



DEPARTMENT OF JUSTICE
GENERAL COUNSEL DIVISION


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MEMORANDUM

DATE: November 3, 2016

TO: Marcus Watt, Executive Director,
Oregon State Board of Pharmacy

Ruby Jason, Executive Director,
Oregon State Board of Nursing

FROM: Thomas W. Cowan
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Business Activities Section 

SUBJECT: Drug Outlet Inspections

QUESTION PRESENTED

Should the specific parameters articulated in ORS 678.390(5)(e) regarding complaint inspections conducted by the Board of Pharmacy be construed to limit the otherwise general authority of the Board to inspect drug outlet dispensing sites operated by a nurse practitioner or clinical nurse specialist?

BRIEF ANSWER

No. While ORS 678.390(5)(e) directs the Board of Nursing to adopt rules requiring recognition of the Board of Pharmacy's authority to enter and inspect a dispensing site operated by a nurse practitioner or a clinical nurse specialist if there is a complaint, the Board of Pharmacy also has general authority to enter and inspect any drug outlet.¹ Practice sites of dispensing practitioners are considered drug outlets, subject to the registration requirements if drugs are dispensed for consideration.² There is nothing in the legislative history that indicates

¹ ORS 689.155(8), OAR 855-001-0040

² Opinion Request OP-2013-12013 WL 604284 (Or. A.G. Feb. 6, 2013)

that the intent of ORS 678.390(5)(e) was to limit the Board of Pharmacy's ability to enter and inspect a dispensing site in the absence of a complaint.

ANALYSIS

I. The Oregon Board of Pharmacy has regulatory authority to inspect all drug outlets that are engaged in dispensing, delivery, and/or distribution of drugs within the State of Oregon.

The Oregon Board of Pharmacy (BOP) has two jurisdictional silos of authority: (1) to regulate the practice of pharmacy; and (2) to regulate all drug outlets. The authority for the BOP to regulate pharmacy practice can be found in ORS 689.151, which provides that the BOP shall be responsible for the control and regulation of the practice of pharmacy in the State of Oregon, including but not limited to actions related to licensing of those engaged in the practice of pharmacy (including pharmacy interns and pharmacy technicians). This authority does not extend to other health licensees specifically authorized by Oregon law whose conduct may otherwise be considered the practice of pharmacy. ORS 689.225(1) Therefore, dispensing nurse practitioners and dispensing certified nurse specialists are exempt from the "practice" regulatory authority of the BOP.

The authority for the BOP to regulate drug outlets can be found in ORS 689.305, which provides that all drug outlets shall annually register with the BOP and the BOP shall establish by rule the criteria which each drug outlet must meet to qualify for registration in each classification designated within this statute. ORS 689.305 provides a list of five drug outlet classifications: (1) retail; (2) institutional; (3) manufacturing; (4) wholesale; and (5) nonprescription. The definition of drug outlet can be found in ORS 689.005(13), which provides:

"Drug outlet" means any pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

(Emphasis added). The BOP has the authority to regulate all drug outlets.

a. The sites where nurse practitioners and certified nurse specialists dispense prescription drugs are defined as drug outlets.

The remaining question is whether practice locations where nurse practitioners and certified nurse specialists dispense prescription drugs are drug outlets for the purposes of ORS 689.305. The meaning of drug outlet is articulated in ORS 689.005(13). While not specifically referenced, the sites where practitioners dispense drugs are encompassed by the last provision

which states: “[a]ny ... other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.”³

As will be discussed later in the legislative history section of this memorandum, the BOP requested an opinion from the Attorney General in 2013 on this very question. The opinion analyzes the definitions of “drug outlet” and “other establishment” and the legislative intent behind the language found in ORS 689.005(13). The opinion concluded that it was not possible to tell precisely what the legislature intended by “other establishment” but opined that the term “most likely includes the facility from which a business or nonprofit organization dispenses, delivers or distributes drugs to Oregonians. The practice sites of dispensing practitioners fit within that definition and, therefore, are ‘drug outlets,’ and must annually register with the board pursuant to ORS 689.305(1).”⁴

II. In the event of a complaint, Board of Nursing dispensing licensees are required to recognize the Oregon Board of Pharmacy’s explicit authority to conduct a complaint inspection.

ORS 678.390 articulates the authority of nurse practitioners and clinical nurse specialists to write prescriptions or dispense drugs. Specifically 678.390(5)(e) establishes that the Oregon State Board of Nursing (BON) shall adopt rules requiring dispensing certified nurse practitioners and dispensing certified clinical nurse specialists to allow the BOP to inspect a dispensing site after a complaint has been received and after prior notice to the BON. This statute clarifies that the BOP/BON relationship and acknowledges the authority to inspect sites wherein a nurse practitioner or certified nurse specialist are dispensing prescription drugs given a complaint. Notwithstanding the statutory parameters around complaint inspections, the language of 678.390(e) should not be seen to curtail the BOP general authority to inspect drug outlets.

III. The Oregon Board of Pharmacy has general regulatory authority to inspect drug outlets including, the facilities where nurse practitioners are dispensing drugs.

