
2. Revise the calculation of physician productivity gains.
3. Correct erroneous estimates used in the 1998 and 1999 expenditure targets.
4. Abandon use of an assumption that utilization growth will accelerate if the expenditure target system is repealed.
5. Recognize new national Medicare coverage policies in the expenditure target.

Second, the Administration has made a Medicare prescription drug benefit its top priority in the health care area. Moreover, in a letter to the House Ways and Means Committee, HHS Secretary Tommy Thompson and Office of Management and Budget Director Mitchell Daniels said the Administration supports reforming physician payments in a budget-neutral fashion. The House-passed FY2003 Budget Resolution provides for $300 billion over 10 years

for the new benefit, while allocating the remaining $50 billion to resolve all other Medicare payment problems--home health, hospitals, and nursing homes. The Senate Budget Committee has reported a budget resolution containing $500 billion for a Medicare prescription benefit, Medicare reform, and Medicare payments to providers over ten years.

The current Federal budget situation is not positive. CBO projects that Medicare spending is projected to grow to $498 billion by 2012, and Medicare's share of the economy to rise by about one-half of a percentage point, from 2.4 percent of GDP in 2002 to 2.9 percent. CBO projects that Medicare spending will grow by 4.9 percent in 2002--a figure that would have been 7.7 percent without the payment shift.

DISCUSSION

The AMA has long advocated overall Medicare reform, under which the AMA has proposed restructuring the entire benefit package to include a broad spectrum of prevention services. Though the AMA continues its strong efforts for this type of reform, any such legislation faces an uphill political fight. The AMA will continue to advocate coverage of prevention services with Congress and the new Administration as staff are appointed to fill key positions within the Department of Health and Human Services.

During the last several years, various laws have been enacted that provide coverage of various preventive benefits, and the AMA has been very active in lobbying for such provisions. Specifically, the AMA strongly supported provisions enacted under the "Balanced Budget Act of 1997," which provided coverage of additional preventive benefits such as mammography, colorectal and bone density screening as well as diabetes self management services. In addition, the AMA also supported provisions in the "Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000," which added a glaucoma screening benefit and expanded the existing colon and cervical cancer screening benefits.

The AMA will continue, when appropriate, to support legislation providing coverage of prevention services. The difficulty, however, in broad support of any legislation that would cover prevention services is that while these services are extremely important, can increase quality, and save costs over the long term, these services have high "front end" costs. Thus, this type of legislation can be politically unpopular and can threaten access to other existing services if reimbursement amounts for existing services are reduced to cover added health care costs in new areas.

RECOMMENDATIONS

In light of the above legislative atmosphere, it would appear expansion of Medicare benefits would not pass either House of Congress in the current session. It should be noted that previous Congressional expansions of Medicare benefits for preventive services, such as mammogram and colorectal screenings, have enjoyed bipartisan support. The fact that the Senate bill does not have any Republican cosponsors does not bode well for preventive health care benefit expansion.

The Board of Trustees recommends that the following recommendations be adopted and the remainder of the report be filed:

1. That our American Medical Association continue to disseminate evidenced-based recommendations regarding the appropriate use of clinical preventive services to physicians, the general public and policymakers.

2. That our AMA continue to collaborate with national medical specialty societies and interest groups to facilitate implementation of these recommendations by practicing physicians.

3. That our AMA urge Congress and the Administration to provide coverage for these clinical preventive services by the Medicare program.

4. That our AMA advocate especially for the provision of these services to populations at high risk for a given condition under guidelines available on the AMA web site.

5. That our AMA pursue the provision of preventive services with the intent of also pursuing additional funding added to the Medicare program without any reduction in reimbursement for other physician services or Medicare updates.

27. USE OF PHYSICIANS' IDENTITY DATA

HOUSE ACTION: REFERRED TO BOARD OF TRUSTEES

At the 2001 Interim Meeting, the House of Delegates adopted Board of Trustees Report 12, "Use of Physicians' Identity Data" in lieu of Resolution 613 (A-01) as amended with the following recommendation:

> That our American Medical Association (a) proactively inform physicians and students with identity data in the Masterfile of their rights to elect "No Contact"; and (b) report back at the 2002 Annual Meeting about the educational actions undertaken, definitions of "No Contact" options, and the implications of selecting such an option.

The above recommendation calls for specific implementation beyond the several recommendations in Board of Trustees Report 12 that called for ongoing diligence and best efforts on the part of the AMA to protect the confidentiality and privacy of physician data in the AMA Physician Masterfile database. These recommendations included: (1) non-release of Social Security numbers, (2) a general view on the AMA web site of Masterfile data elements that are collected, (3) monitoring of AMA collection and licensing practices to minimize improper or inaccurate identity of particular physicians, and (4) proactive measures to inform physicians of their privacy options.

This informational status report reviews the AMA's ongoing compliance with the recommendations adopted in the referenced Board Report. It discusses progress to date towards full implementation of the recommendation to proactively inform physicians and students of their rights to elect "No Contact" for their Masterfile records. Finally, it describes the educational actions undertaken to inform physicians of the implications of their selecting a "No Contact" and/or "Do Not Release" indicator for their Masterfile records.

REVIEW OF AND COMPLIANCE WITH PREVIOUSLY ADOPTED RECOMMENDATIONS

Non-Release of Physician Social Security Numbers

Prior to July 2001, the AMA prohibited the licensing of Social Security Numbers except for those licensees who have contracts for AMA's Credentialing Products. SSNs were used by credentialers as an additional identifier to validate that the correct physician was being credentialed and to facilitate the granting of privileges by Credential Verification Organizations (CVOs), hospitals, and managed care organizations. However, AMA policy was changed in July 2001 so that credentialers, along with everyone else, no longer receive SSNs. Today, a physician's SSN is not released unless the physician specifically authorizes the AMA to do so.

Disclosure of AMA Physician Data on the AMA Web Site

The AMA web site continues to provide general information about the physician and student data collected and licensed by the AMA. This information includes: (1) how an AMA Physician Masterfile record is created; (2) a description of the primary data elements; and (3) a list of the AMA Database Licensing companies.

Monitoring of AMA Collection and Licensing Practices

The AMA continues to enforce its licensing policy that requires a licensing agreement with either the AMA or a Database Licensee (DBL) and each end user of AMA Masterfile data. The AMA Office of General Counsel reviews and approves all license agreements, which must describe in detail restrictions on the use of these data. Data elements included in the AMA Internet ID, like other AMA Masterfile data elements, remain subject to strict security controls. The AMA Internet ID also requires physician approval for its use.

As for AMA collection practices, the AMA still derives the vast majority of AMA Masterfile data from primary sources that preclude alterations of data variables such as physician's name, date of birth, medical school, residency training, DEA number, or license number without legal documentation and primary source verification.

REQUESTED PROGRESS REPORT

Development of AMA Database Licensing Privacy Statement

In 2001, as part of its routine business review and in advance of Board of Trustees Report 12-I-01, the AMA took steps to inform both member and nonmember physicians and medical students of their privacy options by beginning development of a formal AMA Database Licensing Privacy Statement (a draft of the statement is available from the Department of Database Licensing). This Privacy Statement, which will be reviewed and updated as events (e.g., changes in the law, changes in AMA policy) dictate, includes information on Masterfile data collection and maintenance procedures, the purpose and scope of the Masterfile, and the AMA's licensing policies and legal agreements regarding the Masterfile. The Privacy Statement also addresses the AMA's efforts towards ensuring data security. In 2001, a leading auditing firm characterized the AMA's overall security profile as meeting industry standards.

The Privacy Statement informs physicians that (a) all licensing of physician identity data on the Masterfile is governed by agreements developed by the AMA; and (b) these written agreements direct that Masterfile licensees may release information only for uses approved by the AMA.

Privacy Options for Physicians

The Privacy Statement explicitly informs physicians how they can prevent the AMA from licensing their Masterfile data for marketing purposes by selecting the "No Contact" or "Do Not Release" indicator for their Masterfile records and the steps they need to take to select these options. The Privacy Statement defines in detail the "No Contact" and "Do Not Release "options (see Definitions below) and answers key questions regarding the implications of physicians' selecting these options for the release of their Masterfile data.

Education Actions to Inform Physicians of their Privacy Options

To provide a broad educational vehicle to inform physicians of their privacy options, the Privacy Statement will be adopted for use as a cost effective insert to accompany Membership Kits and the Physicians' Professional Activities (PPA) Survey. The distribution of the Privacy Statement will begin with the dissemination of these products in the summer of 2002 and be continuous.

The Privacy Statement will also be accessible to all member and nonmember physicians and medical students through a link on the AMA web site to the AMA Data Licensing page, where the entire text of the Privacy Statement will be available to all physicians as a PDF download.

DEFINITIONS

No Contact and Do Not Release

The Privacy Statement provides clear and succinct definitions of the "No Contact" and "Do Not Release" indicators so that physicians are apprised of the consequences of selecting these options. The definitions of these indicators in the Privacy Statement are as follows:

> No Contact
>
> The No Contact status on a physician's Masterfile record ensures that the physician's name will not be licensed for marketing purposes. You will still receive health hazard warnings, drug recalls, and AMA related information. Your information will be released to state licensing boards or hospitals to verify credentials. However, if a physician chooses No Contact, AMA Database Licensees will not be permitted to use the Masterfile for purposes of distributing drug samples, journals or for other promotional purposes. A pharmaceutical representative may still contact a physician if using information from a source outside of the AMA.

As part of its efforts to afford physicians' privacy options with respect to their Masterfile data, the AMA also offers physicians a more restrictive "Do Not Release" option.

Do Not Release

The Do Not Release policy prohibits the AMA from releasing any Masterfile information on the physician. Thus, it is an all or nothing system. If a physician instructs the AMA to flag his/her record as Do Not Release, AMA Database Licensees will no longer have the right to use Masterfile information for the purpose of contacting the physician including health hazard warnings and drug recalls. The Do Not Release flag will also prohibit release of Masterfile information to state licensing boards and hospitals who use this information to verify credentials, unless the AMA has written permission from the physician to release his/her Masterfile information to a specific organization.

CONCLUSION

The AMA will continue to make information about its Masterfile collection and licensing policies, including privacy options, available to member and non-member physicians and students. The AMA will also engage in ongoing efforts to update its Masterfile data collection and licensing policy as events dictate.

28. 2001 GRANTS AND DONATIONS

HOUSE ACTION: FILED

In response to Resolution 612 (A-99), attached is a financial report which details all grants and donations received by the American Medical Association during 2001. This material is presented for the information of the House of Delegates.

(The report is available from the Division of Corporate Accounting.)

29. AUDITOR'S REPORT

HOUSE ACTION: FILED

The Consolidated Financials Statements for the years ended December 31, 2001 and 2000, and the Independent Auditor's report have been included in a separate booklet, titled "2001 Annual Report." This booklet is included in the handbook mailing to members of the House of Delegates and will be discussed at the Reference Committee F hearing.

(The 2001 Annual Report referenced in Report 29 of the Board of Trustees is available from the Group on Member and Business Communications.)

30. AMA DUES - 2003

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At its April meeting, the Board of Trustees reviewed the 2003 dues recommendation. The past practice used a three-year financial forecast as a basis for the annual dues recommendation. Recent experience with declining membership has highlighted the need to assess membership dues on a more strategic level. Using financial need as the basis for a dues increase has been discontinued. Extensive research has been performed to develop pilot programs and alternative dues and benefit structures designed to increase membership market share. The Advisory Committee on Membership and staff will continue to explore options to achieve membership growth while attempting to minimize the financial impact of such options.

RECOMMENDATION

The Board of Trustees recommends:

1. That there be no change to AMA dues levels for 2003, dues will remain as follows:

Regular Members	$420
Physicians in Their Second Year of Practice	$315
Physicians in Military Service	$280
Physicians in Their First Year of Practice	$210
Physicians in Resident Training	$45
Medical Students	$20

   Regular physician members of unified societies dues rebate for 2003 will be in the form of a reduced dues level of $300.

2. That the remainder of this report be filed.

31. LITIGATION CENTER CASES TO COMBAT AUTOMATIC DOWNCODING AND/OR RECODING

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the 2001 Annual Meeting, the House of Delegates adopted as amended Resolution 813, asking that the Board of Trustees urge the Litigation Center of the American Medical Association and the State Medical Societies (the "Litigation Center") to investigate and consider legal action, under appropriate legal theories, to seek redress from insurers who engage in inappropriate or inaccurate downcoding and/or recoding. The resolution further required that a report be returned to the House of Delegates at the 2002 Annual Meeting.

This report advises the House of Delegates of activities by the Litigation Center in response to such claims of automatic downcoding and/or recoding, and recommends their continuation.

DISCUSSION

Limitation on Full Disclosure

This report discusses active litigation and investigations of pending and contemplated lawsuits. Much of the information pertinent to such cases is of a confidential nature. Full disclosure of such information would prejudice the rights of the AMA and of those medical societies and physicians who are allied with the AMA. Accordingly, this report is necessarily incomplete.

Litigation Center Operations

The Litigation Center is a coalition of the AMA and those state medical societies that pay dues to the Litigation Center. Currently, forty-nine state medical societies do pay such dues and are members of the Litigation Center. The mission of the Litigation Center is to advocate for the interests of the medical profession in the courts by bringing or supporting cases of broad impact and by coordinating litigation within the Federation. Litigation Center cases must satisfy both of the following criteria: (a) the Litigation Center position must be consistent with AMA policies; and (b) the medical society of the state in which a case is to be filed must support Litigation Center involvement.

When the Litigation Center appears in court, it does so under the name of the AMA. The General Counsel of the AMA must approve the use of the AMA's name in litigation, whether such use is through the filing of a brief or the initiation of a lawsuit. If the Litigation Center initiates a lawsuit in the name of the AMA, the AMA Board of Trustees must also approve such action.

The vast majority of all AMA litigation, other than cases arising from its business operations, is handled through the Litigation Center. This includes all of the downcoding/recoding cases discussed in this report.

While most of the business of the Litigation Center is conducted through closed meetings of its Executive Committee, the Litigation Center also holds open meetings during each Annual and Interim Meeting of the AMA House of Delegates. These meetings are open to the general public, including, of course, any interested delegate or alternate delegate. Also, at each Annual Meeting the Litigation Center holds a second open meeting, specifically for delegates and alternate delegates.

Legal Theories

Cases based on inaccurate downcoding/recoding are generally brought under one or more of the legal theories described below.

Breach of Contract

The easiest legal theory to prove, both as a general proposition of law and within the downcoding/recoding context, is based on breach of contract. The most straightforward such breach occurs when the participation agreement between an insurance company and its panel physicians provides, either directly or by implication, that the physicians will be paid in accordance with the principles of Current Procedural Terminology (CPT). If this is the promise that the insurance company makes to its panel physicians and that promise is not kept, a breach occurs.

A closely related claim can arise by an out-of-network physician who is an assignee of benefits from his or her patients. The underlying insurance policy between the patient and the carrier may provide that the patient is to be paid in accordance with the fair market value (or, more typically, "usual, customary, and reasonable" value or some other comparable term) for the physician's services. If the insurance company downcodes or recodes the claim for services, the carrier, in effect, assigns a lower value to those services. Hence, the carrier will have breached its obligation to its patient and, through the assignment of benefits, to the physician who rendered the services. When such assignment has occurred in connection with an employer's health insurance plan, the breach of contract suit may be brought under a provision of the Employee Retirement Income Security Act (ERISA), which allows for such claims.

In either type of case, the plaintiff must show that he or she did not agree to the insurance company's downcoding/recoding. In other words, if the physician's participation agreement or the patient's insurance policy allows the carrier to downcode or recode the physician's services, the insurance company has a defense against such claims.

Common Law Fraud

Common law fraud actions can arise when an insurance company explicitly represents to a physician that it is paying benefits in conformity with CPT principles when, in fact, the insurance company knows that it is not doing so. By way of example, this situation may arise if the insurance company has programmed its computers to disregard CPT principles, but it claims otherwise. In a case of egregious fraud, the court may award punitive damages.

Fraud, however, requires deception. If the insurance company openly tells physicians that it will downcode or recode claims, then it cannot be liable in fraud.

State Unfair Business Practice or Consumer Protection Laws

Most states have statutes which protect the public against unfair trade practices. Such statutes vary from state to state, but they frequently allow punitive damages or attorney fees in favor of a party who can prove a violation of these laws. Automatic downcoding and/or recoding may be a violation of such statutes. Typically, though, as with common law fraud claims, plaintiffs suing under these statutes must show that they have been deceived. Thus, if the insurance company publicly states that it engages in downcoding or recoding, it will probably not be violating these laws.

RICO

By far, the most difficult legal theory to prove in this area is a violation of the federal Racketeer Influenced and Corrupt Organizations Act (RICO). To do so, the physicians must demonstrate that the wrongdoing by the insurance company amounts to a crime. Generally, the crime in question will involve some aspect of fraud. The physicians must also prove various other, more technical elements of liability.

Although RICO is the most difficult legal theory to prove, the potential benefits under it are the most far reaching. Because RICO is a federal statute, an appropriate case can be brought in federal court with, possibly, a nationwide remedy. Remedies for a RICO violation may include treble damages and attorneys fees.

Specific Cases

Kaiser v. CIGNA

Of the many lawsuits that allege downcoding/recoding claims, this one appears to have a strong probability of success. The principal case is pending as a class action in a downstate Illinois state court, but a collateral suit is also pending in the United States Court of Appeals for the Seventh Circuit. The state court lawsuit alleges that, through the use of Claimcheck software, CIGNA improperly "bundles" and "downcodes" CPT in order to reduce payments to the physicians on CIGNA's preferred provider organization (PPO) panel. To justify such actions, CIGNA contends that the AMA approves the use of its edits. The Litigation Center, along with the Illinois State Medical Society, is helping the plaintiff physicians receive the payments to which they are entitled.

The standard managed care contract between CIGNA and the physicians on its PPO panel provides that the physicians will be reimbursed for "covered services" at "the lesser of Physician's usual and customary charge for the service provided or CIGNA's...maximum fee schedule in effect at the time of the service, plus applicable Copayments." The contract, which CIGNA drafted, does not define what is meant by a physician's "services," but CIGNA has informed its panel physicians that it relies on CPT guidelines to determine what is meant by a service.

On March 29, 2001, the state court case was certified as a nationwide class action. To assist the plaintiffs at the class certification hearing, the AMA's CPT Department submitted an affidavit to the court which pointed out that the AMA interpreted CIGNA's software edits differently from the way that CIGNA claimed those edits should be interpreted. When confronted with this affidavit, CIGNA's attorney apologized, on the record, for misleading the court. More than 350,000 physicians and approximately 100,000 nonphysicians are now members of the plaintiff class.

