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February 6, 2013

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Re: Opinion Request OP-2013-1

Dear Executive Directors:

Among other things, the State Board of Pharmacy (board) is responsible for regulating the practice of pharmacy in Oregon, which includes issuing licenses to persons to engage in the practice of pharmacy. ORS 689.151. The board is also responsible for issuing “certificates of registration” to “drug outlets.” ORS 689.305. Pursuant to ORS 689.225(1), physicians, dentists, veterinarians, osteopaths and “other practitioners of the healing arts” do not need to obtain a license to engage in the practice of pharmacy to administer and dispense drugs to their patients if their own licensing laws authorize them to do so.

The pharmacy, nursing, dentistry, medical, naturopathic, and veterinary boards ask the following question concerning whether the exemption in ORS 689.225(1) affects the drug outlet registration requirement in ORS 689.305.

QUESTION

Are 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 imposed by ORS 689.305?

SHORT ANSWER

We conclude that ORS 689.225(1) does not exempt those practice sites from the drug outlet registration requirement. We also conclude, although the answer is not free from all doubt, that those sites are “drug outlets” subject to the registration requirement if drugs are dispensed for consideration from them.

DISCUSSION

A. Methodology

To answer the question, we must interpret several statutes in ORS chapter 689. The Oregon Supreme Court has established the following methodology for interpreting statutes: The goal is to determine the intent of the legislature by first examining the statute’s text, in context, and, where appropriate, we also may also consult legislative history to the extent that it is helpful. *PGE v. Bureau of Labor and Industries*, 317 Or 606, 610, 859 P2d 1143 (1993); *State v. Gaines*, 346 Or 160, 171-73, 206 P3d 1042 (2009).

B. Scope of exception in ORS 689.225(1)

ORS 689.225(1) provides that:

A person may not engage in the practice of pharmacy unless the person is licensed under this chapter. Nothing in this section prevents physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

ORS 689.151 gives the board authority to regulate and control the practice of pharmacy, including issuing licenses. A qualified applicant may obtain a license to practice pharmacy either by taking an examination or through reciprocity. ORS 689.151(1).

ORS 689.005 contains the definitions as used in chapter 689. Subsection (28)(b) of that statute defines the “practice of pharmacy” to include “[t]he compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs or devices.” ORS 689.005(28)(b). “Dispense” or

“dispensing” means “the preparation and delivery of a prescription drug pursuant to the lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.”
ORS 689.005(8).

Read in that context, ORS 689.225(1), generally prevents a person from dispensing drugs unless the person has obtained, through examination or reciprocity, a license to engage in the practice of pharmacy under ORS 689.151(1). But ORS 689.225(1) specifies “[n]othing in this section prevents” Oregon-licensed practitioners of the healing arts who are authorized by their own licensing laws to dispense drugs from dispensing drugs in accordance with their own licensing laws. “Nothing in this section prevents” means nothing in ORS 689.225(1). ORS 689.225(1) prevents only engaging in the practice of pharmacy without having obtained a license and that license is obtained through examination or reciprocity under ORS 689.151(1). Stated another way, this language merely clarifies that ORS 689.225(1) does not require practitioners whose own licensing laws authorize them to dispense and administer prescription drugs to obtain a license under ORS 689.151(1).

ORS 689.225(1) does *not* say that the practice sites of those practitioners are exempt from registration. ORS 689.225(1) is concerned solely with the professional licensing of pharmacists. Other provisions in ORS 689 govern the registration of drug outlets. Specifically, ORS 689.305(1) provides that “[a]ll drug outlets shall annually register with the State Board of Pharmacy.” (Emphasis added). ORS 689.335(1) states that “[n]o drug outlet designated in ORS 689.305 shall be operated until a certificate of registration has been issued to said facility.”

We conclude that the legislature did not intend the exemption in ORS 689.225(1) to exempt the practice sites of dispensing practitioners from the drug outlet registration requirement.

The drug outlet registration requirement applies to “all” drug outlets and “no” outlet may operate without a certificate of registration. There are no exceptions. We turn to whether the practice sites of dispensing practitioners are “drug outlets” for purposes of the registration requirement.

C. Definition of drug outlet

ORS 689.005(12) defines a “drug outlet” as:

[A]ny 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.

There is no question that nursing homes, shelter homes, convalescent homes, extended care facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics and student health centers are “drug outlets” subject to the registration requirement regardless of whether practitioners who are exempt from the licensing requirement under ORS 689.225(1) dispense drugs at those places. “Dispensing practitioner’s offices” or “dispensing practitioner’s clinics,” however, are not specifically listed and, therefore, must fit within one of the more general types of listed “drug outlet.”