The BOP is authorized by ORS 689.205 to make, adopt, and amend such rules as may be deemed necessary by the board. One such rule is OAR 855-001-0040, which governs procedural rules for inspections. OAR 855-001-0040 provides in relevant part that the BOP “may enter and shall be allowed entry to any drug outlet where drugs are stored, and the premises where the records associated with those drugs are stored, to conduct inspections at reasonable times in a reasonable manner for the purposes of”, amongst other things, inspecting reports and equipment, making a physical inventory of all drugs on hand, collecting drug samples, and “[a]ll other things appropriate for verification of records, reports, documents referred to above or otherwise bearing on the provisions of the Uniform Controlled Substances Act, the Oregon Pharmacy Act or these rules.” There is no language within this rule that provides that there must be a complaint before the inspection takes place. Further, the rule provides:

³ *Id.*

⁴ *Id.*

The inspections hereunder may be conducted in connection with applications for initial or renewal registration or modification or amendment thereof and at such other times where the Board determines there is a reasonable basis for concluding the inspection is necessitated in order to ensure that there is compliance with the Uniform Controlled Substance Act, the Oregon Pharmacy Act, and these rules. .

Under the Uniform Controlled Substance Act, ORS 475.125(1) states that “[e]very person who manufactures, delivers or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state, must obtain annually a registration issued by the State Board of Pharmacy in accordance with its rules.” Further, and more to the point, ORS 475.125 authorizes the BOP to inspect the establishment of a registrant or applicant for registration in accordance with the rules.

IV. Legislative history provides some insight into what the legislative intent was behind the question at hand.

There were several statutes that prompted legislative history tracings to determine if there was any mention of the BOP’s authority to enter a dispensing site operated by a nurse practitioner or certified nurse specialist without a complaint first being received specific to the dispensing practices of the site.

Oregon Laws 2003, chapter 617 (Senate Bill 708) was the first bill that amended ORS 678.390 to include the language that is now found in subsection (5)(e), requiring BON to recognize that the BOP, upon the receipt of a complaint, is authorized to conduct a complaint inspection of a dispensing site with prior notice to the BON. Unfortunately, majority of the legislative record is focused on either the advocacy for or opposition of nurse practitioners having the ability to dispense drugs to their patients, and no mention of complaint instigated inspections. As would be expected, nurse practitioners were advocating for the ability to dispense prescriptions and presented extensive testimony about how critical the need is for the following reasons: (1) indigent drug programs; (2) patients lacking adequate funds; and (3) transportation issues preventing access to pharmacies.⁵ In opposition were pharmacists and those representing pharmacists. One of their main concerns was “whether advanced practice nurses are the appropriate people to oversee the dispensing of the same medications that they write the prescriptions for.”⁶ Again, there was no discussion of inspections.

The most recent amendment to ORS 678.390 is found in Oregon Laws 2013, chapter 402, section 1 (Senate Bill 8). The legislative record for SB 8 provides the most insight into the question at hand. Susan King, Executive Director of Oregon’s Nursing Association, provided testimony in response to concern about the unregulated drug dispensaries and what the appropriate level of regulation is for a provider’s office when that provider is dispensing incidental to a visit.⁷ Susan King further provided that the BOP looked to the Attorney General’s office for clarity on if the BOP has authority over that particular situation and the intent was to

⁵ Testimony of Representative Laurie Monnes Anderson, Senate Health Policy Committee (SB 708), March 27, 2003, at 1:24:15.

⁶ Testimony of Tom Holt, Senate Health Policy Committee (SB 708), March 27, 2003, at 1:39:11.

⁷ Testimony of Susan King, Senate Health and Human Services (SB 8), February 4, 2013, at 30:50.

bring the disciplines back together once that opinion was received to have further discussion about whether any provider that dispenses occasionally should be regulated as a dispensing drug outlet.⁸ That Attorney General opinion was published on February 6, 2016 (Opinion Request OP-2013-1).⁹ The essential question presented was “[a]re the practice sites of dispensing practitioners who are exempt from the requirement to obtain a license to practice pharmacy under ORS 689.225(1) subject to the ‘drug outlet’ registration requirement[s] imposed by ORS 689.305?”¹⁰ The opinion goes into great detail in the discussion section and includes the methodology, the scope of exception in ORS 689.225(1), the definition of drug outlet, the outlet classification, the legislative history, and the conclusion. The conclusion provides in relevant part “that the practice sites of practitioners who dispense drugs ... to their patients in accordance with their own professional licensing laws” but are exempt “under ORS 689.225(1) to obtain a license to engage in the practice of pharmacy ... are ‘drug outlets’” as “defined under ORS 689.005(12) and subject to the drug outlet registration requirements of ORS 689.305.”¹¹

CONCLUSION

There is nothing in the plain reading of ORS 678.390(5)(e) or in the legislative history that prevents the BOP from entering a dispensing site operated by a Nurse Practitioner or Clinical Nurse Specialist without a complaint being first received specific to the dispensing practices of the site. Practice sites of dispensing practitioners who are exempt from the requirements to obtain a license to practice pharmacy are considered drug outlets and are subject to the registration requirements imposed by ORS 689.305. The BOP has authority to regulate and inspect drug outlets and therefore, there is nothing in ORS 678.390(5)(e) that supersedes that authority or would prevent the BOP from conducting routine inspections at drug outlets, regardless of whether there has been a complaint.

⁸ *Id.*

⁹ Opinion Request OP-2013-12013 WL 604284 (Or. A.G. Feb. 6, 2013).

¹⁰ *Id.*

¹¹ *Id.*