CIGNA moved in the state court to dismiss or stay the majority of the claims, contending that they are subject to arbitration agreements. CIGNA also filed a defendant's class action lawsuit in the United States District Court for the Northern District of Illinois to compel arbitration under the Federal Arbitration Act. On January 15, 2002, the federal district court, in light of the parallel proceedings in state court, declined to exercise jurisdiction. CIGNA is appealing this decision by the district court to the United States Court of Appeals for the Seventh Circuit.

At one point, the AMA considered whether to intervene in the state court lawsuit or file its own case against CIGNA. The claim would have alleged that CIGNA informs physicians that it pays them according to CPT guidelines when, in fact, it knows full well that it does not.

The AMA decided that it would not sue CIGNA directly. However, the AMA's CPT Department has been consulting with the plaintiffs and may provide expert witness testimony. The Litigation Center and the Illinois State Medical Society have offered to provide the plaintiffs with continued assistance.

AMA v. United HealthCare

This case challenges the basis under which two managed care organizations, United Healthcare and Metropolitan Life Insurance, calculate "usual, customary, and reasonable" charges when paying physicians or reimbursing patients for medical services. Most reimbursement health insurance policies provide that insurance benefits are to be based on: (1) the physician's actual charge; (2) the physician's usual charge; or (3) the "reasonable and customary charge" for the services. The insurance company determines the reasonable and customary charge, based

on information available to it but not to the general public. This class action lawsuit, brought on behalf of patients and out-of-network physicians, contends that the defendant insurance companies use unreliable or insufficient data to determine the reasonable and customary charges. To the extent that the insurance companies employ systematic downcoding/recoding, they would be paying less than the amount promised.

Suit was filed on March 15, 2000, with the AMA, the Medical Society of the State of New York, and the Missouri State Medical Association designated as the first named plaintiffs. On July 30, 2001, pursuant to a motion by the defendants, the court dismissed most of the claims, although it let some of them stand. The plaintiffs filed an amended complaint, which the defendants have again moved to dismiss. That motion is being briefed.

MDL Cases

Several state medical societies, plus numerous individual physicians, have sued many of the largest health insurance companies in the United States under a variety of legal theories, including those based on RICO. Among the claims is that the insurance companies systematically downcode and recode health insurance claims. The cases have been consolidated, for pre-trial purposes, into a single federal lawsuit in a Florida district court, and a judge in Miami is hearing the case. This type of consolidated case, arising from complaints filed in several district courts throughout the United States, is known as "multi-district litigation" or, simply, "MDL." Although suit was filed in early 2000, the case is still at a preliminary stage. Recently, the United States Court of Appeals for the Eleventh Circuit ruled that, although certain issues in the case could not be litigated due to an arbitration clause in the contracts between the physicians and some of the defendant insurance companies, other issues could move forward in court. It is unclear whether the case will continue as a single, consolidated lawsuit or whether it will be divided into separate cases, based on the variety of the claims and the distinct defendants.

The AMA has pledged to assist the MDL cases. Such assistance could come through evaluation of coding issues and, possibly, provision of expert witnesses. At this time, it is unclear how much assistance the AMA will be asked to give and whether those requests could overtax its resources.

Medical Society State Court Lawsuits

Several state medical societies have brought lawsuits in state court. Like the MDL cases, these lawsuits allege a variety of claims, including issues of downcoding/recoding against several insurance companies. However, they do not allege RICO or other federal statutory violations. Also, each insurance company is sued in a separate lawsuit, and each claim is made on a state by state basis. These cases, too, are at a relatively early stage.

As in the MDL cases, the AMA and the Litigation Center have promised to provide assistance. The extent and nature of such assistance is still undetermined.

Investigations

The foregoing summary, while it captures the major lawsuits, is not exhaustive. The Litigation Center is investigating various other downcoding/recoding claims, which may result in litigation. Possibly, the Litigation Center may participate in or support other lawsuits of the same nature between the date of preparation of this report and the 2002 Annual Meeting.

RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted and that the remainder of this report be filed:

1. That the Litigation Center of the American Medical Association and the State Medical Societies continue to initiate or support lawsuits that seek redress from insurers who engage in inappropriate or inaccurate downcoding and/or recoding practices.

2. That delegates and alternate delegates should attend the open meetings of the Litigation Center.

32. NATIONAL REGISTRY OF MEDICAL EXPERT TESTIMONY (RESOLUTION 3, I-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

At the 2001 Interim Meeting, the Reference Committee on Amendments to Constitution and Bylaws heard testimony on the issues surrounding false testimony by physicians. Resolution 3 (I-01), introduced by the Florida Delegation, calls for the AMA to (1) go on record condemning any physician who would harm a colleague with false testimony; (2) explore the feasibility of all specialty societies establishing a registry for all depositions and testimony given by any of their members and, if determined to be feasible, encourage all specialty societies to develop such a registry; and (3) encourage sanctions or expulsion against medical society members who harm a colleague by testifying falsely. The resolution would further require that the AMA's legal counsel assist those medical societies who ask for help in these situations.

Testimony was heard on the professional liability crisis and the possible liability exposure, as well as the potential benefits, arising from the establishment of such a registry. Testimony was also heard that establishing such a registry would be prohibitively expensive and impractical.

The House of Delegates referred Resolution 3 to the Board of Trustees for a report at the 2002 Annual Meeting. This report reviews and makes recommendations on the issues raised in the resolution.

AMA POLICY

Physicians have an ethical obligation to assist in the administration of justice. If a patient with a legal claim requests a physician's assistance, the physician should furnish medical evidence, with the patient's consent, to secure the patient's legal rights. Medical experts should have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise. Medical witnesses should be adequately prepared and should testify honestly and truthfully to the best of their medical knowledge (Policy E-9.07, AMA Policy Database).

DISCUSSION

The first part of the resolution calls for the AMA to go on record condemning any physician who would harm a colleague with false testimony. Policy E-9.07 already condemns any physician who testifies falsely, whether in the context of harming a colleague or not. Thus, the first part of the resolution is already satisfied.

The crux of the resolution is the development of a registry for depositions and other expert testimony. The Board of Trustees believes that this undertaking would, in all probability, be of limited value, and might even have negative repercussions. The costs of such a registry would probably outweigh its benefits.

Although court reporters keep records of depositions, those records are frequently not transcribed. Even if they are transcribed, they are usually unavailable to the public. Court testimony is also generally not transcribed. Transcription costs can run as high as several dollars a page, and either depositions or court testimony of experts can run to hundreds of pages. Thus, to the extent the proposed resolution contemplates a registry of all depositions and testimony, as it states, it would be financially unworkable. Furthermore, even if price were not an object, it would be impractical to obtain copies of all such testimony. Conceivably, though, the registry could be limited to those transcripts that might happen to come into the hands of members of specialty medical societies.

The most fundamental problem with the proposed registry is that it would be of, at best, minimal value. Quite simply, false testimony does not speak by itself. It requires diligent evaluation to determine that testimony is unfounded. Such evaluation can only be made by trial attorneys and by medical specialists in the field of the testimony. This effort is both difficult and expensive. Passive maintenance of a transcript registry, by itself, would do little to expose false medical testimony.

On the other hand, one group of people regularly studies testimonial transcripts to determine trial strategies. These are plaintiff's lawyers, who share information from one case to another. Generally, that information is most valuable in cases against large manufacturing companies or other businesses, who may be subject to multiple claims,

arising from a common factual nexus. For that reason, organizations of plaintiff's attorneys will maintain registries of depositions and other forms of testimony. Plaintiff's lawyers are in the business of studying such materials and using the information gained to mount repetitive attacks against large corporate defendants. Medical societies are not in this business.

While unlikely, it is conceivable that, if such a registry were to be established, the information might become available to plaintiff's lawyers. Lawyers have subpoena powers to compel discovery of potentially useful evidence, and courts are liberal in determining what information might be useful. Thus, there is some chance that the proposed registry might be of more benefit to plaintiff's attorneys than to the physicians who those attorneys attack.

If a member of a medical society feels that he or she has been harmed by false testimony of another member, he or she may, without the contemplated registry, obtain the necessary transcripts and develop the proof needed to substantiate the allegation of falsity. Such information was used to devastating effect in the recent case of *Austin v. American Association of Neurological Surgeons*, 253 F.3d 967 (7th Circuit 2001), *cert. denied*, 122 S.Ct. 807 (2002). In that case, an AANS member proved that Dr. Austin, another AANS member, had testified without a sound medical basis for his opinions. AANS suspended Dr. Austin, and the trial and appellate courts upheld that suspension. All of this was done without a registry, which, had it existed, would have accomplished little or nothing for the medical society.

AMA staff has contacted several of the larger specialty societies, seeking their feedback on the contemplated registry. Generally, their reactions were negative. They felt that the value of such an undertaking would not justify its cost.

As indicated above, delegates raised questions as to whether maintenance of the contemplated registry could subject medical societies to liability. Such possibility seems highly remote.

The third part of the proposed resolution, encouraging sanctions or expulsion against medical society members who harm a colleague by testifying falsely, is unnecessary. It seems likely that almost all Federation societies will subscribe to Policy E-9.07, which finds that false testimony is unethical. If any medical societies reject this proposition, then it is unlikely that further exhortation by the House of Delegates will moderate that position.

Finally, the last part of the resolution is also unnecessary. This part would require that the AMA's legal counsel assist those medical societies who ask for help in these situations. The AMA's legal counsel is already committed to furthering AMA policies, including the enforcement of Policy E-9.07. Thus, the AMA, through the Litigation Center, submitted an amicus curiae brief in *Austin v. American Association of Neurological Surgeons*. If a similar issue should arise, the AMA stands ready to lend its support, without need for a House of Delegates resolution.

RECOMMENDATIONS

The Board of Trustees recommends that:

1. Resolution 3 (I-01) be adopted.

2. The remainder of this report be filed.

33. AMA REVIEW OF PRINCIPLES ON CORPORATE RELATIONSHIPS

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

PURPOSE

The House of Delegates adopted the Board of Trustees Report 20, "Revised AMA Principles on Corporate Relationships," in June 1999. (See Appendix A: Policy H-530.944 [AMA Policy Database], "Revised AMA Principles on Corporate Relationships," now Policy H-630.040, "Principles on Corporate Relationships," hereon referred to as Guidelines for American Medical Association Corporate Relationships, June 1999).

In 2001 the Board requested an AMA staff group (hereon referred to as "the AMA") representing Ethics, Membership, Professional Standards, Science, Advocacy, AMA Foundation and Corporate Relations, Business Products, Risk Management, Communications and Office of the General Counsel to review and determine if any updates were needed to the Guidelines for American Medical Association Corporate Relationships, June 1999.

The following summarizes and discusses the recommended changes to the guidelines with the proposed edits indicated in full context in Attachment A.

RECOMMENDED CHANGES

General Principles

Guideline One - The AMA's vision and values must drive the proposed activity.

The AMA's vision and values ultimately must determine whether a proposed relationship is appropriate for the AMA. The AMA should not have relationships with organizations or industries whose principles, policies or actions obviously conflict with the AMA's vision and values. For example, relationships with producers of products that harm the public health (e.g., tobacco) are not appropriate for the AMA. ~~In general, rather than responding to others,~~ The AMA will proactively choose its priorities for external relationships and ~~participate~~ collaborate in those that fulfill these priorities.

The wording of the last sentence describing this guideline has been altered to make the point that the AMA chooses its priorities but does not restrict the AMA from collaborating with other organizations regarding good ideas.

Guideline Three - The Relationship must maintain the AMA's objectivity with respect to health issues.

The AMA accepts funds or royalties from external organizations only if acceptance does not pose a conflict of interest and in no way impacts the objectivity of the association, its members, activities, programs or employees. For example, exclusive relationships with manufacturers of health-related products marketed to the public could impair the AMA's objectivity in promoting the health of America. ~~Relationships that might bias, or appear to bias,~~ The AMA's objectivity with respect to health issues ~~are not acceptable~~ should not be biased by external relationships.

The language of the last sentence of the guideline description was changed to give the AMA room for prudent judgement.

Guideline Four - The activity must provide benefit to the public's health, patients' care, or physicians' practice.

Public education campaigns and programs for AMA or Federation members are potentially of significant benefit. Corporate-supported programs that provide financial benefits to the AMA but no significant benefit to the public or direct professional benefits to AMA or Federation members are not acceptable. In the case of member benefits, external relations should ~~advance~~ not detract from AMA's professionalism or be neutral to it.

The last sentence under the guideline description was edited to portray the idea that external relations should not detract from the AMA's professionalism.

Special Guidelines

Special Guideline Three - The relationship must preserve AMA's control over any projects and products bearing AMA name or logo. The AMA retains editorial control over any information produced as part of a corporate/externally funded arrangement.

When an AMA program receives external financial support, the AMA must remain in control of its name, logo, and AMA ~~entire~~ content, and must approve all marketing materials to ensure that the message is congruent with the AMA's vision and values. A statement regarding AMA editorial control as well as the name(s) of the program's supporter(s) must appear in all public materials describing the program and in all educational materials produced

by the program. (This principle is intended to apply only to those situations where an outside entity requests the AMA to put its name on products produced by the outside entity, and not to those situations where the AMA only licenses its own products for use in conjunction with another entity's products.)

Where the AMA collaborates with external parties on such activities as conferences or periodicals, it has been made clear that the AMA maintains control over its name and logo and has the right to review everything, but room should be left for collaboration.

Special Guideline Four - Relationships must not permit or encourage influence by the corporate partner on the AMA.

An AMA corporate relationship must ~~should~~ not permit influence by the corporate partner on AMA policies, priorities, and actions. For example, agreements stipulating access by corporate partners to the House of Delegates or access to AMA leadership would be of concern. Additionally, relationships that appear to be acceptable when viewed alone may become unacceptable when viewed in light of other existing or proposed activities.

A discussion took place regarding whether or not the word "undue" should be used to describe "influence" in this guideline. The AMA also considered deleting the following sentence in the guideline description, "*For example, agreements stipulating access by corporate partners to the House of Delegates or access to AMA leadership would be of concern."* Most corporations expect some access to AMA leadership and it is not realistic to expect otherwise. Access does not necessarily indicate influence over policies. However, for more emphasis it is recommended that the word "should" be changed to "must" in the first line of the guideline explanation.

Organizational Review

The remaining changes are in the Organizational Review area of the corporate guidelines as follows.

2. ~~*The Board of Trustees must approve all proposals for AMA corporate relationships.*~~*Every new AMA Corporate relationship must be approved by the Board of Trustees, or through a procedure adopted by the Board.*

   Every new AMA Corporate relationship must be approved by the Board of Trustees, or through a procedure adopted by the Board. Specific procedures and policies regarding Board review are as follows: (1) The Board routinely should be informed of all AMA corporate relationships; (2) The Board should perform an annual audit of an appropriate sample of AMA corporate relations activities; (3) Upon request of a dissenting member of the CRT, any dissenting votes within the CRT, and instances when the CRT and the Board committee differ in the disposition of a proposal, are brought to the attention of the full Board; (4) All externally supported corporate activities directed to the public, except patient materials linked to CME, should receive Board review and approval; (5) All activities that have support from only one corporation within an industry should either be in compliance with ACCME guidelines or receive Board review; and (6) All relationships where the AMA takes on a risk of substantial financial penalties for cancellation should receive Board review prior to enactment.

The AMA discussed organizational guideline two that stipulates which activities are forwarded onto the Board. Criteria three of organizational guideline two was updated to reflect the current practice of reviewing dissenting Corporate Review Team (CRT) votes upon request of CRT members as approved by the Board in December 1999. A change was suggested to criteria four which would exempt patient self-study activities that are linked to CME from Executive Committee review, as they would already be ACCME compliant.

4. *The Corporate Review Team reviews corporate arrangements to ensure consistency with the principles and guidelines.*

   The Corporate Review Team is the internal, cross-organizational staff group that is charged with the review of all activities with external funding to assure adherence to the guidelines.

   The Corporate Review Team is chaired by the ~~Vice President for Corporate, Foundation and International Relations~~ Senior Vice President, Governance and Operations and composed of senior managers from Ethics Standards; Legal; Finance; Communications; Publishing; ~~Marketing;~~ AMA Press; Membership; Advocacy and Science.

Organizational Review Guideline Four has been updated to reflect that the CRT is now chaired by the Senior Vice President, Governance and Operations, rather than the Vice President for Corporate, Foundation and International Relations due to an organizational change made in June, 2000. Other organizational changes include: "Marketing" should also be changed to "AMA Press" and "Advocacy" should be added.

5. The AMA's ~~Group on Foundation and Corporate Relations~~ Office of Risk Management in consultation with the Office of the General Counsel will review and approve all marketing materials that are prepared by others for use in the US and that bear the AMA's name and/or corporate identity.

Organizational Guideline Five should read "The Office of Risk Management" and not the "Group on Foundation and Corporate Relations" to reflect the AMA's current organization.

RECOMMENDATIONS

The Board of Trustees recommends:

1. That American Medical Association Policy H-630.040, Guideline Four, be amended as follows:

   Guideline Four - The activity must provide benefit to the public's health, patients' care, or physicians' practice.

   Public education campaigns and programs for AMA or Federation are potentially of significant benefit. Corporate-supported programs that provide financial benefits to the AMA but no significant benefit to the public or direct professional benefits to AMA or Federation members are not acceptable. In the case of member benefits, external relations ~~should advance~~ must not detract from AMA's professionalism ~~or be neutral to it~~.

2. That the House of Delegates adopt the other proposed changes to the Guidelines for American Medical Association Corporate Relationships, June 1999, Policy H-630.040, as presented in this report.

3. That the remainder of this report be filed.

APPENDIX - POLICY H-630.040, "PRINCIPLES ON CORPORATE RELATIONSHIPS"

The AMA House of Delegates adopted these revised principles at the 1999 Annual Meeting. Proposed changes are indicated with underscores and strikethroughs.

The House of Delegates adopts the following revised principles on Corporate Relationships and the Board will review annually and, if necessary, make recommendations for revisions to be presented to the House of Delegates.

Guidelines For AMA Corporate Relationships

Principles to guide AMA's relationships with corporate America were adopted by the AMA House of Delegates at its December 1997 meeting and slightly modified at its June meeting. Subsequently, they have been edited to reflect the recommendations from the Task Force on Association/Corporate Relations, including among its members experts external to the AMA. The following principles are based on the premise that in certain circumstances, the AMA should participate in corporate arrangements when guidelines are met, which can further the AMA's core purpose, retain AMA's independence, avoid conflicts of interest, and guard our professional values.

