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To: Wisconsin Pharmacy Examining Board
From: William A. Black

Re: Review and analysis of 2005 Wis. Act 14- Regulation of Pseudoephedrine Products

Set forth below is a section breakdown and analysis of the effect of 2005 Wis. Act 14, the (“Act”), on current pharmacy practice.

1. Storage requirements for distributors and manufacturers

A concern was raised that scheduling pseudoephedrine as a controlled substance would require distributors and manufacturers to modify storage practices. Section 8 of the Act addressed this concern by amending Wis. Stat. § 450.07, to prohibit storage rules for controlled substances from applying to pseudoephedrine, or any substance, if that substance is not scheduled by Wisconsin as a schedule I-IV substance nor scheduled under federal law. Therefore, pseudoephedrine, as a schedule V substance in Wisconsin, and unscheduled under federal law, is exempt at this time from additional storage security requirements.

450.07 (4) (b) (intro.) The board shall adopt rules prescribing minimum standards for manufacturing and distributing drugs. Rules adopted under this paragraph may not impose requirements regarding the storage of a controlled substance in a safe, a steel cabinet, a vault, or any other secure storage compartment, area, room, or building unless one of the following applies:

1. The controlled substance is included in schedule I, II, III, or IV under ch. 961.
2. The controlled substance is also a controlled substance under federal law.

Effect on Wisconsin Licensed Distributors and Manufacturers.

No additional security measures for pseudoephedrine products need to be implemented at this time.

2. Pseudoephedrine products regulated.

The Act addresses three types of pseudoephedrine substances, a “product”, a “liquid” and a “gelcap”. All pseudoephedrine “products” are subject to the Act, if they are not “liquids” or “gelcaps”.

A “Pseudoephedrine product” is defined as:

961.01 (20c) "Pseudoephedrine product" means a material, compound, mixture, or

preparation containing any quantity of pseudoephedrine or any of its salts, isomers, or salts of isomers but does not include such a product if any of the following applies:

(a) The product is a pseudoephedrine liquid or a liquid-filled pseudoephedrine gelcap. This paragraph does not apply if the controlled substances board has determined, by rule, that the product can be readily used in the manufacture of methamphetamine.

(b) The controlled substances board has determined, by rule, that the product cannot be readily used in the manufacture of methamphetamine.

A "Pseudoephedrine liquid" is defined as:

A product that is intended to be sold at retail, that is a liquid at room temperature, and that contains pseudoephedrine or any of its salts, isomers, or salts of isomers.

A "Liquid-filled pseudoephedrine gelcap" is defined as:

A soft, liquid-filled gelatin capsule that is intended to be sold at retail and that contains pseudoephedrine or any of its salts, isomers, or salts of isomers.

Therefore, the above sections provide that all pseudoephedrine products ARE schedule V controlled substances EXCEPT:

1. A pseudoephedrine liquid
2. A liquid filled pseudoephedrine gelcap
3. A substance determined by the controlled substances board which cannot be readily used in the manufacture of methamphetamine.

The controlled substances board MAY schedule a substance listed in #'s 1 or 2 above, as a schedule V controlled substance if it determines by rule that the substance can be readily used in the manufacture of methamphetamine.

3. Effect on Retail Sale of Pseudoephedrine Products

A. Pseudoephedrine liquids and gelcaps are NOT subject to sale and possession provisions of the Act.

These products may remain on consumer access display and sold as per current practice for non narcotic Over the Counter drugs.

B. All non liquid and non gelcap pseudoephedrine products ARE subject to the sale and possession provisions of the Act.

961.23 Dispensing of schedule V substances. The dispensing of schedule V substances is subject to the following conditions added to Wis. Stat. § 961.23:

1. Paragraph (1)- (1) ~~That they~~ They may be dispensed and sold only in good faith as a medicine, and not for the purpose of evading this chapter.

Comment- None.

Effect on Pharmacy Practice- No additional requirements.

2. Paragraph (2)- (2) ~~That they~~ They may be sold at retail only by a registered pharmacist or, if the substance is a pseudoephedrine product, by a person who is working under the direction of a registered pharmacist when sold in a retail establishment.

Comment- The sale of a pseudoephedrine product may be accomplished by a pharmacist or a person working under the direction of a pharmacist.

Effect on pharmacy practice-

1. The pharmacist or directee salesperson must account for and authenticate the purchase of the pseudoephedrine product and maintain sales limit controls. The “direction” of the supervising pharmacist would appear to require the pharmacist to be onsite during any time the sales process is occurring, although the pharmacist is not required to inspect and monitor each directee’s work contemporaneously with each sale.

3. Paragraph (3)- (3) ~~That, when~~ When sold in a retail establishment, they shall bear the name and address of the establishment on the immediate container of said preparation.

Comment- No change to current law.