The most general of those is “[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.” The practice sites of dispensing practitioners are engaged in dispensing drugs in Oregon. The question is whether they are “establishments” for purposes of the statute. “Establishment” is not defined for purposes of ORS chapter 689 so we give it its plain meaning. *See PGE v. BOLI*, 316 Or at 610 (providing that, in interpreting the text, we give words that are not statutorily defined, their plain, natural and ordinary meanings).

There are three potentially pertinent plain meanings of “establishment”: (1) “something that has been established”; (2) “a more or less fixed and usually sizable place of business or residence together with all the things that are an essential part of it (as grounds, furniture, fixtures, retinue, employees)”; and, (3) “a public or private institution (as a school or hospital).” WEBSTER’S THIRD NEW INT’L DICTIONARY at 778 (2d ed 2002). “Establish,” as pertinent, means “to place, install, or set up in a permanent or relatively enduring position especially as regards living quarters, business, social life, or possession.” *Id.*

Under those definitions, an “establishment” potentially could mean either a place or an established entity. ORS 689.005(12) refers to “an establishment *with* facilities [whether within or without Oregon]* * * that is engaged in dispensing[.]” (Emphasis added). The “establishment” is the drug outlet, rather than the “facilities” because an establishment is singular and the statute uses the singular “is” whereas “facilities” is plural and the statute does not use the plural “are engaged.” But an “establishment” could still be a “facility” that has facilities in or outside Oregon. The pertinent definitions of “facility” are “**5a** : something that promotes the ease of any action, operation, transaction, or code of conduct – usually used in the plural < excellent *facilities* for graduate study> **b**: something (as a hospital, machinery, plumbing) that is built, constructed, installed or established to serve some particular function or to serve or facilitate some particular end.” WEBSTER’S at 812.

ORS 689.005(12) refers to “other establishment” at the end of a long list, suggesting that the things that preceded “other establishment” on the list are “establishments” too. The list includes both places (such as pharmacies, hospitals and retail stores) and entities, such as a “manufacturer” (defined as “a person” by ORS 689.005(21)), a “wholesaler” (which is not defined, but a “wholesale drug outlet” is defined as “any person” ORS 689.006(36)) and mail order vendors (which is not defined but appears to refer to a type of business entity). The common thread between listed outlets that are not physical places (manufacturer [the definition of which excludes the preparation of drugs by an individual for their own use, ORS 689.005(20)]

wholesaler, and mail order vendor) is that they are entities involved in disseminating drugs in Oregon. Therefore “establishment” does not appear to mean a personal residence no matter how sizeable it is. Nor are those places limited to “institutions.”

Turning to other context, the statutes appear to use “drug outlet” somewhat inconsistently. As discussed, some “drug outlets” are defined as persons, rather than facilities. But ORS 689.335(1) prohibits a “drug outlet designated in ORS 689.305” from being operated “until a certificate of registration has been issued *to said facility*.” (Emphasis added). “Said facility” necessarily means “drug outlet” for purposes of that statute. On the other hand, while “manufacturer” and “wholesale drug outlets” are defined as “persons,” ORS 689.315(4)(a) provides that manufacturers and wholesalers shall acquire a separate registration for each place at which they carry on their business. In those instances, the “manufacturer” or “wholesaler” “person” may have the obligation to apply for a certificate, but the certificate applies to the specific places where they do business.

Another piece of relevant context is the use of the word “establishment” in a related statute in ORS chapter 689. Generally, when the legislature uses the same word in a related statute, we presume that it intends the same meaning. *Tharp v. PSRB*, 338 Or 413, 110 P3d 103 (2005). The legislature uses the term “establishment” in ORS 689.005(34), which defines “shopkeeper” (which is subject to the registration requirement as a “nonprescription drug outlet” under ORS 689.005(22)). A shopkeeper is defined as “a business *or other establishment*, open to the general public, for the sale or nonprofit distribution of drugs.” (Emphasis added). That use of “establishment” is particularly pertinent not only because it is used in a related statute, but because the legislature added “other establishment” in that provision at the same time that it added “other establishment” to the definition in ORS 689.005(12). Or Laws 2005, ch 313, section 11. As used in ORS 689.005(34), “other” refers to an “establishment” other than a “business” suggesting both that the legislature considered a “business” to be one type of establishment and that it considered things that were not businesses to be establishments as well. A “business” can be either “a commercial or industrial enterprise” or “a place where such an enterprise is carried on.” WEBSTER’S at 302. Other language in the definition of “shopkeeper” specifies that the “business or other establishment” must be “open to the public for the sale or nonprofit distribution of drugs.” This provision is helpful context insofar as it shows that the legislature considered both businesses and nonprofits to be types of “establishments.”