Overview of Principles

The American Medical Association's principles to guide corporate relationships have been organized into the following categories: General Principles that apply to most situations; Special Guidelines that deal with specific issues and concerns; Organizational Review that outlines the roles and responsibilities of the Board of Trustees, Executive Vice President, the Corporate Review Team and other staff units; and Operational Issues that outline the

annual reports to the Board of Trustees (Board) and House of Delegates (House). These guidelines should be reviewed over time to assure their continued relevance to the policies and operations of the AMA and to our business environment. The principles should serve as a starting point for anyone reviewing or developing AMA's relationships with outside groups.

General Principles

The AMA's vision and values statement should provide guidance for externally funded relationships. Relations that are not motivated by the association's mission threaten the AMA's ability to provide representation and leadership for the profession.

1. The AMA's vision and values must drive the proposed activity.

   The AMA's vision and values ultimately must determine whether a proposed relationship is appropriate for the AMA. The AMA should not have relationships with organizations or industries whose principles, policies or actions obviously conflict with the AMA's vision and values. For example, relationships with producers of products that harm the public health (e.g., tobacco) are not appropriate for the AMA. ~~In general, rather than responding to others,~~ The AMA will proactively choose its priorities for external relationships and ~~participate~~ collaborate in those that fulfill these priorities.

2. The relationship must preserve or promote trust in the AMA and the medical profession.

   To be effective, medical professionalism requires the public's trust. Corporate relationships that could undermine the public's trust in the AMA or the profession are not acceptable. For example, no relationship should raise questions about the scientific content of the AMA's health information publications, AMA's advocacy on public health issues, or the truthfulness of its public statements.

3. The relationship must maintain the AMA's objectivity with respect to health issues.

   The AMA accepts funds or royalties from external organizations only if acceptance does not pose a conflict of interest and in no way impacts the objectivity of the association, its members, activities, programs or employees. For example, exclusive relationships with manufacturers of health-related products marketed to the public could impair the AMA's objectivity in promoting the health of America. ~~Relationships that might bias, or appear to bias,~~ The AMA's objectivity with respect to health issues ~~are not acceptable~~ should not be biased by external relationships.

4. The activity must provide benefit to the public's health, patients' care, or physicians' practice.

   Public education campaigns and programs for AMA or Federation members are potentially of significant benefit. Corporate-supported programs that provide financial benefits to the AMA but no significant benefit to the public or direct professional benefits to AMA or Federation members are not acceptable. In the case of member benefits, external relations should ~~advance~~ not detract from AMA's professionalism or be neutral to it.

Special Guidelines

The following guidelines address a number of special situations where the AMA cannot utilize external funding. There are specific guidelines already in place regarding advertising in publications.

1. The AMA will provide health and medical information, but should not involve itself in the production, sale, or marketing to consumers of products that claim a health benefit.

   Marketing health-related products (e.g., pharmaceuticals, home health care products) undermines the AMA's objectivity and diminishes its role in representing health care values and educating the public about their health and health care.

2. Activities should be funded from multiple sources whenever possible.

   Activities funded from a single external source are at greater risk for inappropriate influence from the supporter- or the perception of it, which may be equally damaging. For example, funding for a patient education brochure should be done with multiple sponsors if possible. For the purposes of this guideline, funding from several companies, but each from a different and non-competing industry category (e.g., one pharmaceutical manufacturer and one health insurance provider), does not constitute multiple-source funding. The AMA recognizes that for some activities the benefits may be so great, the harms so minimal, and the prospects for developing multiple sources of funding so unlikely that single-source funding is a reasonable option. Even so, funding exclusivity must be limited to program only (e.g., asthma conference) and shall not extend to a therapeutic category (e.g., asthma). The Board should review single-sponsored activities prior to implementation to ensure that: (a) reasonable attempts have been made to locate additional sources of funds (for example, issuing an open request for proposals to companies in the category); and (b) the expected benefits of the project merit the additional risk to the AMA of accepting single-source funding. In all cases of single-source funding, the AMA will guard against conflict of interest.

3. The relationship must preserve AMA's control over any projects and products bearing the AMA name or logo. The AMA retains editorial control over any information produced as part of a corporate/externally funded arrangement.

   When an AMA program receives external financial support, the AMA must remain in control of its name, logo, and AMA ~~entire~~ content, and must approve all marketing materials to ensure that the message is congruent with the AMA's vision and values. A statement regarding AMA editorial control as well as the name(s) of the program's supporter(s) must appear in all public materials describing the program and in all educational materials produced by the program. (This principle is intended to apply only to those situations where an outside entity requests the AMA to put its name on products produced by the outside entity, and not to those situations where the AMA only licenses its own products for use in conjunction with another entity's products.)

4. Relationships must not permit or encourage influence by the corporate partner on the AMA.

   An AMA corporate relationship must ~~should~~ not permit influence by the corporate partner on AMA policies, priorities, and actions. For example, agreements stipulating access by corporate partners to the House of Delegates or access to AMA leadership would be of concern. Additionally, relationships that appear to be acceptable when viewed alone may become unacceptable when viewed in light of other existing or proposed activities.

5. Participation in a sponsorship program does not imply AMA's endorsement of an entity or its policies.

   Participation in sponsorship of an AMA program does not imply AMA approval of that corporation's general policies, nor does it imply that the AMA will exert any influence to advance the corporation's interests outside the substance of the arrangement itself. The AMA's name and logo should not be used in a manner that would express or imply an AMA endorsement of the corporation or its policies.

6. To remove any appearance of undue influence on the affairs of the AMA, the AMA should not depend on funding from corporate relations for core governance activities.

   Funding core governance activities from corporate sponsors, ie, the financial support for conduct of the House of Delegates, the Board of Trustees and Council meetings could make the AMA become dependent on external funding for its existence or could allow a supporter, or group of supporters, to have undue influence on the affairs of the AMA.

7. Funds from corporate relations must not be used to support political advocacy activities.

   A full and effective separation should exist, as it currently does, between political activities and corporate funding. The AMA should not advocate for a particular issue because it has received funding from an interested corporation. Public concern would be heightened if it appeared that the AMA's advocacy agenda was influenced by corporate funding.

Organizational Review

Every proposal for an AMA corporate relationship must be thoroughly screened prior to staff implementation. Currently, all proposed corporate arrangements are reviewed by a cross-disciplinary group of senior managers called the Corporate Review Team (CRT). CRT recommendations that meet certain criteria requiring further review are forwarded to a committee of the Board of Trustees. The full Board reviews any proposals that meet defined criteria for a heightened level of scrutiny.

1. All AMA corporate arrangements will be annually reported by the Board of Trustees to the House of Delegates at the Interim meeting in December.

   It is important for the AMA to have an orderly and predictable reporting process to the Board and the House of Delegates. The Board of Trustees will present a summary report to the House of Delegates at each Interim Meeting.

2. ~~The Board of Trustees must approve all proposals for AMA corporate relationships.~~Every new AMA Corporate Relationship must be approved by the Board of Trustees, or through a procedure adopted by the Board.

   Every new AMA Corporate relationship must be approved by the Board of Trustees, or through a procedure adopted by the Board. Specific procedures and policies regarding Board review are as follows: (a) The Board routinely should be informed of all AMA corporate relationships; (b) The Board should perform an annual audit of an appropriate sample of AMA corporate relations activities; (c) Upon request of a dissenting member of the CRT, any dissenting votes within the CRT, and instances when the CRT and the Board committee differ in the disposition of a proposal, are brought to the attention of the full Board; (d) All externally supported corporate activities directed to the public, except patient materials linked to CME, should receive Board review and approval; (e) All activities that have support from only one corporation within an industry should either be in compliance with ACCME guidelines or receive Board review; and (f) All relationships where the AMA takes on a risk of substantial financial penalties for cancellation should receive Board review prior to enactment.

3. The Executive Vice President is responsible for the review and implementation of each specific arrangement according to the previously described principles.

   The Executive Vice President is responsible for obtaining the Board of Trustees authorization for externally funded arrangements that have an economic and/or policy impact on the AMA.

4. The Corporate Review Team reviews corporate arrangements to ensure consistency with the principles and guidelines.

   The Corporate Review Team is the internal, cross-organizational staff group that is charged with the review of all activities with external funding to assure adherence to the guidelines.

   The Corporate Review Team is chaired by the ~~Vice President for Corporate, Foundation and International Relations~~ Senior Vice President, Governance and Operations and composed of senior managers from Ethics Standards; Legal; Finance; Communications; Publishing; ~~Marketing;~~ AMA Press; Membership; Advocacy and Science.

   The review process is structured to specifically address issues pertaining to AMA's policy, ethics, business practices, corporate identity, and reputation. Written procedures formalize the committee's process for review of corporate arrangements.

   All activities placed on the Corporate Review Team agenda have had the senior manager's review and consent, and following CRT approval will continue to require the routine approvals of the Office of Finance and Office of the General Counsel.

   The Corporate Review Team reports its findings and recommendations directly to a committee of the Board.

5. The AMA's ~~Group on Foundation and Corporate Relations~~ Office of Risk Management in consultation with the Office of the General Counsel will review and approve all marketing materials that are prepared by others for use in the US and that bear the AMA's name and/or corporate identity.

All marketing materials will be reviewed for appropriate use of AMA's logos and trademarks, perception of implied endorsement of the external entity's policies or products, unsubstantiated claims, misleading, exaggerated or false claims, and reference to appropriate documentation when claims are made. In the instance of international publishing of JAMA and the Archives, the AMA will require review and approval of representative marketing materials by the editor of each international edition in compliance with these principles and guidelines.

Organizational Culture and its Influence on Externally Funded Programs

1. Organizational culture has a profound impact on whether and how AMA corporate relationships are pursued. AMA activities reflect on all physicians. Moreover, all physicians are represented to some extent by AMA actions. Thus, the AMA must act as the professional representative for all physicians, and not merely as an advocacy group or club for AMA members.

2. As a professional organization, the AMA operates with a higher level of purpose representing the ideals of medicine. Nevertheless, non-profit associations today do require the generation of non-dues revenues. The AMA should set goals that do not create an undue expectation to raise increasing amounts of money. Such financial pressures can provide an incentive to evade, minimize, or overlook guidelines for fundraising through external sources.

3. Every staff member in the association must be accountable to explicit ethical standards that are derived from the vision and values of the association. In turn, leaders of the AMA must recognize the critical role the organization plays as the sole nationally representative professional association for medicine in America. AMA leaders must make programmatic choices that reflect a commitment to professional values and the core organizational purpose.

34. CPT EDITORIAL PANEL REPRESENTATION

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At the American Medical Association House of Delegates 2001 Interim Meeting, Resolution 803, "Pediatric Representation on the CPT Editorial Panel," was submitted by the American Academy of Pediatrics. Resolution 803 called on the AMA Board of Trustees to designate a permanent seat on the CPT Editorial Panel to a physician with pediatric primary care training. During Reference Committee, significant testimony was presented in strong opposition to slotted specialty seats on the CPT Editorial Panel. The argument was made that slotted seats for one specialty would lead to slotted seats for all specialties in the House of Delegates. Also, the point was made that the real issue is the difficulty pediatricians have in uniquely describing the services provided to their patient population and problems associated with appropriate payment for services on very young and fragile patients. A substitute resolution was proposed that requested that the Board study the issue, but limited the study to a few specialties. The Reference Committee believed that a study was necessary and chose to expand the scope to all physicians who provide care to special populations.

In response to Reference Committee concerns and testimony, Substitute Resolution 803, was retitled "CPT Editorial Panel Representation," and was adopted. Substitute Resolution 803 calls on the AMA Board of Trustees to study, document and report on the mechanism for choosing CPT Editorial Panel participants and delineate the process for including physicians who care for special populations on the Panel.

This Board of Trustees report is intended to respond to and clarify issues raised in Substitute Resolution 803 (I-01). The report will also review the issue of designating slotted specialty seats that was originally raised in Resolution 803. The report further discusses: (1) past BOT actions related to appropriate medical specialty representation on the Panel; (2) criteria for nomination and selection of CPT Editorial Panel members; (3) the current CPT Editorial Panel composition, specialty mix, and Advisory process; and (4) considerations and consequences of expanding the CPT Editorial Panel.

BACKGROUND

At its August 1998 and April 1999 meetings, the AMA Board of Trustees addressed several issues regarding the composition of the CPT editorial process. Among the topics discussed, the Board focused on specialty society representation, rotation of specialty society seats, and the concept of slotted specialty seats.

During these discussion, the Board reviewed the nominating and selection process for the CPT Editorial Panel and Advisory Committee. The Board expressed concern regarding whether the current process provides the optimal mix of candidates representing the broadest speciality mix. Additionally, the Board expressed concern about whether the panel and advisory committee were adequately comprised of physicians who were involved in direct patient care with the necessary technical expertise in clinical issues and in coding.

The Board requested a review of the criteria for nominees for the Editorial Panel and Advisory Committee as well as a review of the selection and evaluation process for Panel and Advisory Committee members, and revision of the criteria as appropriate to address their concerns. The Board requested a report back at its April 1999 meeting.

At its April 1999 meeting, the Board received a discussion paper which outlined the current criteria for nominees and the selection process. The following recommendations were approved:

1. Adopted criteria for selection of AMA appointments to the CPT Editorial Panel:

    - Physicians licensed to practice in the US
    - Current AMA member
    - Agreement to comply with the rules of the CPT Editorial Panel as approved by the AMA Board of Trustees
    - Agreement to comply with the guidelines for committee and council expenses
    - Participation in AMA staff orientation session and/or mentoring by current Panel members
    - Availability to attend scheduled CPT Editorial Panel meetings
    - Disclose conflict of interest
    - Technical expertise in coding and related topics

2. Requested that the criteria be distributed to specialty Executive Directors and signed by the Panel member.

When nominations to the Editorial Panel are submitted, the sponsoring organization must include information on the nominee's specialty, professional appointments, membership on AMA councils and committees, state/county medical society activities, and a curriculum vitae to assist the Board in its review and appointment of nominees. A nomination summary form is also forwarded requesting the nominee's signature to verify his or her ability/willingness to carry out their responsibilities to the Panel.

Nominations for the Editorial Panel are solicited from national medical specialty societies. Letters are sent from the AMA's Executive Vice President to the Chief Executive Officers of the specialty societies requesting nominations for all vacant positions. These letters indicate the criteria for nomination as indicated above.

Once nominations are received, AMA physician profiles are checked to verify membership status, specialty designation, and board certification. This information is compiled for review and discussion by the Nominating Committee of the Board who then makes recommendations to the entire Board. The full Board votes and selects the Editorial Panel members.

In addition to adopting revised criteria for nominees and revision of the selection process, the Board discussed the issue of slotted seats on the CPT Editorial Panel. Excerpts from the April 1999 Discussion Paper state:

> Recently, the issue of slotted seats on the CPT Editorial Panel has been raised by the American College of Radiology. Over the years, the composition and mix of specialty societies represented on the Panel have been taken into account as new members were added to the Panel. A concerted effort has been made to assure that the major specialties have representation and rotating subspecialty representation on the Panel. While there have been a few complaints over the years by a specialty that failed to win a seat, overall the composition of the Panel has been effective. Experience also suggests that it would be impossible to limit slotted seats to a few specialties only or to maintain the Editorial Panel size at a level compatible with its

functioning as an effective, working editorial board. Therefore, **it is recommended that formal slotted seats on the Editorial Panel be avoided**. Additionally, it is recommended that Rule 3, of the CPT Editorial Panel Rules of Procedures, should be modified to clarify the intent to have representation of a broad range of specialty and practice mix on the CPT Editorial Panel.

The Board accepted this recommendation and modified Rule 3 of the CPT Editorial Panel Rules of Procedures as follows:

Rule 3 - Members:

The CPT Editorial Panel shall be composed of fifteen (15) physicians who are knowledgeable in matters of medical procedure nomenclature and coding. All physicians serving on the Panel must be AMA members. *Panel Members shall be chosen to effect representation of a broad range of specialty and practice settings consistent with the scope of CPT.*

As highlighted above, the Board has reviewed the issue of broad representation of medical specialty societies on the CPT Editorial Panel on several occassions. As a result of these discussions, efforts have been made to include physicians who care for special populations. However, special consideration has not been given to some specialty groups over others based on patient population. This consideration is generally reserved for the Advisory Committee.

CPT EDITORIAL PANEL TERMS AND COMPOSITION

The CPT Editorial Panel maintains CPT. This sixteen-member (15 physician) panel is authorized to revise, update, or modify CPT. The CPT code set is updated annually to ensure that it accurately reflects current medical practice. The AMA Board of Trustees appoints all members of the CPT Editorial Panel from nominations. Eleven of the seats on the Editorial Panel are nominated by the AMA from the national medical specialty societies with one seat reserved to represent the managed care industry. The remaining seats are nominated by the Blue Cross and Blue Shield Association, the Health Insurance Association of America, the Centers for Medicare and Medicaid Services, the American Hospital Association and the co-chair of the Health Care Professional Advisory Committee (HCPAC) representing non-MD/DO health professionals.

Of the 11 AMA seats on the Panel, seven are regular seats, have a maximum tenure of two four-year terms, or a total of eight years for any one individual. The four remaining seats, called rotating seats, have one four-year term. These rotating seats allow more multi-disciplinary input.

In October 1996, the AMA completed successful negotiations with the Centers for Medicare and Medicaid Services (CMS) (formerly Health Care Financing Administration) to expand the size of the Panel by two voting members from 14-16 to include a representative from the managed care industry and a non-physician health professional. In addition, at this time the Chair of the CPT Editorial Panel requested changes in the Panel's structure and terms. Specifically, the length of term for the full and rotating seats was increased from 3 years to 4 years. This was done to allow individuals to learn the editorial process and CPT coding more completely and to allow the Panel to benefit from their experience. Longer terms also provide greater continuity while preserving the rotation concept.

Since 1995 the following specialties have been on the Panel and rotated off, illustrating the effectiveness of rotating seats and the breadth of medical specialties on the CPT Editorial Panel:

- American Academy of Family Physicians
- American Academy of Orthopaedic Surgeons
- American Academy of Pediatrics
- American Association of Neurological Surgeons
- American College of Cardiology
- American College of Emergency Physicians
- American College of Physicians - American Society of Internal Medicine
- American College of Radiology
- American Podiatric Medical Association
- College of American Pathologists

The CPT Editorial Panel has an Executive Committee to handle the appeals process and other administrative activities. The Executive Committee includes the chair, the vice chair, and three other members of the Panel, as elected by the entire Panel. One of the three members at-large of the executive committee must be a third party payor representative.