4. Paragraph (4)- (4) ~~That any~~ Any person purchasing such a substance shall, at the time of purchase, present to the seller that person's correct name ~~and~~, address, and, if the person is purchasing a pseudoephedrine product, an identification card containing the person's photograph. The seller shall record the name and address and the name and quantity of the product sold. The purchaser and either the seller or, if the substance is a pseudoephedrine product and is being sold by a person who is not a registered pharmacist, the pharmacist supervising the seller shall sign the record of this transaction. The giving of a false name or false address by the purchaser shall be prima facie evidence of a violation of s. 961.43 (1) (a).

Comment- To purchase a pseudoephedrine product an additional requirement now exists whereby a photo id must be presented. The seller is allowed to record the required information, verify the photo id, and complete the sale. If the sale is not performed by a pharmacist the supervising pharmacist must sign the record of the transaction.

In context it does not appear that the signing of the record by the pharmacist is required contemporaneously with the sales transaction. To require a contemporaneous signing by the pharmacist would render any sale by the directee to be essentially still a sale by a pharmacist with contemporaneous presence. Such a reading would severely hamper a pharmacist’s time allocation to otherwise conduct the required dispensing activities under Wis. Admin. Code § Phar Ch. 7, for prescription order patients. Moreover, such a reading would render moot the explicit amendment of this paragraph to create the ability of a directee to accomplish a sale.

Effect on Pharmacy Practice-

1. The pharmacist may conduct all aspects of the sale.

2. A person working under the direction of a pharmacist may conduct all aspect of the sale and the record of the transaction may at a later time be reviewed and signed by the supervising pharmacist.

5. Paragraph (5)-

(5) ~~That no~~ No person may purchase more than 8 ounces of a product containing opium or more than 4 ounces of a product containing any other schedule V substance within a 48-hour period without the authorization of a physician, dentist, or veterinarian ~~nor~~. This subsection does not apply to a pseudoephedrine product unless it contains another schedule V substance.

Comment- None.

6. Paragraph (6)-

(6) No person other than a physician, dentist, veterinarian, or pharmacist may purchase more than 7.5 grams of a pseudoephedrine product within a 30-day period without the authorization of a physician, dentist, or veterinarian.

Comment- A person may purchase no more than 7.5 grams of a pseudoephedrine product over the counter within a 30 day period. A person may purchase more than 7.5 grams of a pseudoephedrine product within a 30 day period pursuant to a valid practitioner order.

Effect on Pharmacy Practice- It is not required for the seller to quiz purchasers as to whether they have made purchases at other stores such that a sale at the present retail establishment would violate the sales restriction.

7. Paragraph (7)-

(7) No person other than a physician, dentist, veterinarian, or pharmacist may possess more than 8 ounces of a product containing opium or more than 4 ounces of a product containing any other schedule V substance be in the possession of any person other than a physician, dentist, veterinarian or pharmacist at any time without the authorization of a physician, dentist, or veterinarian. This subsection does not apply to a pseudoephedrine product unless it contains another schedule V substance.

Comment- None

8. Paragraph (8)-

(8) No person may sell a pseudoephedrine product to a person under 18 years of age, and no person under 18 years of age may purchase a pseudoephedrine product.

Comment- The issue arises whether a parent or guardian may purchase for a minor child. The answer is, yes. There is no requirement that the seller inquire into, nor record, the purpose of the purchase. The sale of a pseudoephedrine product is not “patient specific” in the same manner as a prescription order for a particular patient.

Effect on pharmacy practice- None

4. Recordkeeping requirements for pharmacies

Section 31. 961.235 of the statutes is created to read:

961.235 Records relating to sales of pseudoephedrine products. Records required under s. 961.23 (4) with respect to the sale of a pseudoephedrine product may be kept in either a paper or electronic format and shall be maintained by the pharmacy for at least 2 years. Only a pharmacist or a law enforcement officer may have access to information recorded under s. 961.23 (4) with respect to the sale of a pseudoephedrine product.

Comment-

1. Retention of records

This section requires that a pharmacy maintain the required records for a period of at least two years.

The record may be kept in either an electronic or paper format. One point not clarified in the section is whether an initial paper format record may be converted to an electronic format, with the paper record thereafter being destroyed. The pseudoephedrine sales record qualifies as a patient health care record as defined by Wis. Stat. § 146.81 (4).

The specific destruction provisions for patient health care records contained in Wis. Stat. § 146.819, do not seem to apply to the destruction of paper records in the normal course of business following the transfer of information from those paper records to an electronic storage medium. Until this point is clarified, it is uncertain whether a paper record may be converted to an electronic format and the paper record destroyed.