In short, it is not possible to tell precisely what the legislature intended by “other establishment” as used in ORS 689.005(12), except that it appears to have been intended to encompass both businesses and nonprofit organizations. Although not free from doubt, we conclude that the legislature most likely used the term consistently with ORS 689.335(1), the provision imposing the prohibition on operating a drug outlet without a certificate, in the sense of a facility. Accordingly, “other establishment” 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).

D. Outlet Classification

ORS 689.305(2)(a) requires “[e]ach drug outlet” to apply for a certificate of registration in one or more of five listed classifications: (1) retail drug outlet; (2) institutional drug outlet; (3) manufacturing drug outlet; (4) wholesale drug outlet; or, (5) nonprescription drug outlet. Drug outlets must meet criteria established by the board to qualify for registration in a particular classification. ORS 689.305(3). The board may issue various types of certificates to drug outlets with “varying restrictions” when the board deems it “necessary by reason of the type of drug outlet requesting the certificate.” *Id.*

Although the board establishes the criteria to qualify for registration in a particular classification, the classifications themselves are defined by statute (with the exception of manufacturing drug outlet, but “manufacturer” is defined). The definitions of institutional drug outlet, wholesale drug outlet and nonprescription drug outlet do not need to be discussed, because they clearly do not include the places from which practitioners dispense drugs to their patients. The only applicable classification is “retail drug outlet,” which is defined as:

[A] place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully occur.

We first note that “retail drug outlet” is defined as “a place,” therefore, the certificate of registration in this classification – consistent with ORS 689.335(1) – applies to the facility. A dispensing practitioner’s office or clinic fits within a place “used for the conduct of * * * dispensing * * * drugs” and also “for * * * dispensing prescriptions.” In fact, those phrases mean exactly the same thing according to the applicable definitions provided in ORS 689.005:

(8) “Dispensing” or “dispensing” means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(10) “Drug” means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animal;

(c) Articles, other than food, intended to affect the structure or function of the body of humans or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

(32) “Prescription * * * means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use of a drug. When the context requires, “prescription” also means the drug prepared under such written, oral or electronically transmitted direction.

According to those definitions, while any kind of drug may be “administered” only prescription drugs are “dispensed.”

That raises the question why the legislature would include both the places used to “dispense drugs” and the places used to “dispense prescriptions” in the definition. We assume that the legislature does not engage in meaningless repetition, but intends all language used to have some independent effect. In other words, we assume that the legislature used “dispense” twice for a reason.

One possible reason is that the definition is intended to be separated into two clauses, the first of which applies to all places that are used to conduct the retail sale, administering or dispensing or compounding of drugs or chemicals” and the second to apply to places used “for the administering or dispensing of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully occur.” As to the latter, a “pharmacy” is the only place defined under ORS 689.005 as “a place that * * * is licensed and approved by the board where the practice of pharmacy may lawfully occur[.]” ORS 689.005(26). If the legislature intended “retail drug outlets” to encompass only “pharmacies” (*i.e.*, be subject to the requirement that the place be a licensed pharmacy) it could simply have defined a “retail drug outlet” as a “pharmacy” particularly since “pharmacy” is defined to exclude manufacturers and wholesalers. *Id.* If the only intended distinction was between places that disseminate nonprescription drugs and places that disseminate prescription drugs, “dispensing” would not have been included in the first clause. We conclude that the legislature intended two separate clauses and that the requirement that the place be licensed by the board as a place wherein the practice of pharmacy may lawfully occur apply only to the second

The next question is whether the adjective “retail” as used in the first clause applies to each listed activity (administering, dispensing and compounding) or only to the “sale.” “Retail” is not defined, but its plain meaning used as an adjective is “of, relating to, or engaged in the sale of commodities at retail.” WEBSTER’S at 1938. The pertinent plain meaning of the verb “retail” is “to sell in small quantities * * * [and] to sell directly to the ultimate consumer.” *Id.* “Sale” means “the act of selling; a contract transferring absolute or general ownership of property from one person or corporate body to another for a price (as a sum of money or any other consideration) * * * distinguished from *gift*.” *Id.* at 2003. Although it is reasonable to conclude that “retail” was intended only to modify “sale,” there also are reasons to conclude that it may have been intended to modify all the activities for the purpose of imposing two requirements: (1) transfer for consideration; (2) and transfer directly to the ultimate consumer. That interpretation is consistent with the purpose of the provision, which is intended to distinguish a “retail drug outlet” from other types of drug outlets, such as “manufacturing” and “wholesale” drug outlets. “Compounding” is an included activity both in the retail drug outlet definition and in the definition of a manufacturer. Applying “retail” to its use in the retail drug outlet definition