Panel members and their specialty affiliation are as follows:

James Adamson, Jr., MD	Infectious Disease (BCBCA)
Karen R. Borman, MD	General Surgery (Vice Chair)
Simon P. Cohn, MD	Emergency Medicine (managed care)
Lee D. Eisenberg, MD	Otolaryngology
Helene M. Fearon, PT	Physical Therapy (HCPAC Co-Chair)
Laurie Feinberg, MD	Physical Medicine and Rehabilitation (CMS)
Blaire C. Filler, MD	Orthopaedic Surgery
Tracy R. Gordy, MD	Psychiatry (Chair)
Diller B. Groff, MD	Pediatric Surgery
Samuel Hassenbusch, MD	Neurological Surgery
Lee H. Hillborne, MD	Pathology (AHA)
Glenn D. Littenberg, MD	Internal Medicine
Gerald E. Silverstein, MD	Internal Medicine (HIAA)
Stanley W. Stead, MD	Anesthesiology
William T. Thorwarth, MD	Radiology
James A. Zalla, MD	Dermatology

As of August 2002, the terms of two members of the CPT Panel terms will expire. One is a "full seat" with a maximum of two terms (8 years). This seat is currently occupied by Glenn Littenberg, MD, whose specialty is internal medicine. Dr. Littenberg is eligible for reappointment. The second seat is a "rotating seat" with a maximum of one term (4 years) currently occupied by James A. Zalla, MD, a dermatologist. Dr. Zalla is not eligible for reappointment. The Board of Trustees will consider these appointments at its June 2002 meeting.

The CPT Editorial Panel is supported in all its activities by the CPT/HCPAC Advisory Committee. The Advisory Committee includes physicians from the national medical specialty societies in the AMA House of Delegates and the Health Care Professionals Advisory Committee. The primary objective of the Advisory Committee is to serve as a resource to the Editorial Panel by giving advice on coding and appropriate nomenclature as relevant to the member's specialty. Advisors also provide the Panel with documentation regarding the clinical appropriateness of various medical and surgical services and procedures under consideration by the Panel. The Advisory Committee meets annually to discuss issues of mutual concern and to keep current on issues in coding and nomenclature. Most importantly, the CPT Advisory Committee provides a means for active participation in the CPT Editorial Process by all specialties in the AMA House of Delegates.

DISCUSSION

Despite the efforts of AMA staff and the Board to achieve a balance and an appropriate clinical mix of specialties on the CPT Editorial Panel, there continue to be concerns about specialty participation and demands for specialty slotted seats. The AMA/Specialty Society RVS Update Committee (RUC) is often used as a model where the slotted seat concept has been a success. In the interest of full discussion, the option and impact of specialty specific slotted seats will be discussed in relation to the RUC model. After discussion of the RUC model, the costs and benefits of applying this model to the Panel will be reviewed. Finally, recommendations will be developed.

The AMA/Specialty Society RVS Update Committee (RUC) was formed in 1991 to make recommendations to the Centers for Medicare and Medicaid Services (CMS) on the relative values to be assigned to new or revised CPT codes as part of the new Resource Based Relative Value Scale (RBRVS) payment methodology for physician payment under Medicare Part B. Nearly 8,000 procedure codes are defined in CPT, and the relative values in the RBRVS have been developed to correspond to the procedure definition in CPT.

The RUC represents the entire medical profession, with 23 of its 29 members appointed by major national medical specialty societies including those recognized by the American Board of Medical Specialties, those with a large percentage of physicians in patient care, and those that account for high percentage of Medicare expenditures. Three seats rotate on a 2-year basis, with two reserved for an internal medicine subspecialty and one for any other specialty. The RUC Chair, the Co-Chair of the HCPAC, a representative of the AMA, the American Osteopathic Association, the Chair of the Practice Expense Advisory Committee (PEAC) and CPT Editorial Panel hold the remaining seats.

The RUC is supported by an Advisory Committee that represents each of the 102 specialty societies seated in the AMA House of Delegates. Specialty societies that are not in the House of Delegates may also be invited to participate in developing relative values for coding changes of particular relevance to their members. Advisory committee members designate an RVS Committee for their specialty, which is responsible for generating relative value recommendations using a survey method developed by the RUC. The Advisors attend the RUC meeting and present their societies' recommendations, which the RUC evaluates. Specialties represented on both the RUC and the Advisory Committee are required to appoint different physicians to each committee to distinguish the role of advocate from the of evaluator.

AMA staff recognizes a disparity in the amount of medical professional representation on the RUC as compared to the number of different specialties seated on the CPT Editorial Panel. However, to attain greater multidisciplinary medical profession representation, the CPT Editorial Panel would need to increase the number of specialty seats from 16 to 31 seats in order to correlate with medical surgical specialty composition on the AMA/Specialty RVS Update Committee (RUC). Although seat appointments from the designated 23 major national medical/surgical specialties, including those recognized by the American Board of Medical Specialties, may resolve concerns regarding permanent specialty representation on the Editorial Panel, it raises many other serious concerns.

The nature of the work conducted by the RUC and the Panel is very different. The RUC is charged with making relative value recommendations to CMS based on survey data and expert opinion on the amount of physician work relative to other services. In order to establish physician work relativity, multi-specialty input is needed to assure proper weighting within the overall fee schedule. In addition, the budget neutrality requirement of the Medicare Fee Schedule means that all of medicine is potentially effected by RUC recommendations, thus requiring broad specialty input. The CPT Editorial Panel operates as a rigorous peer review body charged with assigning code descriptors that are clinically accurate, internally consistent, and functionally integrated into the overall coding structure. In order to accomplish this, Panel members struggle over coding conventions, nomenclature, and language nuances. While Panel deliberations need to be informed by broad multidisciplinary clinical input, Panel decision-making is facilitated by maintaining a relatively small group that is expert on procedure coding nomenclature and associated established conventions. Exposing Panel decision-making to broad specialty input on the scale of the RUC would bog the process down and potentially risk the quality of the end product by encumbering the decision making.

Currently the Editorial Panel is under considerable pressure from physicians, other health care professionals, and manufactures to expedite the CPT code development and maintenance process. In addition, the designation of CPT as a national standard under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that code set developers maintain current and up-to-data code sets so that coded services and procedures can be included on electronic financial and administrative claims. The addition of slotted seats to include the major medical specialty societies would have the effect of slowing the Panel decision-making process at a time when the Panel is considering steps to expedite the process.

The financial commitment of the AMA to the CPT Editorial Panel is much greater than to the RUC. The AMA assumes all the costs of the Editorial Panel. The expenses of each member of the CPT Editorial Panel and all meeting expenses are paid by the AMA. For the RUC, the AMA only pays for meeting costs and the expenses of the two AMA appointees. Increasing the Panel members from 16 to 31 to mirror the RUC would almost double the cost of the quarterly Panel meetings.

The expansion of the CPT Editorial Panel might not end the call for specialty specific representation. Despite 23 slotted seats, the RUC is regularly petitioned to add permanent seats for specialties not currently represented. With more than100 medical specialty societies in the AMA House of Delegates the demand for permanent seats is constant. Opening the CPT Editorial Panel to slotted seats would subject the Editorial process to demands of even greater expansion.

CONCLUSION

The Board of Trustees believes that the addition of slotted specialty seats, along the lines of the RUC process, is flawed when applied to the work of the CPT Editorial Panel and the establishment of only a few slotted seats on the Panel is unsustainable for the following reasons:

- Jeopardize Editorial Decision Making - Slotted seats would greatly increase the size of the panel, thus constraining editorial decision making which is facilitated by a limited number of individuals who are free to engage in active deliberations on the nuances of clinical terminology, language and conventions for classification.

- Bog the Process Down - Increasing the size of the CPT Editorial Panel would greatly slow the process of code development at a time when the Panel is under pressure to make its processes more efficient, to streamline code development and maintenance.

- Increase Costs - Any increase to the size of the Panel would proportionally increase the cost of the CPT Editorial process to the AMA.

- Slippery Slope - The addition of a few specialty specific slotted seat would result in a flood of other specialties requesting similar treatment, making it difficult to limit the size of the Panel.

For these reasons, it is recommended that slotted seats on the Editorial Panel be avoided. In addition, the CPT Advisory Committee provides a direct and productive mechanism for broad specialty input to Panel deliberations. Indeed, specialty Advisors are relied on by the Panel for their technical expertise and clinical contributions. Thus, the additional complexity of special physician representation for unique patient populations is not only unnecessary but also potentially detrimental to the Panel's efficiency and effectiveness as a working editorial board. Additionally, the AMA Board of Trustees has duly exercised its' oversight of the CPT Panel appointment process by expressing concern that the CPT Editorial Panel have representation of a broad range of specialty and practice mix. Language was added to the Panel Rules of Procedure to require that Panel members be chosen to effect representation of a broad range of specialty and practice settings.

The process established to include input from medical specialties through the CPT Advisory Committee is functioning smoothly. However, the Panel has long recognized the need to involve those who are affected by change in CPT, but are outside the practice of medicine. The designation of CPT as a national standard code set under HIPAA has placed new responsibilities on the AMA and the Editorial Panel as the maintainer of CPT. As such it is necessary to explore the further opening of the CPT Editorial Process to include new interests. To examine the pros and cons of greater Panel openness, the AMA contracted with a consultant, Bart McCann, MD, former CPT Editorial Panel member and representative of the Health Care Financing Administration (currently CMS). Dr. McCann was commissioned to develop a background paper which was entitled, "Expansion of the CPT Editorial Process". This paper was discussed at the annual CPT/HCPAC Advisory Committee meeting in November 2001 and offered survey results of key stakeholders of CPT and their views concerning the extent that the CPT process should be more open. The paper has not been finalized, but it is expected for the Board's discussion in June. At that time the Board will review all options for changes to the Panel process and make recommendations.

RECOMMENDATIONS

The Board of Trustees recommends that:

1. That the CPT Editorial Panel be kept at a size compatible with its functioning as an efficient and effective editorial board and should not be subject to the requirement of formal slotted seats for individual specialty societies.

2. That while the role of the CPT Advisory Committee as clinical and technical experts to the CPT Editorial Panel is important, necessary, and currently of satisfactory composition, the need to expand as the practice of medicine changes or the scope of the CPT code set changes should be regularly evaluated.

3. That the remainder of this report be filed.

35. LIABILITY REFORM

HOUSE ACTION: FILED

HOUSE OF DELEGATES ACTION

At the 2001 Interim Meeting, the House of Delegates adopted Substitute Resolution 212, which makes a strong statement about the American Medical Association's renewed commitment to working at the state and federal levels to enact meaningful liability reform. The resolution specifically mentions the importance of the Association's Advocacy Resource Center in these efforts. As adopted, the resolution provides:

> That our AMA immediately reestablish tort reform, particularly a cap on non-economic damages, as a top legislative priority, with special emphasis on support for states attempting to enact or preserve legislation addressing this issue, in addition to a renewed push for comprehensive professional liability reforms at the federal level;
>
> That our AMA convene, as soon as possible, a new coalition comprised of our AMA, state and national medical specialty associations to develop and implement a comprehensive strategic plan that will address all aspects of the growing professional liability crisis, including but not limited to: (1) seeking Federal and state professional liability reform legislation, including a cap on non-economic damages; (2) evaluating and developing methods for improving the adequacy of reimbursement for professional liability expenses under Federal, state and private health insurance programs; and (3) developing mechanisms aimed at reducing the incidence of professional liability lawsuits and their associated costs;
>
> That as a complement to new coalition activities on tort reform, our AMA convene an initial planning/ strategy meeting on state tort reform, through our AMA Advocacy Resource Center at the January 2002 AMA State Health Legislation meeting;
>
> That in advancing any federal legislative solution to the professional liability crisis, our AMA closely follow existing Policy H-435.964, relating to federal non-preemption of state constitutional, statutory, regulatory and common laws on professional liability; and
>
> That the Board of Trustees report back to the House of Delegates at the 2002 Annual Meeting.

This report responds to Resolution 212 to inform the House of Delegates about the current liability situation and Association activities taken since the last House meeting.

BACKGROUND

The medical liability issue has been a decades-long battle for physicians across the country. Throughout this period, medicine has been able to slow down and manage this issue with some success. Unfortunately, this issue has been virtually impossible to solve on a permanent basis at the national level. While there has been some success on the state level, only a few states have been successful in legislating strong medical liability reforms that have been lasting. Some state laws have been sustained by the courts, while others have been found unconstitutional.

What has not changed are physicians' concerns regarding the fairness of the legal system, insurance affordability and insurance availability, and in some cases a lack of coverage options at any cost. During the mid-1970s, physicians coped by starting their own insurance companies to provide protection and the AMA created a reinsurance subsidiary for medical liability claims (AMACO). Since then, there have been reoccurring problems in both the decades of the 1980s and 90s. Cost and availability of coverage are again becoming problems in select locations as we enter the twenty first century.

CURRENT SITUATION

The general trend of all jury awards recently has seen a dramatic increase in monetary awards and settlements. The median medical liability award is rising, as a greater number of awards have topped $1 million. According to data released in March by Jury Verdict Research, median jury awards in medical liability cases increased 43 percent in 1 year (1999-2000) from $700,000 to $1,000,000. Jury awards are now averaging near $3.5 million. While the

number of final settlements have decreased 16%, the expense of settling a medical liability case has also increased significantly. The insurance underwriting cycle is now at a point where insurers have both pricing power and a need to increase revenues through premiums as returns on investments are no longer able to subsidize underwriting loses and as insurers have suffered large claims losses in other areas. This situation has created the "perfect storm" of increasing jury awards, coupled with adjustments in professional liability insurance underwriting, fueling double-digit annual increases in premiums. Some insurers are reported to be refusing to cover select categories of physicians (e.g., obstetrics & gynecology, neurology, etc.). Some insurers are dropping medical liability insurance all together (e.g., St. Paul Insurance). Mississippi, Florida, West Virginia, New York, Nevada, and Pennsylvania are in a crisis situation today. Some state-operated liability programs (e.g., New York, Pennsylvania) are facing severe funding shortages and post-September 11 tax revenues are not meeting earlier projections.

The litigation climate, coupled with these economic conditions and business decisions, is reported to be adversely impacting access to care by forcing physicians to retire early, reduce the scopes of their practice or, in some reported instances, relocate. For some parts of the country, it has been reported in the press that access issues are reaching crisis proportions. Shortly, certain physician specialties will be non-existent in select areas around the country. Across the country, reports are increasing regarding the scope of the liability problem.

- Medical liability insurance premiums are soaring at the highest rate since the mid-1980s, adding to rising health care costs.

- Some of the biggest insurers are raising rates in many states more than 30 percent. Even insurers owned by doctors and hospitals, which strive to keep rates low, are increasing premium rates 10% to 18%. This is happening at the same time as Medicare has reduced physician payment rates by 5.4 percent. The impact of the Medicare reductions goes far beyond the federal program since many health insurers peg their payment to a percentage of the Medicare rate.

- Insurers began raising rates in 2000, after several years of price-cutting competition that left premiums trailing inflation. A 14% rise in premiums in that year was the largest since 1994, and insurers say the increases are accelerating greatly this year.

- Kenneth S. Abramowitz, a managing director at the Carlyle Group, a New York investment firm, who specializes in the health care industry, said: "The rising cost of malpractice coverage is becoming one of the most important factors driving inflation for physicians' services, particularly for high-priced specialists in surgery and obstetrics."

- The price increases are highest for obstetricians, gynecologists, and surgeons, the specialists who are sued the most frequently. In New York and Florida, these physicians pay more than $100,000 a year for $1 million in coverage.

- The Clarendon Insurance Group, one of the market leaders in Florida, has raised its premiums for obstetricians and gynecologists in the southeastern part of the state to more than $200,000, up from about $158,000 last year, said Carol Brierly Golin, editor of the *Medical Liability Monitor*, an industry newsletter.

- Insurers put most of the blame for the increases on a jump in big awards by juries and large settlements. While the number of liability suits has been holding steady, the average jury award rose to $3.49 million in 1999, up 79 percent from $1.95 million in 1993, according to the latest compilation by Jury Verdict Research of Horsham, Pennsylvania.

- For several years, insurers kept prices artificially low while competing for market share and new revenue to invest in a booming stock market. As the bull market surged, investments by these historically conservative insurers rose to 10.6% in 1999, up from a more typical 3% in 1992. With the market now in a slump, the insurers can no longer use investment gains to subsidize low rates. The industry reported realized capital gains of $381 million last year, down 30% from the high point in 1998, according to the A.M. Best Company, one of the most comprehensive sources of insurance industry data. About 60% of the liability insurance is provided by mutual companies, owned by doctors and hospitals that are inclined to err on the side of keeping rates low. Commercial insurers, battling for market share, also restrained their prices.

- One of the largest companies, PHICO, which sells insurance nationally but concentrates on New Jersey and Pennsylvania, was taken over in August, 2001 by regulators in Pennsylvania, where it is based, when claims threatened to outrun the company's ability to pay. Later in the month, another big company, the Frontier Insurance Group, based in Rock Hills, New York, was taken over by New York regulators. Insurers now acknowledge their miscalculations. "We should have raised prices sooner," said Mike Miller, the senior executive in charge of liability coverage at the St. Paul Companies. St. Paul, the second-largest liability insurer, had raised rates for doctors an average of 24% in 2001 in 25 states, with rates jumping 65% in Ohio and Mississippi.

- On December 12, 2001, St. Paul announced that it was completely withdrawing from the medical liability market. It had withdrawn coverage of obstetricians/gynecologists, general surgeons, and emergency physicians about a year prior to that. SCPIE Companies is raising rates an average of 30% to 50% in a dozen states, including Florida and Texas.

- In New York, one of the most litigious states, where neurosurgeons on Long Island pay $155,000 a year for $1 million in coverage, insurance executives say they are seeing rising costs that could soon result in still-higher premiums. Donald J. Fager, who is in charge of daily operations for the MLMIC Group, the state's largest liability insurer, said that by midyear, claims costs were running $21 million, or 12%, ahead of last year. In New Jersey, insurers do not expect the market leaders to make sharp increases this year. In Connecticut, one of the leading companies, the Connecticut Medical Insurance Company, has raised its rates 16% this year. State regulators said the company also cut dividends to doctors, who are both customers and owners, effectively raising its rates another 33%. SCPIE, one of the smaller companies in the state, has raised its rates 35%.

- During 2001, in California, juries awarded more than $1 million in 39 liability lawsuits, up from 28 seven years earlier, according to Medical Underwriters of California. The average award rose to $2.9 million from $2 million.

