

Nurse Practitioners and Clinical Nurse Specialists with Prescriptive Authority and Prescriptive Remedies

Statement of Purpose

To establish guidelines and provide clear direction for Oregon nurses with prescriptive authority who want to prescribe remedies that are off label, compounded, or were marketed before the FDA approval process.

Background information

Nurse Practitioners have been authorized to prescribe in Oregon since 1979. The majority of prescribing has been done under a Board approved formulary which was initially reviewed by a committee of physicians, pharmacists and nurse practitioners, and later through a Board of Nursing formulary committee. In 1993 the Board adopted *Drug Facts and Comparisons* as its prescribing formulary.

In the 2007 interim legislative session, SB 1062 eliminated the requirement for a Nurse Practitioner formulary. By this time Clinical Nurse Specialists had also obtained the ability to apply for Schedule II-V prescriptive authority. The Board directed rulemaking to remove the formulary and draft rules were proposed at the February 2008 Board meeting and adopted April 10, 2008. These regulations made the following recommendations based upon legislative direction, formulary committee recommendation, and Board direction:

- The requirement for FDA approval of all drugs prescribed was retained;
- Orphan drugs, expanded access drugs and IRB approved investigational drugs were added as exceptions to the FDA approval requirement (OAR 851-056-0010).

The Board has been asked by nurse prescribers to clarify their ability to prescribe drugs which are in common use and may not meet the above categories.

Definitions

Compounded drug- A *compounded drug* means a combination preparation the active ingredients of which are components of an FDA approved drug or a drug which is still in common usage and predates the FDA approval process.

DESI drug- A *DESI drug* is one marketed in the United States under the 1938-1962 NDAs (safety only) review prior to FDA approval requirements.

Legend Drug- A *legend drug* means a drug which is:

- a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the following statements:
“Caution: Federal law prohibits dispensing without prescription”; or
“Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”; or
- b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only. ORS 689.0005 (Oregon Pharmacy Statute)

Off-Label- An *off-label* prescription means prescription of an FDA approved drug for other than its FDA approved indications or dosing.

Questions for Clarification

- 1) May a nurse prescriber prescribe off-label?
- 2) May a nurse prescriber prescribe drugs marketed before the FDA process requirements (DESI) drugs?
- 3) May a nurse prescriber designate preparation for a drug such as compounding or non-FDA approved administration instructions?

Scope of Practice Statement

The Oregon State Board of Nursing affirms the following statements. The Board will consider the principles of informed consent, clinical efficacy, patient safety, and patient preference in evaluating practice complaints related to prescriptions which are provided off label, DESI, or compounded for administration (see applicable Rules and Policies).

- 1) It is within the scope of practice for a nurse prescriber (NP or CNS) to prescribe medications for off label use.
- 2) It is within the scope of practice for a nurse prescriber (NP or CNS) to prescribe medications which are not FDA approved solely because their marketing predates the FDA approval requirements and process (DESI drugs).
- 3) It is within the scope of practice for a nurse prescriber (NP or CNS) to prescribe medications with patient specific instructions for preparation and administration including compounding that meets the guidelines found in the Oregon Nurse Practice Act, Division 56.

Applicable Rules and Policies

Oregon State Board of Nursing (2009). Complementary and alternative modalities and nursing practice. Available at http://www.oregon.gov/OSBN/pdfs/policies/complementary-alternative_modalities.pdf.

Oregon State Board of Nursing (2001/2008). Nurse practitioners and clinical nurse specialists with prescriptive authority and non-prescriptive remedies. Available at <http://www.oregon.gov/OSBN/pdfs/policies/herbpoli.pdf>.

Oregon State Board of Nursing (2003/2009). Prescriptive authority in Oregon for nurse practitioners and clinical nurse specialists. Available at http://www.oregon.gov/OSBN/pdfs/publications/prescriptive_booklet.pdf.

Oregon State Board of Nursing (2010). Division 56. *Clinical Nurse Specialist and Nurse Practitioner Authority to Prescribe and Dispense*. Available at <http://www.oregon.gov/OSBN/pdfs/npa/Div56.pdf>

Oregon State Board of Pharmacy (2010). Division 45. Sterile and non-sterile compounding. Available at http://arcweb.sos.state.or.us/rules/OARS_800/OAR_855/855_045.html.

References

Cully, C., Carroll, B. & Skledar, S. (2008). Formulary decisions for pre-1938 medications. *American Journal of Health System Pharmacy*, 65(14), 1363-1367.

Food and Drug Administration. (2010). Drugs@FDA frequently asked questions. Available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm075234.htm>.

Mayhew, M. (2009). Off-label prescribing. *The Journal for Nurse Practitioners*, 122-123. Doi: 10.1016/j.nurpra.2008.11.009.

US Department of Health and Human Services (June,2006). Guidance for FDA staff and industry: marketed unapproved drugs—compliance guideline. Rockville: Center for Drug Evaluation and Research.

USP (2010). USP compounding backgrounder. Available at www.usp.org.

Adopted 09/2011

The Oregon State Board of Nursing (OSBN) is authorized by Oregon Revised Statutes Chapter 678 to exercise general supervision over the practice of nursing in Oregon to include regulation of nursing licensure, education and practice in order to assure that the citizens of Oregon receive safe and effective care.

The OSBN further interprets statute and rule and issues opinions in the form of Board Policies, Policy Guidelines and Position Statements. Although they do not have the force and effect of law, these opinions are advisory in nature and issued as guidelines for safe nursing practice.