supports the distinction between the two that the classifications are attempting to draw. We also note that practitioner compounding is explicitly excluded from the definition of “manufacturer.” See ORS 689.005(20) (defining “manufacture” to include the preparation, compounding, packaging or labeling of a drug, but excluding those activities when done “[b]y a practitioner as an incident to administering or dispensing of a drug in the course of professional practice.”). No similar exclusion is provided in the definition of “retail drug outlet” suggesting that no exclusion was intended.

The interpretation that “retail” applies to all of the activities in the first clause is also consistent with how the legislature applied a similar modifying term in another definition. ORS 689.005(36) defines “wholesale drug outlet” as “any person who imports, stores, distributes or sells for resale any drugs including legend drugs or nonprescription drugs.” Unless the “for resale” language modifies activities other than “sells” in that definition, any “person” who stores drugs would qualify as a “wholesale drug outlet.” We doubt that the wholesale drug outlet classification was intended to encompass anyone who stores drugs. We also doubt that the retail drug outlet classification was intended to include compounding by a manufacturer.

We conclude that the text and context suggest that “retail drug outlet” as defined in ORS 689.005(33) most likely includes all places used for dispensing drugs to an ultimate consumer for consideration, including the places where dispensing practitioners dispense medications to their patients for consideration.

E. Legislative History

Finally, we have examined the legislative history, but the history does not change our conclusions based on the text and context. The drug outlet registration requirement was enacted in 1979 as part Senate Bill 866 (1979), which was an overhaul and recodification of the pharmacy code. The issue whether the practice sites of dispensing practitioners were subject to the drug outlet registration requirement was not discussed.

The language “other establishment with facilities within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state” was not part of the original definition of “drug outlet”, but was added to the definition in 2005 as a –A4 amendment to Senate Bill 512. One non-legislator witness testified before a House Committee that the amendment was a “technical amendment” needed to ensure that the Oregon Food Bank could be registered as a drug outlet. The Food Bank wished to provide donated nonprescription drugs to Oregonians. Testimony of Tom Holt, House Health and Human Services Committee (SB 512), May 18, 2005, <http://landru.leg.state.or.us.audio> at 1:10:00. At the time, no wording in the definition of “drug outlet” fit the Food Bank. As discussed, the definition of “shopkeeper” also was amended at that time to include establishments other than businesses and the nonprofit distribution of drugs.

Although according to the testimony of one non-legislator witness, the reason for requesting the amendment was to ensure that the Oregon Food Bank qualified as a drug outlet, the language that was enacted into law is much broader. The Oregon Supreme Court recently reiterated that:

[T]here is no more persuasive evidence of the intent of the legislature than the words by which the legislature undertook to give expression to its wishes. Only the text of a statute receives the consideration and approval of a majority of the members of the legislature, as required to have the effect of the law. The formal requirements of lawmaking produce the best source from which to discern the legislature's intent, for it is not the intent of the individual legislators that governs, but the intent of the legislature as formally enacted into law[.]

Halperin v. Pitts, 352 Or 482, 486, 287 P3d 1069 (2012).

Finally, we note that, in 2012, the legislature enacted Senate Bill 1565, concerning physician assistant dispensing. Section 2(2)(b) (D) of that bill requires the board to adopt rules that require “[t]he supervising physician or supervising physician organization that applies for dispensing authority for a physician assistant to * * * * [s]ubmit to the board documentation showing that the supervising physician or supervising physician organization has registered the facility from which the physician assistant will dispense drugs as a drug outlet with the State Board of Pharmacy under ORS 689.305.” Although that is a later-enacted statute and does not illuminate the intent of earlier enactments, we point it out merely to demonstrate that our conclusion that ORS 689.305 requires such facilities to be registered is consistent with the legislature's understanding of what ORS 689.305 requires.

F. Conclusion

We conclude that the practice sites of practitioners who dispense drugs for consideration to their patients in accordance with their own professional licensing laws, but who are not required under ORS 689.225(1) to obtain a license to engage in the practice of pharmacy from the board to do so, are “drug outlets” under ORS 689.005(12) and subject to the drug outlet registration requirement in ORS 689.305.

Sincerely,

[*Steven A. Wolf*]

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General Counsel Division