- Select Manual Rates (as reported by *Medical Liability Monitor*)

  Internists
  - Florida (Dade and Broward counties) - $17,611-$50,774
  - Michigan (Detroit area) - $18,376-$40,233
  - Illinois (Chicago/Cook County) - $15,539-$28,153
  - Ohio (Cleveland area) - $10,853-$16,270
  - Texas (Dallas, Houston, Galveston) - $14,552-$25,563
  - Nevada (Las Vegas area) - $11,636-$15,804
  - New York (New York, Nassau, Suffolk counties) - $16,751-$21,648

  General surgeons
  - Florida (Dade/Broward counties) - $63,189-$126,599
  - Texas (Dallas, Houston, Galveston) - $34,306-$133,957
  - Michigan (Detroit area) - $66,611-$94,195
  - Illinois (Chicago/Cook County) - $50,021-$70,178
  - Ohio (Cleveland area) - $33,397-$60,021
  - Nevada (Las Vegas area) - $40,388-$56,892
  - West Virginia - $36,094-$56,371

  Obstetricians/gynecologists
  - Florida (Dade/Broward counties) - $143,249-$202,949
  - Texas (Dallas, Houston, Galveston) - $69,918-$160,746
  - New York (New York, Nassau, Suffolk counties) - $89,317-$115,429
  - Michigan (Detroit area) - $87,444-$123,890
  - Illinois (Chicago/Cook County) - $88,928-$110,091
  - Ohio (Cleveland) - $58,131-$95,310
  - Nevada (Las Vegas area) - $71,092-$94,820
  - Ohio (Cleveland) - $58,131-$95,310
  - West Virginia - $63,165-$84,551

- Late in 2001, insurance coverage in West Virginia began to dry up and premiums began to increase. As a stop-gap measure, the legislature opened up the plan that covers physicians employed by the state to private practitioners who could not obtain alternate coverage (at a premium of 110% of the highest private coverage available in the state).

- In Pennsylvania, major medical centers were faced with the closure of emergency departments due to a lack of coverage for certain specialists. Pennsylvania requires coverage as a condition of licensure. A stop-gap was put in place at the very end of the year and some tort reform were enacted this year, after an extended struggle.

- In Mississippi, the state medical society pressed for major tort reforms, but while the legislation passed the House in 2002, it died in the Senate.

- In Nevada, the Las Vegas area has been especially hard hit by the withdrawal of St. Paul. Many physicians in the Las Vegas area having trouble obtaining coverage at an affordable rate. The University of Nevada at Las Vegas has announced that it may not be able to maintain 7/24 coverage for its trauma unit due to a lack of coverage for two of its surgeons. Many physicians left their practice for a day to attend a meeting with of the state insurance commissioner. There is no legislative session this year and the governor has authorized a bridge coverage program to go into effect on April 15.

- In the last three months, 3 significant writers of medical liability policies have had their ratings lowered by the A.M. Best Co., indicating a further deterioration of the market for coverage.

CURRENT CLIMATE FOR REFORM

Federal - Historically, the makeup of the Senate has long been a major hurdle towards a federal solution to this issue. Majority party philosophies, difficult committees of jurisdiction, trial lawyer legislators, trial lawyer financial support and filibuster-proof vote margins have prevented enactment of MICRA style tort reforms. Likewise, during most of the 1990s, it was clear that President Clinton would not sign any major reforms in this arena.

A few developments have been responsible for review of a federal strategy. A number of members of the House and Senate have begun to express interest in reviewing this issue and determining if there is a remedy on the federal level. Second, the White House now seems to be looking into this issue. Leadership on this issue by the White House would open the door.

In the near term, Congress will remain a difficult arena in which to accomplish significant tort reform. There will be tremendous pressure to preserve and promote MICRA reforms. The effort on this level will probably take an extended period of time. National specialty societies will be welcome partners in this campaign. By most estimates, at this time there are no more than 41 or 42 favorable votes in the US Senate (of the needed 60 to close off a filibuster) and support has slipped in the U.S. House of Representatives.

States - This has long been an issue on the state level. Every state has enacted some type of statutory reform in an effort to discourage filing and adjudication of frivolous lawsuits. State medical societies are closely re-evaluating their existing laws in light of increasing jury verdicts, dramatic increases in physician insurance premiums, and concerns regarding access to care. During the current cycle, the results have been mixed, with West Virginia basically providing availability of coverage over the short term, Pennsylvania enacting certain reforms that provide a good first step for their state, and Mississippi having adjourned for the year with no final action, after a major effort by the State Medical Society. In Nevada, the legislature does not meet this year, though the Governor has put in place a temporary insurance solution and legislative hearings began in March. As a result, short-term results may be more feasible in the state legislatures.

Judicial - Although the judicial system has not been an ally on this issue, the constitutionality of state tort reform measures is being addressed by state supreme courts. The extent of the statutes challenged has ranged from damage caps to comprehensive reforms. While some courts have overturned the reform laws on constitutional grounds, others have upheld them. For example, Texas Medical Association made it a priority to seek to change the composition of the state's highest court through political action, though 2002 could see major changes on that court due to the election of new members. The Pennsylvania Medical Society has also begun such a process and other states are considering such action. In some states, it may be possible to pursue such a strategy, giving reforms, when passed, a better opportunity to succeed. The courts are important players and cannot be ignored. By only one vote,

the Ohio Supreme Court overturned major reforms passed in 1996, after major battles in the Legislature. AMA is a founding and active member of the American Tort Reform Association (ATRA) and various civil justice groups throughout the country. ATRA, along with state based civil-justice reform leagues, is activating a campaign targeting select state supreme court races for action. Many medical specialty societies also belong to ATRA. Likewise, most state medical association are highly supportive and actively involved in civil just reform coalitions in their states.

House of Medicine - The climate of the "House of Medicine" is critical to any success. While professional liability has always been a priority with the AMA, a number of states again are facing crises, elevating this issue to top priority for advocacy. As noted above, the House of Delegates at the 2001 Interim Meeting, made one of its strongest statements in years, renewing the AMA's commitment to working at the state and federal levels to enact meaningful liability reform. Likewise, many, national medical specialty societies have prioritized liability reform as a major issue. As part of its prioritization pilot program, 95.1 percent of Delegates responding to Reference Committee B items cited liability reform (Resolution 212) as a "high" priority. (The next highest priority assigned by the House as part of this experiment was HIPAA privacy with a 75.2% high rating.) Data from physician surveys, focus groups and member-connect demonstrate that this is an issue that they want the AMA to make a major priority.

OVERVIEW OF REFORMS

At this time, AMA will be pursuing reforms to the tort system that have been proven to have impact on medical liability.

Statute of Limitations - State laws specify when an action for medical liability must be commenced. The statute of limitations for medical liability varies across the states. Generally, the statute of limitations begins to run when services are rendered, when an injury is discovered or should have been discovered, or some combination of the two. Many states also have a definite time frame within which claims must be commenced. Some state laws distinguish time frames for minors. Usually, these laws require actions to be commenced within a set number of years, or before the minor reaches a certain age, usually 18 or the age of majority. Other states distinguish between claims against health care providers and wrongful death actions. Finally, a few states distinguish claims brought by persons deemed incompetent by reason of mental illness, imprisonment, or disability.

Abolition of Joint and Several Liability - Some states require that joint tortfeasors each be responsible for the entire judgment. Often, the percentage of a party's fault determines if they are jointly and severally liable. For example, if 50% or more of the fault is attributed to one party, he or she is jointly and severally liable, but if that party is less than 50% liable, he or she is responsible only for his proportionate share. This benefits the claimant, who can seek total compensation from the "deep pocket" defendant. However, it is unfair to physicians and other defendants who may be required to pay the entire amount of the judgment, even if they were only partially at fault. In states that have abolished joint and several liability, physicians may not be held liable for the negligence of other defendants.

Contributory/Comparative Negligence - States with comparative negligence prohibit plaintiffs who are partially at fault for an injury from seeking the entire amount of damages from a defendant. The threshold percentage of fault varies from state to state. Comparative and contributory negligence laws serve to more accurately and fairly apportion damages among the parties.

Damage Caps - Most states have enacted some type of cap on damages recoverable in medical liability cases. These include caps on noneconomic damages, which include recovery for things like pain and suffering, loss of marital companionship, and loss of consortium. Noneconomic damages are nebulous and impossible to quantify, so some legislators believe that some reasonable limits must be placed on recovery. Punitive damages, intended to punish the defendant for his or her negligent behavior, are also not quantifiable and are therefore capped. Some states (such as Indiana), also have a cap on total damages including economic damages, and a few states index damage caps at the rate of inflation or some other economic indicator.

California enacted comprehensive tort reform in 1975. Entitled the "Medical Injury Compensation Reform Act" (MICRA), the law was enacted in response to skyrocketing judgments, increases in professional liability premiums, and diminishing access to care. The linchpin of the reforms was the - $250,000 cap set on noneconomic damages. Since MICRA's enactment, California's liability insurance market has stabilized and remained stable. Insurance rates for California physicians are among the lowest in the nation.

Other states were quick to follow California's lead, enacting some form of cap on recoverable damages. Currently, 25 states have enforceable damage caps. While some states have laws limiting damages, courts in their jurisdictions have ruled that damage caps are a violation of states constitutional rights to jury trials and/or access to courts. Supreme Courts in Illinois, Ohio, Oregon, and Washington issued rulings to this effect. In other states--among them Arizona and Wyoming--statutes have not been enacted because the state constitution prohibits capping damages. Damage caps can be an effective way of stabilizing the liability insurance market by prohibiting excessive damage awards. Such awards can result in increased liability insurance premiums for all physicians and ultimately may result in access problems for patients. Caps strike a balance between compensating injured patients for damages impossible to quantify, and encouraging the availability of health care. To demonstrate the effectiveness of MICRO reforms, one need only look to the comparisons between insurance premium rates in California and its neighbor, Nevada:

Specialty	Nevada	California	% Difference
Family and General Practice	$40,000	$28,000	42.9
Obstetrics & Gynecology	$83,000	$43,000	93.0
Internal Medicine	$16,000	$9,000	77.8
General Surgery	$50,000	$29,000	72.4
Orthopaedic Surgery	$51,000	$30,000	70.0

Source: The Doctors Company, 1998-2002 average rate by specialty

Limitations on Attorneys' Fees - Medical liability plaintiffs' attorney fees are capped in some states. Traditionally, these caps are structured as a percentage of total compensation in contingency fee cases. A few states apply a sliding scale based on the total amount of damages awarded in a case.

Patient Compensation Fund - Some states have established a patient compensation fund to provide coverage to physicians in excess of other coverage. Some funds are administered by the state; others are administered by a quasi-legislative entity. Generally, these are funded through surcharges from the physician community, but in some states, including New York, the fund receives money from the state budget.

Periodic Payment of Damages - Periodic damages are required in some states, allowing a defendant to pay the claimant a fixed amount periodically until the death of the claimant. Generally, this type of payment system is used for economic damages only. In medical liability cases, periodic payments are usually made for future medical expenses of the claimant. Other states do not mandate periodic payment, but allow any party to a lawsuit to request periodic payments. The court in some states must order such payment if requested; in other states, the court may exercise discretion in determining whether periodic payment is appropriate. This type of payment arrangement generally benefits physicians and insurers, who are sometimes required to pay huge verdicts that primarily benefit a claimant's beneficiaries. This prevents pay-outs of large amounts of money after the claimant's death and helps lessen the insurer's risk.

Abolition of Collateral Source Rule - In states with the collateral source rule, juries are prohibited from hearing evidence that the claimant has been compensated from other sources (e.g., insurance) for his injuries. Often, this means that the claimant collects twice for his injuries. In jurisdictions that have abolished the collateral source rule, juries are permitted to consider evidence that a plaintiff has been compensated from an external source in determining the damages payable to a claimant. In other states, evidence may be introduced, but only after a verdict is rendered. The judge then uses this information in determining the award. Courts in these states are more informed when determining how much a claimant should be compensated to make himself "whole." This information is helpful in determining the amount of damages that should fairly be awarded to a plaintiff.

Pre-trial Screening Panels - A few jurisdictions require medical liability cases to be heard before screening panels prior to litigation. Other states permit screening panels but do not require them as a prerequisite to litigation. In jurisdictions where the panel's decision is non-binding, the panel's decision may be admissible into evidence. Because they are a prerequisite to litigation, pre-trial screening panels discourage frivolous lawsuits. For example, they would discourage attorneys from pursuing cases where patients experience an adverse outcome from medical treatment but have not been injured through negligence. Because cases without merit clog the court system, screening panels also help ensure that only cases with merit are adjudicated and the court systems are not overburdened.

Arbitration/ADR - Over the last decade, an attempt has been made to discourage frivolous lawsuits by requiring or permitting arbitration in medical liability cases in lieu of litigation. In some states, arbitration may be binding; in others, litigation may commence after a decision unfavorable to one party. The benefits of arbitration parallel those of pre-trial screening panels. Not only does arbitration discourage frivolous lawsuits, but it also helps the judicial process run smoothly by eliminating from the court system such meritless cases. It also saves defendants money because these cases might not proceed through the costly litigation system.

Affidavit of Merit - An affidavit of merit, sometimes called a certificate of merit, is a procedural tool that some states employ to limit the adjudication of frivolous lawsuits. These affidavits generally may be filed by a plaintiff or a defendant in a medical liability action and must be filed within a definite time frame. A defendant may file an affidavit with the court certifying that he or she was not involved in the occurrence alleged in the lawsuit. Unless this affidavit is opposed, the court will dismiss the actions without prejudice. A party may oppose the dismissal if it can establish that the party filing the affidavit was involved the occurrence. In some states, a plaintiff must file an affidavit along with the complaint to establish that the claim has merit. In other states, plaintiffs must file such an affidavit following a defendant's answer to the complaint. It is usually signed by a health care professional who qualifies under state law as an expert witness. As with other pre-trial mechanisms, affidavits of merit help eliminate frivolous lawsuits which burden the court system, and can save defendants the costs of litigation.

AMA STRATEGIES

Communications - The House of Delegates, ongoing market research, and anecdotal field evidence all indicate that physicians want to know that the AMA is fighting for tort reform in an aggressive and public manner, with high impact action. The twin objectives: effect needed change and build membership.

The AMA will execute a three-pronged strategy: (1) demonstrating to physicians that the AMA, state medical societies, national medical specialty societies and other partners are fighting hard for their best interests; (2) building public understanding and support; and (3) putting pressure on key state legislatures and federal lawmakers.

Important strategic elements will include:

- Build support--it's about patients, not doctors.
- The <u>fight</u> is a message--and physicians are needed to help us win.
- Deploy resources to key states.
- Link communications + grassroots activism + lobbying for membership results.
- Dramatize/personalize/simplify the message.
- Develop and implement state and national media strategies.
- Organize a national physician leadership spokesperson/appearance program.
- Leverage proven success of AMA's National House Call.
- Create special education campaign aimed at judiciary.

The current problems in the liability area can only be remedied through significant legislative action. AMA will work to maximize the Association's impact through assistance to medical societies in the passage of effective reforms at the state level and work with coalitions (including medical societies) for enactment of federal legislation. Research will be conducted in the short to mid-term to enhance our advocacy efforts and all efforts will be supplemented by a comprehensive and unified communications strategy.

States - Much can be accomplished at the state level to enact reforms. At this time, states generally fit into three categories: states where there is a real crisis; states that are at-risk of crisis (contagious states); and states with no current crisis. There are many reforms that will be pursued, with those selected and the level of activity dictated by existing state law and circumstances. Other reform ideas can and should be developed. Included in this area could be initiatives in expert witness criteria (both professional and licensing authority over expert witnesses), educational programs, including education of judges regarding issues in medical liability cases, and alternative dispute resolution systems including administrative fault-based systems. It will be important to assist both state medical societies and national medical specialty societies in their campaigns with state legislatures. The AMA will use make available its services to assist states and specialties coordinate their efforts to maximize medicine's impact. Also, in the near future, the AMA will:

- Analyze state laws and legislation to identify effective reforms and trends.
- Draft and update existing AMA state model legislation on provisions that have been effective.
- Gather and interpret data on premiums and the effect of increases on delivery of and access to care.
- Gather and interpret information on median verdicts and settlements in medical liability cases.
- Analyze and summarize state supreme court cases overturning and upholding state tort reforms, including the rationale for doing so.
- Gather information on states that have pursued judicial reforms and identify states where similar reform could be effective.
- Participate in coalitions of state, county and specialty organizations in pursuing reforms at the state level.
- Collect and make available online links to relevant articles and educational data and communications materials.
- Develop model communications materials, including: letters to the editor, editorials, media ads., legislative talking points and fact sheets, Q&A sheets and letters from physicians to legislators.
- Collect and analyze data on issues relating to professional liability, including: the method by which PLI insurers rate particular specialties, mean PLI premiums for self-employed physicians by specialty manual PLI rates by specialty and geographic region for certain insurers, trends in median awards and settlements in medical liability cases, trends in underwriting of PLI, an examination of states where premiums are flat (e.g., California, Louisiana, Indiana), study whether physicians with good coverage are more likely to be sued.
- Study whether there are marketplace solutions to the liability issue that should be considered and/or advocated.

Federal - At the federal level, we will work to educate members of Congress on the issues, secure our support in the House and work to convince additional members of the Senate. Currently we are:

- Rebuilding and re-energizing existing coalitions. The AMA has rejoined the Health Care Liability Alliance (HCLA) that has served as the principal lobbying coalition for reforms at the federal level. HCLA is now operating under new leadership from the American College of Surgeons.
- In response to the House of Delegates action, a steering committee consisting of the AMA, state medical societies, and national medical specialty societies has been meeting to determine the best way to coordinate activities and collaborate on joint projects at the national level. Initial staff discussions began in January, 2002.
- The AMA recently agreed to co-chair a medical liability committee of the American Tort Reform Association (ATRA). The American Association of Health Plans will serve as the other co-chair. Although ATRA has focused primarily on state tort reforms, the reconstituted medical liability committee will enhance efforts to advance federal initiatives. ATRA is also developing projects for direct intervention into judicial races and is working with state-based civil justice reform coalitions in this area.

- On April 25, Representatives Jim Greenwood (R-PA), Chris Cox (R-CA) and Jim Moran (D-VA) led a press conference unveiling H.R. 4600, the HEALTH Act of 2002 (Help Efficient, Accessible, Low Cost, Timely Health Care). The bill is medical liability reform legislation based on California's MICRA reforms. Also joining as original co-sponsors were Murtha (D-PA), Toomey (R-PA), Peterson (D-MN), Pickering (R-MI), Stenholm (D-TX), Weldon (R-FL), and Lucas (D-KY). Energy and Commerce (E&C) Chairman Tauzin (R-LA) and E&C Health subcommittee chair Bilirakis (R-FL) submitted statements of support at the press conference. Judiciary Chairman Sensenbrenner (R-WI) has also expressed his support. The AMA, working with the steering committee, participated in the press conference launching the bill and will develop a comprehensive education plan for Congress in support of this bill.

- Ensure that medical liability reform is a priority element of the Bush Administration's tort reform initiatives.

- Demonstrate broad support for medical liability reforms by organizing a series of policy backgrounders for congressional staff and the media sponsored both medical groups and independent health policy forums such as the Alliance for Health Reform, Heritage Foundation and Progressive Policy Institute.

- Develop a strategy to improve the adequacy of reimbursement for professional liability expenses under Federal, state and private health insurance programs.

- Utilize AMA House Call activities to advance state and federal reforms.

- Pursue medical society and AMA roles in potential White House media events to promote tort reform.

- Urge Administration officials to include tort reform in future State of the Union addresses and federal budget proposals.

- Convince congressional champions to hold hearings on growing medical liability crisis to build momentum for legislative action.

Political - Political tools will be key to accomplishing our goals at both the federal and state levels. We intend to:

- Address the role of the state courts in the battle to implement meaningful professional liability reforms. In the 14 states where state supreme court judges are elected, judicial races will be monitored with an eye to supporting candidates who could be expected to rule in favor of liability reforms.

- Monitor the voting and sponsorship records of members of Congress on key liability and tort reform bills.

- Encourage state medical societies to review the voting records of state lawmakers and receive feedback on their political efforts at the state level.

- Galvanize activists through a number of mechanisms. Some of the mechanisms we have at our disposal include: physician grassroots fax database, cyberdoc, e-mail activists database, Federation activities, key congressional contacts, toll free hotline to congress, regular web site updates, in district meetings.

Research - Experience has taught us that research will be a key factor in achieving our goals. Not only is it necessary to develop our own facts and arguments, it will be necessary to devote substantial resources to counter adversaries' false and misleading statements and research.

- Baseline Data - Initially, efforts will start with data collection from each state and national medical specialty society to create a databank of information on the current liability situation. A survey has been initiated with all state and specialty societies represented in the House of Delegates.

- Insurance Markets and Premium Stability - We will study elements that contribute to the problem of premium stability (underwriting cycle, predatory pricing, etc.) and review literature in this area including the impact of previous under pricing of liability insurance premiums on the current premium increases and the relationship between medical liability insurance premiums and health insurance premiums.

- Tort Reforms - We will study what works and what doesn't, including effects of various legislative provisions (such as MICRA) on claim frequency, award sizes, and ultimately premiums.

- Patient Safety and Risk Management - We will review what works and what initiatives are available.

- Risk Retention Groups - We will examine the roll of off-shore risk retention groups, how they are regulated, and their impact on cost and premium stability.

ACTIVITIES SINCE THE 2001 HOUSE OF DELEGATES INTERIM MEETING

- Meetings have been held with strategic alliances such as the American Tort Reform Association and the Health Care Liability Alliance. The AMA has a seat on the Board of ATRA as well as Co-Chair of the ATRA Subcommittee on Medical Liability Reform (ATRA sponsors civil justice reform coalitions in most all states). AMA also has a seat on the Board of HCLA and HCLA has been re-energized during the last few months.

- Staff has also convened an Advocacy Resource Center Executive Committee meeting to prepare an ARC campaign on liability reform.

- The Health Policy Group developed a draft report, "Data of Assessing the State of Medical Professional Liability Insurance in 2002."

- The 2002 State Health Legislative Meeting in January had a significant program segment on liability reform.

- Working meetings with representatives from national medical specialty societies were conducted at the State Health Legislation Meeting (January 2002) and again in late January and April. This Steering Committee has established subcommittees (Federal Strategy, State Strategy, Research and Communications) to coordinate activities and develop joint projects for the Federation of medicine.

- The Council on Legislation (COL) has taken on the issue of liability reform during its October and December meetings in 2001. A subcommittee of COL was also created to provide a stronger work product.

- The Council on Medical Service has developed a report on "The Rise in Professional Liability Insurance Premiums" for the 2002 Annual Meeting.

- Washington Office staff have met with White House policy personnel encouraging the Administration to support liability reform efforts.

- The AMA is coordinating polling and survey activities with specialty societies to develop specialty specific data on the impact of the liability crisis.

- The AMA participated in a doctors' rally at the capital in Jackson, Mississippi. An AMA press release was issued endorsing the efforts of Mississippi physicians to bring about liability reform. Provided expert advice on liability reforms.

CONCLUSION

It is obvious that there is a crisis in the medical liability area, in certain areas of the country and in certain specialties. The Board of Trustees understands the problem and has returned liability reform to the highest level of priority. However, it must be noted that our task will not be simple or short. There is strong opposition to any changes in the judicial system. Trial lawyers continue to oppose changes and they are strong, well financed, and effective. To defeat them and bring about real change, we will have to be as strong and single purposed as they are. We will need to fight every point and our information and arguments must be impeccable. We must be unified throughout the Federation and we will need to marshal resources at an unprecedented level.

Even if we were able to match the opposition today, it will take an extended period of time and a long-term commitment by the AMA and all of organized medicine. One lesson we must not forget is that our will to achieve reform must continue unabated, regardless of the condition of the insurance market at any particular time. Whether premiums are high or low, we must continue to keep liability reform at the top of our agendas. This is a lesson that we cannot forget.

We will keep you informed as we move forward on this high-priority issue. You will hear from us at each and every available opportunity, reporting to you on what we are doing. You will hear from us asking for help from and offering help to state medical societies. You will hear from us as we work with national specialty societies to maximize our collective impact at the state level and to enact federal legislation. You will hear from us as we provide resources for evaluating judicial races across the country. And, you will hear from us as we determine the scope of resources medicine will need to accomplish our goals. Your Board of Trustees will be diligent in its efforts to address this priority issue.

36. HEALTH PLAN LIABILITY FOR COMPLEMENTARY AND ALTERNATIVE THERAPY REQUESTS (RESOLUTION 202, A-01)

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 202 (A-01) AND REMAINDER OF REPORT FILED

At the 2001 Annual Meeting, Resolution 202, introduced by the Young Physicians Section, was referred to the Board of Trustees for a report back. Resolution 202 asks that our American Medical Association encourage health plans who contract with alternative medicine providers to indemnify physicians when such treatments result in delays in care or injury to patients.

This report provides an overview of complementary and alternative therapies (CAT), and discusses the evolving theories of liability for physicians pertaining to CAT. This report recommends that the AMA: (1) seek legislation requiring health plans to indemnify physicians when patient referrals to CAT providers required by health plans result in delay of treatment or injury to patients; and (2) vigorously oppose any coercion that a physician engage in any practice or treatment which has no scientific basis.

AMA POLICY

Current AMA policy supports objective, scientific evaluation of unconventional therapies, encourages physicians to be better informed regarding CAT, and to routinely inquire of patients regarding use of CAT. The AMA supports education of patients by physicians regarding scientific knowledge of CAT and the risks associated with postponing or stopping conventional medical treatment. The AMA also supports legislation providing that health plans not require primary care physicians refer patients for CAT and that physicians not be at risk for the costs of such services (Policies H-285.933, H-480.962, H-480.964, H-480.967, H-480.973, AMA Policy Database).

BACKGROUND

Resolution 202 (A-01) asks the AMA to encourage health plans who contract with alternative medicine providers to indemnify physicians when such-treatments result in delay in care or injury. Reference committee testimony described the concern of physicians that referrals to CAT in essence endorse such therapies and that physicians should be removed from the referral or authorization process. The majority of the testimony focused on the need for indemnification of physicians where health plan referrals to CAT are required. The AMA has no data on the number of health plans that require CAT referrals.

DISCUSSION

Evolution of CAT

CAT refers to modalities, practices, techniques and systems of healing that are used in conjunction with ("complementary") or instead of ("alternative") conventional medicine. The nomenclature of these therapies varies. Sometimes known as Complementary and Alternative Medicine, Healing Arts, and Holistic Health among others, such therapies are more appropriately called Complementary and Alternative Therapies (CAT). Among the modalities most often associated with CAT are chiropractic, acupuncture, massage therapy, biofeedback, meditation, forms of nutritional therapy (dietary supplements/herbs), and homeopathy.

CAT has gained increased public acceptance and has been integrated to some extent into conventional medicine. A 1997 study indicated over 42 percent of the US population has used CAT or consulted with CAT providers. Almost 90 percent of these users are self-referred and often utilize CAT without the knowledge or supervision of their physician.

Interaction between the physician and CAT communities has been limited for many reasons. Many alternative therapies have not been scientifically studied. By definition, CAT is not part of the array of therapies accepted as standard medical treatment. CAT has not been widely taught in medical schools and many physicians are unfamiliar with CAT.

There is also wide variability in the level of training and education of CAT providers. In some states, CAT providers are not required to meet education or examination thresholds. Also, not all CAT techniques are regulated. Some disciplines like chiropractic, massage therapy, and acupuncture require completion of a formal program and state licensure, but the level of regulation and oversight varies from state to state. And while CAT providers practicing in hospitals are subject to some credentialing process, many CAT providers practice independently outside the hospital setting and are not necessarily credentialed by any organization.

CAT as a Component of Conventional Medicine

CAT is becoming more familiar to and accepted by health care consumers. A 1990 study indicated that Americans made over 425 million visits to CAT providers and spent $13.7 billion on CAT, three-quarters of which was not reimbursed by insurance. A follow up study in 1997 (referred to above) reported that Americans spent $27 billion on CAT. Employer sponsored health plans, as one of the major purchasers of health care, sometimes include CAT in a variety of health insurance packages in response to employee requests. The Health Insurance Association of America (HIAA) reports that several states require insurance companies to cover some CAT modalities such as chiropractic and naturopathy. Many physicians have integrated some CAT modalities into their practice by referring patients to CAT providers or administering CAT modalities themselves. Approximately 40 US medical schools sometimes includes CAT courses in their curricula. Many hospitals are also beginning to offer CAT in conjunction with standard treatment of chronic conditions, such as in pain, oncology and AIDS clinics.

Federal and State Legislative Action

Both state and federal lawmakers have become interested in the practice, availability, and reimbursement of CAT. In 1997, 137 laws addressing access and reimbursement of CAT were enacted in 41 states. In 1998, 91 laws were enacted in 39 states. By the end of 2000, 38 states required insurers to offer chiropractic coverage and seven required acupuncture coverage. One state, Alaska, requires coverage of naturopathy.

Among the issues of concern, particularly at the state level, is scope of practice and licensure. State law varies in regard to the extent to which CAT is delivered by licensed providers. State laws generally are designed to protect health care consumers. Minnesota, for example, enacted a law sanctioning the practice of CAT with state oversight of CAT providers. For physicians who practice or incorporate CAT into their practices, some states have enacted laws clarifying that CAT practiced by licensed physicians does not constitute unprofessional conduct, nor will it constitute cause for disciplinary action by the state licensing authority.

Due to questions regarding the safety and efficacy of CAT and its increased use in the United States, Congress established the Office of Alternative Medicine at the National Institutes of Health in 1992 to conduct research on CAT. Now operating as the National Center for Complementary and Alternative Medicine (NCCAM), it not only conducts and supports CAT research, it provides CAT information to health care providers and the public.

In March, 2000, Congress created the White House Commission on Complementary and Alternative Medicine Policy. The purpose of this commission was to develop legislative and administrative policy recommendations regarding CAT practices and products. The commission considered: (1) coordination of research of CAT; (2) coordination of providing reliable CAT information to health care workers; (3) appropriate access to and delivery of CAT; and (4) education and training of CAT providers.

The final report of the Commission, published in late March, 2002, included 29 recommendations, attached hereto as Appendix A. The full text of the final report can be accessed at www.whccamp.hhs.gov/final report.html.

Legal Issues

Claims experience, to date, for CAT providers is lower than that for physicians. This may be due to the non-invasiveness of most CAT modalities, the lower severity of injury from CAT, the evolving nature of CAT or the undeveloped state of CAT malpractice litigation. Nevertheless, health care professionals are increasingly concerned about their liability for using CAT modalities, referring patients to CAT providers or discussing CAT with patients. Physicians are also concerned about participating in a health plan that requires referral to a CAT provider when such treatments result in delay of care or injury to patients. Although health plans may seek to minimize the concern of physicians, malpractice liability for CAT has not been widely tested in the courts for physicians or health plans. As CAT becomes more prevalent and as theories of liability evolve in this area, liability will remain an important consideration for physicians who practice using CAT, or who refer a patient to a CAT provider or who manage patients previously treated by a CAT provider.

Potential theories of liability for physicians include negligence and vicarious liability. Direct liability for negligence occurs when a physician fails to meet the requisite standard of care. With respect to referral for CAT, a physician could be liable for negligent referral if a referral was made to a CAT provider instead of a conventional medical practitioner or if the referral results in a delay of treatment or elimination of the opportunity for the patient to receive necessary treatment. Health plan guidelines and policy may influence or control the use of CAT. It is difficult to predict whether or not such guidelines or policies will affect the issue of liability for referral to a CAT provider.

Vicarious liability imputes liability to one person for the negligent acts of another person. The general rule is that a physician who refers a patient to another provider is not liable for the negligence of that other provider. The exception to the rule, however, depends upon whether (1) the referring physician knows the other provider is not appropriately credentialed or is incompetent; (2) the referring physician has, or appears to have, supervisory control of the providers' care; or (3) a referring physician appears to be associated or integrated with the provider. If a physician does participate with or supervise the CAT provider, it may be more likely that liability for the CAT provider's negligent acts will fall upon the physician.

A physician also has a duty to inform patients of appropriate and available treatments. The standard of care used to determine whether a physician disclosed appropriate treatment options is a "reasonable" physician standard. Currently, courts do not recognize an obligation to refer patients for CAT therapy, but as CAT becomes more accepted, it may come to be considered an appropriate or reasonable treatment.

Another issue to be resolved is the standard of care for physicians who perform CAT. For established, recognized therapies, a CAT provider would likely be held to a reasonable CAT provider standard; that is, a "reasonable acupuncturist" standard of care if acupuncture were involved. Physicians who deliver CAT in conjunction with conventional medicine ("dual practitioners") represent a more complicated case in determining the appropriate standard of care. It could be that of a "reasonable physician" or that of "a reasonable CAT provider". As a result, currently, a physician cannot be certain of the standard by which integrated CAT therapies will be measured.

CONCLUSION

As acceptance of CAT grows and more physicians are faced with decisions regarding use of CAT, assignment of liability will remain an important question with uncertain answers. Until the law on physician liability for CAT is more clearly articulated physicians should: (1) be knowledgeable about their state licensing laws and regulations pertaining to CAT; (2) become better informed about CAT modalities; (3) inform patients of the risks associated with CAT and the conventional treatments available; (4) obtain informed consent for treatment which should include safety, effectiveness and risk of any CAT modality involved in the treatment; (5) inform patients that the CAT provider to whom the patient is referred is an independent provider and is not under the control or supervision of the physician, and, if applicable, document this disclaimer with patient signature; and (6) to the extent allowed by state law, include an indemnification clause in health plan contracts and professional service agreements whereby the plan or health care entity indemnifies and holds the physician harmless for injuries to patients sustained due to previous CAT therapy or due to a referral to a CAT provider required by the plan or health care entity (model language for such a clause is attached as Appendix B).

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 202 (A-01) and that the remainder of this report be filed.

1. That our American Medical Association consider legislation requiring health plans to indemnify physicians for plan mandated referrals to Complementary and Alternative Therapy (CAT) providers.

2. That our AMA recommend that physicians include indemnification clauses for CAT referrals in all health plan contracts when such plans require referral for CAT (see model language in Appendix B).

3. That physicians inform patients who choose CAT modalities about the risks of CAT.

4. That our AMA vigorously oppose any coercion that a physician engage in any practice or treatment which has no scientific basis.

5. That our AMA reaffirm Policy H-285.933, “Financial Liability Encountered in Referrals for Alternative Care.”

6. That the Council on Long Range Planning and Development change all references in the AMA policy database from “CAM” to “CAT” and that an appropriate cross-reference be developed in the database.

APPENDIX A - RECOMMENDATIONS OF WHITE HOUSE COMMISSION ON ALTERNATIVE AND COMPLEMENTARY MEDICINE

1. Federal agencies should receive increased funding for clinical, basic and health services research on CAM.
2. Congress and the Administration should consider enacting legislative and administrative incentives to stimulate private sector investment CAM research on products that may not be patentable.
3. Federal, private and nonprofit sectors should support research on CAM modalities and approaches that are designed to improve self-care and behaviors that promote wellness.
4. Federal, private and nonprofit sectors should support new and innovative CAM research on core questions posed by frontier areas of scientific study associated with CAM that might expand our understanding of health and disease.
5. Investigators engaged in research on CAM should ensure that human subjects participating in clinical studies receive the same protections as are required in conventional medical research and to which they are entitled.
6. The Commission recommends that state professional regulatory bodies include language in their guidelines stating that licensed, certified, or otherwise authorized providers who are engaged in research on CAM will not be sanctioned solely because they are engaged in such research if they:
   (a) are engaged in well-designed research that is approved by an appropriately constituted IRB;
   (b) are following the requirements for the protection of human subjects, and
   (c) are meeting their professional and ethical responsibilities. All CAM and conventional providers, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.

7. Increased efforts should be made to strengthen the emerging dialogue among CAM and conventional medical providers, researchers and accredited research institutions; federal and state research, health care, and regulatory agencies; the private and nonprofit sectors; and the general public.
8. Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions and to expand the cadre of basic, clinical, and health services researchers who are knowledgeable about CAM and have received rigorous research training.
9. Public and private resources should be used to support, conduct, and update systematic reviews of the peer-reviewed research literature on the safety, efficacy, and cost-benefit if CAM practices and products.
10. The education and training of CAM and conventional providers should be designed to ensure public safety, improve health, and increase the availability of qualified and knowledgeable CAM and conventional providers and enhance the collaboration among them.
11. The federal government should make available accurate, useful, and easily accessible information on CAM practices and products, including information on safety and effectiveness.
12. The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, a public education campaign, and actions to protect consumers' privacy.
13. Information on the training and education of providers of CAM services should be made easily available to the public.
14. CAM products that are available to US consumers should be safe and meet appropriate standards of quality and consistency.
15. Provisions of the Federal Food, Drug, and Cosmetic Act, as modified by the Dietary Supplement Health and Education Act of 1994, should be fully implemented, funded, enforced, and evaluated.
16. Activities to ensure that advertising of dietary supplements and other CAM practices and products is truthful and not misleading should be increased.
17. The collection and dissemination of information about adverse events stemming from the use of dietary supplements should be improved.
18. The Department of Health and Human Services should evaluate current barriers to consumer access to safe and effective CAM practices and to qualified providers and should develop strategies for removing those barriers in order to increase access and to ensure accountability.
19. The federal government should offer assistance to states and professional organizations in (a) developing and evaluating guidelines for provider accountability and competence in CAM delivery, including regulation of practice, and (b) periodic review and assessment of the effects of regulations on consumer protection.
20. States should evaluate and review their regulation of CAM providers and ensure their accountability to the public. States should, as appropriate, implement provisions for licensure, registration, and exemption consistent with the providers' education, training and scope of practice.
21. Nationally recognized accrediting bodies should evaluate how health care organizations under their oversight are using CAM practices and should develop strategies for the safe and appropriate use of qualified CAM providers and safe and effective products in these organizations.
22. The federal government should facilitate and support the evaluation and implementation of safe and effective CAM practices to help meet the health care needs of special and vulnerable populations.
23. Evidence should be developed and disseminated regarding the safety, benefits, and cost-effectiveness of CAM interventions, as well as the optimum models for complementary and integrated care.
24. Insurers and managed care organizations should offer purchasers the option of health benefit plans that incorporate coverage of safe and effective CAM interventions provided by qualified providers.
25. Purchasers, including federal agencies and employers, should evaluate the possibility of covering benefits or adding health benefit plans that incorporate safe and effective CAM interventions.
26. The Department of Health and Human Services and other Federal agencies and public and private organizations should evaluate CAM practices and products that have been shown to be safe and effective to determine their potential to promote wellness and help achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to have benefit.
27. Federal, state, public, and private health care delivery systems and programs should evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health. Demonstration programs should be funded for those determined to be beneficial.
28. Research on the role of CAM in wellness and health promotion, the application of CAM principles and practices, and the role of CAM providers in the management of chronic disease should be expanded.
29. The President, Secretary of Health and Human Services, or Congress should create an office to coordinate federal CAM activities and to facilitate the integration into the nation's health care system of those complementary and alternative health care practices determined to be safe and effective.

APPENDIX B - MODEL LANGUAGE FOR INDEMNIFICATION CLAUSE

INDEMNIFICATION Managed Care Organization (MCO) agrees to indemnify and hold PHYSICIAN harmless from any and all liability, losses, damages, suits, actions, verdicts, settlements or any other costs, including attorneys' fees, that PHYSICIAN incurs as a result of the patient, (i) at the request or direction of the MCO, or (ii) pursuant to the MCO's established policies for referral to Complementary and Alternative Therapies (CAT), having been previously treated with CAT or referred for CAT. At PHYSICIAN'S option, MCO shall, at its expense, defend PHYSICIAN against any and all claims as to which PHYSICIAN would be entitled to indemnification provided, that PHYSICIAN shall have notified MCO of such claims in a timely manner.

37. AMA MEMBERSHIP UPDATE

HOUSE ACTION: RECOMMENDATION ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

INTRODUCTION

Membership recruitment and retention are crucial elements to any association's livelihood. Today, more than ever, medical associations must be innovative, yet relevant, to encourage medical students and physicians to join organized medicine. That innovation and relevancy must help build a connection, a relationship with the individual to aid in the retention of the member. The American Medical Association is no different. In fact, like many other associations across the country, the AMA is challenged continually to stem the downward trend in membership.

The AMA membership decline began more than three decades ago, prompting in the ensuing years the formation of several staff and member committees to study the membership problem. While many conclusions were drawn and ideas were implemented, not one committee or single plan created to alter AMA's membership has been able to reverse the trend. The following table shows the changes in membership by lifecycle in 2001 compared to the 2000 membership baseline.

Table 1 - 2000-2001 Membership Lifecycle Comparison

Lifecycle	2000	2001	Change	Percent Change
Medical Student	48,205	49,931	1,726	3.6%
Resident	33,538	32,494	(1,044)	(3.1)%
Young Physician (under age 40)	31,674	28,110	(3,564)	(11.3)%
Established Physician (40-55 years of age)	83,653	77,787	(5,866)	(7.0)%
Senior Physician (55+ years of age)	55,723	50,922	(4,801)	(8.6)%
Retired Physician	37,564	39,058	1,494	4.0%
Total AMA Membership	**290,357**	**278,302**	**(12,055)**	**(4.2)%**

DISCUSSION

The AMA's Direct Program originated in 1982 based on a long-term, in-depth analysis by the Council on Long Range Planning and Development on the complex factors affecting membership recruitment and retention. The Council viewed the membership situation from a marketing perspective and was concerned that the AMA's direct access to the physician population was inadequate. The creation of the new membership portal, direct, and a new program, the Direct Program, complemented the AMA's marketing relationship with the geographic medical societies that billed, collected, and remitted AMA dues. It also provided the opportunity to build a direct relationship with the individual because AMA messages were not sent through a circuitous method.

In 1993 the Partnership for Growth (PfG) was formalized, outlining optimal marketing strategies and time parameters that geographic medical societies were to follow when billing, collecting, and remitting AMA membership dues. Since then, the PfG has become the fundamental membership agreement between the AMA and the geographic medical societies. And while the physician environment and methods to market effectively to physicians have changed, the PfG remained stagnant with the exception of slight modifications over the years.

There has been a growing concern within the AMA, as well as within the Federation, about the PfG. The PfG is an agreement with many cumbersome requirements. Geographic medical societies must bill for the AMA a certain number of times throughout the year and follow a specific time line. The AMA must be listed on their membership invoices with explicit language. The agreement does not take into account the geographic medical societies' environment and method of membership marketing. Because of the agreement's inflexibility and lack of incentives, Hawaii, Kansas, and Washington opted out of the 2002 program and the AMA was forced to "go direct" in those states, resulting in a total of eight direct geographic societies. (The other five direct geographic societies include Maine, New Hampshire, Puerto Rico, Vermont and the Virgin Islands.) It is believed that several other geographic medical societies will follow suit in 2003 if the PfG is not altered.

Many have expressed an interest in allowing the AMA to "go direct" throughout the country; however, the AMA is not prepared to embrace direct marketing for all of the nation's physicians at this time. The Direct Program achieves higher acquisition rates; however, AMA membership retention is stronger through the Federation. In addition, direct states had an average market share of 13% during the 2001 membership year, while federated states maintained a market share of 26% for physicians after residency.

Despite the differences in market share among the membership channels, the AMA has experienced an overall shift in its membership through the Federation. Since the inception of the PfG, AMA membership through the Federation has declined 29% while the Direct Program has increased 46% for physicians after residency. (It is important to note that student membership increased 22% and resident membership decreased 9% over the same period of time. The Federation plays a significant role in the recruitment and retention of student and resident members; however, the PfG does not include these two career segments as components of the agreement.)

More recently and specifically, below is a comparison of physicians after residency through the two marketing channels, Federation and Direct.

Table 2 - 2000-2001 Membership Channel Comparison for Physicians After Residency

	2000	2001	Change	Percent Change
Market Size	725,988	744,609	18,621	2.6%
Federation	141,401	127,799	(13,602)	(9.6)%
Direct	67,213	68,077	864	1.3%
Total AMA Members after Residency	**208,614**	**195,876**	**(12,738)**	**(6.1)%**

The AMA experienced its largest Federation membership decline in 2001. Essentially, the AMA, the geographic societies, and the specialty societies are competing for the same dues dollar, which is becoming increasingly difficult to come by as physicians' discretionary income decreases. Also, the purchasing habits of physicians in different career stages are starting to impact membership; younger generations are not joiners typically, which makes the sell of membership more difficult. The Board believes that the AMA should continue to entrust its partners to market AMA effectively and successfully; however, it should not discount its own abilities to recruit and retain physicians. In essence, enhancements to the direct and Federation programs are believed to have the greatest likelihood of improved total membership in coming years.

With the advice of AMA member committees and several geographic medical society executives, the Board has determined that dramatic changes within the PfG must occur. The AMA should take more control of its membership marketing, collection, and dues processing, where appropriate; and explore membership marketing opportunities that strengthen AMA membership with our Federation partners. This could be accomplished by forming new membership marketing relationships with national medical specialty societies and redefining current relationships with geographic medical societies. In addition, it was determined that the AMA should offer a more streamlined, more flexible, more incentivized, and more partnership-oriented membership agreement with the geographic societies.

Currently, the AMA cannot market AMA membership to a physician who is a non-renewed state member until March 1. This late direct marketing entry date hinders the AMA in its ability to market appropriately a full-year of membership and to make up for member loss through the Federation. It is proposed that beginning with the 2003 membership marketing year, the geographic societies' exclusivity to market to non-state renewed physicians end on December 31, 2002.

Pilot Programs

The membership decline, experienced by many organizations, is forcing medical societies to try modern ways to market membership. AMA pilot programs were created to examine creative marketing ideas and concepts with our membership marketing partners. Unfortunately, the majority of them were not successful. The AMA pilot programs included the following:

- *AMA Dues Reduction* - The AMA reduced membership dues for medical students and young physicians in select states.

- *Joint Dues Reduction* - The AMA, along with a geographic medical society, reduced the membership dues for physicians after residency.

- *Joint Dues Reduction with Recruitment and Retention Incentives* - The AMA, along with a geographic medical society, reduced the membership dues for physicians after residency. In addition, the AMA provided the geographic medical society with financial incentives for each member recruited and retained through this program.

- *Alternative Direct Billing Incentive* - The geographic society would alternate months in which it would bill state medical society dues and AMA dues.

While a few of these pilots showed promising starts, the end results were lackluster. Additionally, these pilots created administrative and processing challenges that were onerous, time consuming, and created a propensity for errors. These pilots did not provide the results needed to institutionalize the concepts; and the Board of Trustees directed the discontinuation of the majority of them.

However, it was determined that three pilot programs should be studied further; the responses to date have been encouraging. These pilots are:

- *10% Membership Discount on the Web* - Medical students and physicians may join and/or renew through the AMA web site to receive a 10% discount on their AMA membership dues.

- *Lifetime Membership* - Medical students and physicians may join the AMA for one lump-sum dues payment that covers AMA membership for that person's life.

- *Special Rate for Unified States* - In addition to the physicians' 10% dues reduction for unification, the full dues paying physicians receive an additional $78 dues reduction, lowering the yearly membership dues to $300 for Delaware, Mississippi, and Oklahoma physicians.

One pilot program, while not offered at this time, is still under review--the *4+1 Student to Resident Transition*. This pilot program gave four-year AMA medical student members the opportunity to receive the first year of residency membership for free in exchange for their new contact information after graduation. This was a three-year pilot program that ended with the 2001 graduation class. The AMA will continue to study the results of the 2000 and 2001 graduation classes for final analysis. The AMA continues to be concerned with the "seams" of a member's career--the transition between medical school to residency and residency to the first years of practice--and will continue to investigate alternatives.

Communications

In addition to testing various hypotheses with pricing and billing, the AMA is implementing numerous methods to reconnect with the individual member. Past reports from the Task Force on Membership indicated that the AMA is disconnected with its members. At one time, communications to our members were sparse and the Association was heavily reliant upon our Federation partners, whether it was through billing, newsletters, etc. The AMA is changing the delivery of information to its members.

AMA members differ widely in age and culture. Because of these variances, our members require different modes of communications. It is readily apparent that large portions of membership rely upon electronic communications, while others rely on print. We must relate to both.

The AMA web site has been revitalized. It includes dynamic links to the Sections and Special Groups--the home base for many members. The AMA recreated the quarterly Section and Special Groups newsletters that provide articles targeted to the specific lifecycle or special group's interests. While the web site and the newsletters are a significant source of information, the AMA realized that additional avenues of two-way communication are critical. Distributing information and AMA messages is important only if the member is interested. To help define their interests and their needs, the AMA created an interactive email communication called Member Connect. Member Connect is an online tool that provides members with the opportunity to voice their opinions on timely advocacy issues that affect their patients and their practices. In return they receive relevant information. Results of the surveys are used in providing testimony during Congressional hearings, in creating responses to current events, and in assisting the Association in its strategic planning. The AMA also conducted a member survey through the 2002 membership information packet inquiring about the member's professional needs so that the AMA can develop the programs, products, and services required to meet their needs better.

The AMA Board of Trustees also approved the development of an AMA print communication vehicle, separate from other communication vehicles, which will show the value of the AMA. As previously mentioned, the AMA relied upon the Federation and the media to educate medical students and physicians about the AMA's activities, accomplishments, and value, as well as editorially independent publications, such as *American Medical News*.

More resources have been devoted to the National House Call Campaign whereby the AMA and local leadership address hot topics in towns throughout the country. The National House Call Campaign uses the media, open forums, and personalized visits to communicate the AMA message, as well as to listen to grassroots physicians.

Print and electronic communications are two methods to create a community for our members, to generate a sense of belonging. Personal interaction is the third method. The AMA has the mechanisms in which a community can thrive--through the Sections' assemblies, Special Groups' meetings, and the House of Delegates. Leaders of these governing bodies are the key conduits to a strong association. To aid the leaders, the delegates and alternate delegates, the AMA is developing tools and seminars to equip them with the knowledge to communicate effectively the AMA activities, accomplishments and policies. The first session will be at this year's Annual Meeting. This program, called the Ambassador Program, was designed to provide this cadre with the tools needed to be the voice for and of the grassroots medical students and physicians. Two-way communication through the delegates and alternate delegates is crucial if true representation is to occur.

Many believe that the AMA needs more personal contact with its members. In addition to the above-mentioned activities, the AMA created the Advisory Committee on Membership (ACM) Retention Campaign in Fall 2001. This campaign, led by the ACM, asked geographic delegations to contact physicians who did not renew their 2001 membership and encourage them to recommit to the Association. Several lessons were learned from this campaign and were taken into account when reconstructing the program for the 2002 non-renewals. Geographic delegations were contacted recently, alerting them to the 2002 ACM Retention Campaign. To build on the community-based approach, the Sections also were asked to participate. Results of the campaign will be shared once they are finalized.

CONCLUSION

The continued membership decline has two deleterious effects: negative impact on membership dues revenue and a potential to jeopardize the Association's effectiveness as an advocate for the profession as a whole. This report outlines several activities and methods the AMA is implementing to market and to communicate effectively with our members and prospective members to rebuild our membership. It is obvious that the AMA's membership decline cannot be solved with one magic bullet. A strategic and integrated approach that includes true partnerships with the Federation (both geographic and specialty societies) through the PfG, better communications, increased member value, enhanced member service, and streamlined processing, are the solutions to the AMA's membership decline.

RECOMMENDATION

The Board of Trustees recommends that the following recommendation be adopted and that the remainder of this report be filed:

That the American Medical Association House of Delegates approve the Partnership for Growth's Direct Program marketing entry date of February 1, beginning with the 2003 membership year.

38. FINANCING OF PHYSICIANS FOR RESPONSIBLE NEGOTIATION

HOUSE ACTION: FILED

BACKGROUND

At the 1999 Annual Meeting, the American Medical Association House of Delegates passed Substitute Resolution 901 calling for the implementation of an AMA-affiliated negotiating organization. In August 1999, the Board of Trustees was provided a discussion paper outlining a request for $1.2 million in funding to cover operations for this negotiating organization from September 1, 1999, through December 31, 2000. Additional future funding to cover the expenses of the organization until it generated sufficient revenues to meet expenses was estimated at $700,000.

As a result of the Board's approval of the discussion paper, the AMA formed Physicians for Responsible Negotiation (PRN), which was incorporated in November 1999 as a limited liability corporation in Delaware. The AMA provided PRN with a model constitution and bylaws, chose its name, selected its initial directors, and also provided start-up capital in the form of the $1.2 million loan. In order for both PRN and the AMA to be in full compliance with the federal Labor Management Relations Act and the National Labor Relations Act (NLRA), PRN was established on the basis of its being independent of the AMA. Although the AMA could make policy and operational suggestions to PRN, the AMA could not control the manner in which PRN conducted its business. Moreover, to avoid any risk that the AMA had impermissibly "contributed" financial support (which could constitute an unfair labor practice), the AMA has extended its financial support in the form of loans provided on a commercially reasonable basis as determined by the Board.

An initial loan of $1.2 million was provided by the AMA at the time of PRN's creation in late 1999 pursuant to a written loan agreement.

PRN was created to help eligible physicians (primarily employed physicians) conduct collective bargaining thereby regaining some control over the manner in which their practice is conducted. PRN was also created as an ethical alternative to traditional labor organizations. PRN adopted the AMA's Principles of Medical Ethics and embraced operational and philosophical principles markedly different from those of traditional labor organizations. Specifically, PRN will not use strikes nor withhold necessary medical services to patients as a collective bargaining device. Also, membership in PRN is not required as a condition of employment in a PRN organized collective bargaining unit. PRN membership is open to all allopathic and osteopathic physicians and medical students. PRN is the only unaffiliated national labor organization committed to including quality of care/patients' rights provisions in its collective bargaining agreements.

KENTUCKY RIVER SUPREME COURT DECISION

On May 29, 2001, the US Supreme Court refused to enforce an order of the National Labor Relations Board (NLRB) requiring Kentucky River Community Care, Inc. (KRCC) to engage in collective bargaining with a labor organization (Kentucky State District of Carpenters), certified to represent employees of KRCC. The central issue was whether six registered nurses, included in the collective bargaining unit by the NLRB, were "employees," eligible for collective bargaining, or "supervisors," who are not. The Supreme Court ruled that these six nurses were engaged in supervisory activities and therefore not eligible to be part of a collective bargaining unit. This ruling negated a longstanding NLRB interpretation that health care workers exercising "ordinary professional or technical judgment in directing less-skilled employees to deliver services" are not using the type of "independent judgment" that would deem them to be considered a supervisor under the NLRA.

This ruling creates serious problems for professional employees, and health care professional employees in particular, who provide any supervisory functions over other health care workers and want to partake in collective bargaining. The Court did suggest that perhaps the NLRB could limit its interpretation of supervisory functions by "distinguishing employees who direct the manner of others' performance of discreet tasks from employees who direct other employees." An example to demonstrate the meaning of this distinction might be a nurse instructing a nurse's aide how to take a blood pressure as opposed to directing the aide to actually take the patient's blood pressure. The Court noted, however, that it did not have occasion to consider this concept, as it was not an issue in this case.

While the uncertainties created by the *Kentucky River* decision have forced PRN to suspend efforts to organize new physician groups in the private sector, PRN has pressed forward with appeals within the NLRB in respect of two organizing efforts already in process at the time of the *Kentucky River* decision. In both of these appeals, recent rulings by NLRB regional directors have been favorable to PRN (embracing the possible distinctions noted by the Supreme Court in its *Kentucky River* decision). Both of these matters are now under review by the full NLRB. PRN will still consider organizing employed physicians in the public sector who are subject to state laws rather than the NLRA. At this time, PRN believes it is the only labor organization with cases pending before the full NLRB where the employer is challenging the composition of a bargaining unit comprised of healthcare workers based on the *Kentucky River* decision.

PRN MEMBERSHIP

PRN has three classifications of membership. Based on recent (May 9, 2002) information obtained from PRN (updated from information in PRN's business plan provided to the Board in April), the status of PRN's membership is as follows:

- *Core Members* - These physicians are in two collective bargaining units where PRN's organizational efforts were completed before the *Kentucky River* decision (these units are unrelated to the two cases pending before the full NLRB referred to above). These members pay $50 per month to support PRN's bargaining and contract administration services. At the present time, 20-25 members pay dues each month.

- *Sustaining Members* - These physicians represent that they do not manage or supervise other physicians. These members pay $50 per year (residents and medical students pay $25 per year) and usually join as a show of support for PRN. PRN currently reports 238 members.

- *Organizational Members* - Recently, PRN began offering medical associations the opportunity to show support for PRN and its activities by becoming organizational members. These organizational members pay $250 per year. There are currently 13 organizational members with a combined physician and medical student membership of approximately 70,000.

ADDITIONAL FUNDING PROVIDED TO PRN

PRN has requested additional loans from the AMA starting in the fall of 2000.

In Fall 2000, PRN requested an additional $1.8 million line of credit and requested a below-market interest rate to reduce the cost of borrowing. The Board approved the additional $1.8 million line of credit and reduced the interest on the new and outstanding loans to the 5-Year US Treasury Note rate. In addition, the Board provided that requests "for additional years of funding be reviewed annually and considered based on the then current needs of PRN, in a responsible manner that is fiscally prudent for the AMA in compliance with all applicable laws."

In June 2001, the Board reviewed PRN's situation following the *Kentucky River* decision. The Board suspended the line of credit extended the previous Fall but provided a $400,000 bridge loan to allow PRN to continue operations pending development of a revised business plan for submission to the Board.

In October 2001, PRN submitted a revised business plan and the Board approved an additional $782,000 in loan commitments to fund PRN for the remainder of 2001 and 2002. In connection with the Board's deliberations, legal counsel to the AMA reviewed prior advice related to NLRA compliance including, specifically, that additional loans be provided on a commercially reasonable basis as determined by the Board.

In April 2002, PRN requested an additional loan of $1.6 million ($392,000 remained available to be drawn down under previously approved loan commitments) to continue operations through 2003. This request would have resulted in AMA loans aggregating $4.4 million to PRN from its inception in November 1999. Financial projections beyond 2003 were not presented.

The Board discussed PRN's additional loan request at its April meeting. During the course of the discussions, the prior advice of AMA legal counsel was confirmed and reviewed. The PRN business case did not evidence a plan for PRN to become self-supporting or the means by which PRN would be capable of repaying AMA loans.

CONCLUSION

The Board conducted lengthy deliberations on PRN's request for an additional loan, and these deliberations reflected strongly held differences of opinion. The Board took into account the impact of its decision in regard to AMA finances, legal considerations, labor law, AMA membership, and the AMA's reputation. Following these deliberations, the Board voted not to approve PRN's April request for an additional loan and directed that a report be submitted to the House of Delegates at the 2002 Annual Meeting providing an update on PRN.

39. SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES - FIVE YEAR REVIEW

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

The Board of Trustees has completed its review of the specialty organizations seated in the House of Delegates scheduled to submit information and materials at the 2002 Annual Meeting in compliance with the five-year review process directed by the House in Report A of the Council on Long Range Planning and Development (A-87) (Policy H-600.020, AMA Policy Database, and Section 8.50 of the AMA Bylaws). Organizations are required to submit information to demonstrate continuing compliance with the guidelines established for admission to the House of Delegates. Also required is compliance with the five responsibilities of national medical specialty organizations as set out in the American Medical Association (AMA) policy statement and Section 8.70 of the AMA Bylaws.

In addition to the organizations scheduled for review at the 2002 Annual Meeting, the Board of Trustees reviewed the groups scheduled for review at the 2001 Interim Meeting. The 2001 Interim Meeting reviews of organization were not completed due to problems processing their membership files in time for the Interim Meeting.

The American Association of Clinical Endocrinologists (AACE) was also reviewed for this meeting. AACE was placed on probation at the 2001 Annual Meeting due to insufficient AMA membership and is required to demonstrate membership compliance by the 2002 Annual Meeting to retain its representation in the House of Delegates.

The following organizations have been reviewed for the 2002 Annual Meeting:

American Academy of Insurance Medicine
American Academy of Sleep Medicine
American Association for Vascular Surgery
American Association of Clinical Endocrinologists (probation group)
American Society for Gastrointestinal Endoscopy
American Society for Reproductive Medicine
American Society for Surgery of the Hand
American Society for Therapeutic Radiology and Oncology
American Society of Cytopathology
American Society of General Surgeons
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Association of Military Surgeons of the United States
College of American Pathologists
Congress of Neurological Surgeons
Contact Lens Association of Ophthalmologists, Inc.
International College of Surgeons
North American Spine Society
Society for Investigative Dermatology, Inc.
Society for Medical Consultants to the Armed Forces
Society of American Gastrointestinal Endoscopic Surgeons
The Endocrine Society
United States and Canadian Academy of Pathology

Organizations being reviewed were asked to submit materials in a format listing the guidelines/requirements followed by the organization's explanation of compliance. Each organization also submitted appropriate membership information that was analyzed to determine AMA membership. A summary of each group's membership data is attached to this report. Also attached is a summary of the guidelines for specialty admission to the House along with the five responsibilities of specialty organizations represented in the House.

Review of the material submitted indicates that the reviewed organizations, with the exception of The Endocrine Society, continue to meet all guidelines and are in compliance with the five requirements. The Endocrine Society, since it has fewer than 1,000 AMA members and only 24% (641 of 2,711) of its members belong to the AMA, is currently not in compliance with the guidelines for specialty representation.

Under the AMA Constitution and Bylaws, Section 8.54, specialty societies found to be not in compliance with the current guidelines for representation in the House of Delegates have a grace period of one year to bring themselves into compliance. AMA staff will work with the Endocrine Society to help it correct its deficiency in AMA members. At the 2003 Annual Meeting (after the grace period), the Board will report back to the House with any appropriate actions as outlined in Section 8.55 of the Bylaws.

The Board of Trustees recommends:

1. That the American Academy of Insurance Medicine, American Academy of Sleep Medicine, American Association for Vascular Surgery, American Society for Gastrointestinal Endoscopy, American Society for Reproductive Medicine, American Society for Surgery of the Hand, American Society for Therapeutic Radiology and Oncology, American Society of Cytopathology, American Society of General Surgeons, American Society of Plastic Surgeons, American Thoracic Society, American Urological Association, Association of Military Surgeons of the United States, College of American Pathologists, Congress of Neurological Surgeons, Contact Lens Association of Ophthalmologists, Inc., International College of Surgeons, North American Spine Society, Society for Investigative Dermatology, Inc., Society for Medical Consultants to the Armed Forces, Society of American Gastrointestinal Endoscopic Surgeons and the United States and Canadian Academy of Pathology retain representation in the AMA House of Delegates.

2. That the American Association of Clinical Endocrinologists be removed from probation and retain representation in the House of Delegates.

3. That the remainder of this report be filed.

APPENDIX

Exhibit A - Summary Membership Information

ORGANIZATION	AMA MEMBERSHIP WITH PERCENT OF TOTAL SOCIETY MEMBERSHIP
American Academy of Insurance Medicine*	138 (55%) of 251
American Academy of Sleep Medicine	1079 (38%) of 2821
American Association for Vascular Surgery	628 (39%) of 1,624
American Association of Clinical Endocrinologists	1043 (31%) of 3364
American Society for Gastrointestinal Endoscopy	1,692 (33%) of 5,063
American Society for Reproductive Medicine	1,854 (45%) of 4,130
American Society for Surgery of the Hand	674 (44%) of 1542
American Society for Therapeutic Radiology and Oncology	1739 (42%) of 4101
American Society of Cytopathology	474 (39%) of 1,217
American Society of General Surgeons	1,356 (47%) of 2,876
American Society of Plastic Surgeons	1477 (36%) of 4,089
American Thoracic Society	1,770 (22%) of 8,181
American Urological Association	3,472 (42%) of 8273
Association of Military Surgeons of the United States	1,480 (42%) of 3,549
College of American Pathologists	2,154 (28%) of 7,602
Congress of Neurological Surgeons	1,070 (47%) of 2,295
Contact Lens Association of Ophthalmologists, Inc.	271 (50%) of 547

ORGANIZATION	AMA MEMBERSHIP WITH PERCENT OF TOTAL SOCIETY MEMBERSHIP
International College of Surgeons	1,067 (50%) of 2,141
North American Spine Society	1,294 (49%) of 2,651
Society for Investigative Dermatology, Inc.	264 (46%) of 583
Society for Medical Consultants to the Armed Forces*	157 (67%) of 233
Society of American Gastrointestinal Endoscopic Surgeons	1,230 (39%) of 3,122
The Endocrine Society	641 (24%) of 2,711
United States and Canadian Academy of Pathology	1,698 (25%) of 6,813

* - AAIM and SMCAF were seated in the House of Delegates prior to 1990 and therefore exempt from the 250 AMA member requirement.

Exhibit B - Summary of Guidelines for Admission to the House

A. The organization must not be in conflict with the Constitution and Bylaws of the American Medical Association by discriminating in membership on the basis of race, religion, national origin, sex, or handicap.

B. The organization must (a) represent a field of medicine that has recognized scientific validity; (b) not have board certification as its primary focus; and (c) not require membership in the specialty organization as a requisite for board certification.

C. The organization must meet one of the following criteria:

1. A specialty organization must demonstrate that it has 1,000 or more AMA members; or

2. A specialty organization must demonstrate that it has a minimum of 250 AMA members and that thirty-five percent (35%) of its physician members who are eligible for AMA membership are members of the AMA; or

3. A specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that thirty-five percent (35%) of its physician members who are eligible for AMA membership are members of the AMA.

D. The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application.

E. Physicians should comprise the majority of the voting membership of the organization.

F. The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges and are eligible to hold office.

G. The organization must be active within its field of medicine and hold at least one meeting of its members per year.

H. The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.

I. The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.

J. If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

Exhibit C - Responsibilities of National Medical Specialty Organizations

1. To cooperate with the AMA in increasing its AMA membership.
2. To keep its delegate to the House of Delegates fully informed on the policy positions of the organization so that the delegate can properly represent the organization in the House of Delegates.
3. To require its delegate to report to the organization on the actions taken by the House of Delegates at each meeting.
4. To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.
5. To provide information and data to the AMA when requested.

40. EXCELLENCE IN GOVERNANCE: IMPLEMENTATION OF THE "FINAL REPORT OF THE AD HOC COMMITTEE ON STRUCTURE, GOVERNANCE AND OPERATIONS" (I-98)

HOUSE ACTION: FILED

This report is normally submitted for the information of the House of Delegates to provide an update on the implementation of the adopted recommendations included in the "Final Report of the Ad Hoc Committee on Structure, Governance, and Operations" (I-98) and the amended recommendations in Board of Trustees Report 20-A-00. In light of the action taken by the House at the 2001 Interim Meeting creating an Ad Hoc Committee to report on the implementation of adopted recommendations, this report is intended to supplement and not duplicate the "Report on Governance" (A-02) submitted by the ongoing House Ad Hoc Committee on Governance.

BACKGROUND

The Board submitted follow-up reports to the House at the 1999 Annual, 1999 Interim, and 2000 Annual Meetings. At the 2000 Annual Meeting, the House adopted the amended recommendations of BOT Report 20-A-00. At the 2001 Interim Meeting, the House directed the Speaker to appoint an ongoing Ad Hoc Committee to:

- Provide ongoing reports to the House of Delegate at Annual and Interim Meetings, beginning with the 2002 Annual Meeting, until the House deems that it has accomplished its charge. The reports shall address the implementation of new recommendations, old recommendations, and policies that have not been fully implemented with respect to governance;

- Examine the responsibilities and relationships among the AMA Executive Vice-President, General Counsel, and Board of Trustees;

- Address the items referred to it from the Select Committee report; and

- Review and make recommendations to the House based in part on previous reports addressing governance.

IMPLEMENTATION OF PREVIOUSLY ADOPTED GOVERNANCE RECOMMENDATIONS

The Board appreciates the thorough and complete work accomplished by the House Ad Hoc Committee on Governance in assessing the Board's implementation of the adopted recommendations from five past governance reports. The Board accepts the report of the Ad Hoc Committee on the status in completing the 72 adopted recommendations listed in Appendix A of the Ad Hoc Committee's report.

The Board is actively working on those recommendations that have been identified by the Ad Hoc Committee as "Partially Accomplished" or "In Progress" from the five past reports and is committed to completing them. The following are those recommendations followed by the page number in the Ad Hoc Committee's "Report on Governance," where a more detailed status is provided.

1. Special Committee to Study the AMA Board of Trustees (Skoglund Report, I-96)

    - Recommendation 12 - An analysis of the four-year term for the Board is due in 2002 and, at the Speaker's direction, will be done by the Ad Hoc Committee (page 23).

2. Ad Hoc Committee to Study the Sunbeam Matter (Levine Report, A-98)

    - Recommendation 6 - Additional special emphasis will be placed on training for the responsibilities of the Board Chair (page 21).

3. Ad Hoc Committee on Structure, Governance and Operations (I-98)

    - Recommendation 3 - To meet the requirement for regular reports by the Board to the House on the implementation of the AMA's strategic plan, the Board will supplement the current reports to the House by the Executive Vice President on this subject (page 27).

    - Recommendation 7 - The Board will be presenting a report to the House at the 2002 Interim Meeting detailing the results of the Audit Committee's work including assessing the Board of Trustee's performance against the AMA's strategic plan (page 18).

    - Recommendation 10 - The Board submits an annual report of its accomplishments in the AMA Annual Report and in the EVP report to the House but, if desired, will submit a separate Board report (page 18).

    - Recommendation 11 - In conducting its self-evaluations, the Board will seek feedback from the AMA's internal stakeholders and other elements of the organization, including staff (page 20).

    - Recommendation 18 - Consultation between the Presidents and the Chair and the EVP is ongoing on a scheduled basis (page 20).

    - Recommendation 19 - The Presidents are serving as the primary spokespersons under the current "Spokesperson Guidelines" and Standing Rules of the Board (page 30).

    - Recommendation 25 - The Board and CLRPD have submitted a joint report at the 2002 Annual Meeting on the implementation of AMA policy and that report also addresses the role of AMA delegates and alternate delegates in two-way communications. The Board will continue to support the members of the House in communicating with their constituents and welcome the feedback on the issues faced by organized medicine (page 35).

    - Recommendation 30 - The prioritization of House actions has been integrated into Board planning and execution by management within available resources (page 35).

    - Recommendation 31 - Communications is a major emphasis of the Board and the EVP and an aggressive program has been initiated (page 31).

    - Recommendation 33 - A two-year fiscal repositioning initiative started in 2000 has been successful in reducing net operating expenses and leading to a positive operating results in 2000 and 2001. The new EVP is evaluating the current staff structure and allocation of resources (page 24).

    - Recommendation 34 - A more aggressive organization-wide representation program is being designed to capture existing participation by the Board and staff and to more effectively utilize staff capabilities in serving on non-AMA panels, and fostering working relationships with other organizations (page 31).

4. Board of Trustees Report 20-A-01

    - Recommendation 6 - Communication initiatives are underway and will be expanded to ensure key stakeholders are timely informed of AMA accomplishments (page 34).

5. Select Committee (I-01)

- Recommendation 14 - The Standing Rules have been amended to make the Speaker an ex officio member of the Executive Committee without the right to vote (page 17).

- Recommendation 17 - The OGC will prepare a final report for the House on the litigation of *Anderson v. AMA* when it is concluded (page 37).

RECOMMENDATIONS OF THE AD HOC COMMITTEE

The Board of Trustees supports the recommendations of the House Ad Hoc Committee on Governance in their Report on Governance (A-02).

41. VIDEO DOCUMENTARY OF THE FUNCTION OF THE AMA HOUSE OF DELEGATES

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

This report responds to Resolution 608, introduced by the Louisiana Delegation at the 2001 Interim Meeting and referred to the Board of Trustees. Resolution 608 asked that the American Medical Association consider developing a documentary videotape, which would illustrate the function and ultimate outcome of a meeting of the AMA House of Delegates, perhaps through cooperation with a media documentary firm or major television network. The reference committee stated its belief that the Board should request the ACM to study the feasibility of the issue as well as other innovative membership communication strategies. In developing this report, the Board sought the views of the Advisory Committee on Membership (ACM) and the AMA's Communications unit.

BACKGROUND

Resolution 608 suggests that the videotape could follow the process of an individual delegate's idea, transformed into a resolution endorsed by his/her organization; illustrate the delegation caucus process, meetings, Reference Committees, Council and Board reports, election deliberations, and House functions; and employ interviews with other delegates, trustees and staff. Resolution 608 notes that the video should emphasize the democratic process involved in the passage of a resolution, the governance of the AMA, and how priorities are established.

The Reference Committee heard conflicting testimony on the merits of developing a video documentary of the function of the House. Some members of the House stated that this documentary could be used as a membership marketing tool. Others testified that the money for this documentary could be better spent on other AMA priorities.

DISCUSSION

The ACM feels that while it is important to show members and members-to-be the House of Delegates policy-setting process, it is not convinced that such a documentary would compel an individual to join or renew.

Further, the Board believes that demand for such a video by membership recruiters would be low, and that the video would become outdated fairly quickly. The Board will continue to seek feedback from key stakeholders, including the sections, councils and outreach recruiters, regarding the use of this type of vehicle. But, at this point in time, due to the high costs associated with producing such a video ($50,000-$125,000), the Board does not believe this video should be considered a communications priority.

RECOMMENDATION

The Board of Trustees therefore recommends that Resolution 608 (I-01) not be adopted, and that the remainder of this report be filed.