2. Persons with access

The section includes the phrase that “only a pharmacist or law enforcement officer”, may have access to information recorded pertaining to the sale of a pseudoephedrine product. It isn’t clear why this provision didn’t reference the applicable provisions of Wis. Stat. § 146.82 (2), related to health care records and access generally. This omission creates several issues.¹

Currently, a patient has a right to access a health care record. The Pharmacy Examining Board and other state agencies also have the right to inspect such records if jurisdictionally appropriate.² Interestingly, one class of persons explicitly entitled to access records under this section, a “law enforcement officer”, does not exist as a class of persons entitled to inspect records under Wis. Stat. Ch. 146 without a court order.³ Chapter 146 requires that before a “law enforcement officer” may obtain access to a patient health care record, a court order must be obtained.⁴

¹ The phrase as used seems to imply access only for a pharmacist or law enforcement officer to the exclusion of all others. Such an implication if applied to construe the text would gut the applicability of Wis. Stat. Ch. 146.

² Wis. Stat. §146.82 (2)(a) 5.

³ A court in construing this section will assume that the legislature knew the law in effect at the time of its actions. State v. Olson, 175 Wis. 2d 628, 641, 498 N.W.2d (1993).

⁴ Wis. Stat. § 146.82 (2) (a) 4.

In other sections of the Act, the legislature has specifically addressed provisions of statute or administrative rules which explicitly would not apply to the Act.⁵ However, Wis. Stat. Ch. 146, has not been expressly exempted from applying to a record created under the Act. Therefore, in construing the intended scope of access to records under the Act, there is no clear legislative intent demonstrated to override current law codified at Wis. Stat. Ch. 146.⁶

Statutory construction must be undertaken so as not to construe a provision to be surplusage. However, it is concluded that the term “law enforcement officer” constitutes only a general statement indicating one class of persons who may seek access to records under Wis. Stat. Ch. 146, but that class is not exclusive and the manner of access must still comply with Wis. Stat. Ch. 146.

This conclusion is based primarily on what isn’t stated in the Act when the phrase “law enforcement officer” is used. The list of persons that should be mentioned as having legitimate access is simply incomplete.⁷ Other persons, not mentioned, may currently conduct legitimate jurisdictional investigations based upon the sales records.⁸ The phrase “law enforcement officer” is also undefined. This indicates a more general usage of the phrase to reinforce that the record can be used for prosecution for violations of the Act. Finally, if read as superceding Wis. Stat. Ch. 146, a patient similarly would not have access to his or her health care record.⁹

Therefore, reading this section to exclude the application of Wis. Stat. Ch. 146, creates more problems in implementation than it solves. Accordingly, the more specific provisions of Wis. Stat. Ch. 146, should apply absent a clear legislative mandate to exclude them.¹⁰

Effect on Pharmacy practice-

1. A court order is still required for a “law enforcement officer” to obtain non consensual access to a record created pursuant to the Act.

4. Wis. Stat. Ch. 146 and HIPAA privacy requirements- Sales Records

The United States Department of Health and Human Services interprets its HIPAA regulations to allow incidental disclosure of patient names on physician sign in sheets that may be viewed by other patients:

Covered entities, such as physician’s offices, may use patient sign-in sheets or call out patient names in waiting rooms, so long as the information disclosed is appropriately limited. The HIPAA Privacy Rule explicitly permits the incidental disclosures that may result from this practice, for example, when other patients in a

⁵ Sections 8, 21

⁶ This conclusion is further supported because a “law enforcement officer” will presumably be searching a patient health care record, not for administrative purposes, but rather to detect evidence of a crime. Wis. Stat. Ch. 146 requires a court order for this purpose.

⁷The list contains only a pharmacist and a “law enforcement officer”.

⁸ Such an interpretation would render a nonsensical result. Ie..the PEB could not administratively investigate a pharmacy or pharmacist for a violation of the Act.

⁹ A patient has a right to access health care records under both Wis. Stat. ch. 146 and HIPAA. The pre-emption provisions of HIPAA would not allow a state statute to remove this patient right. State law may provide more protection, not less.

¹⁰ HIPAA regulations also require a “court order” for a “law enforcement official” to view a patient health care record. Because HIPAA pre-empts inconsistent state law which would lower a HIPAA standard (without a waiver), Act 14 could not be interpreted to implicitly or explicitly waive this HIPAA requirement. 45 CFR 164.512 (f).

waiting room hear the identity of the person whose name is called, or see other patient names on a sign-in sheet. However, these incidental disclosures are permitted only when the covered entity has implemented reasonable safeguards and the minimum necessary standard, where appropriate. For example, the sign-in sheet may not display medical information that is not necessary for the purpose of signing in (e.g., the medical problem for which the patient is seeing the physician). See 45 CFR 164.502(a)(1)(iii).

a. Recordkeeping- chronological sales “log” vs. patient specific pages

A chronological schedule V controlled substances “log” differs from a patient sign in sheet as it not only includes a purchaser name, it includes the purchaser address, and the name and quantity of pseudoephedrine sold.¹¹ Such a log therefore substantially differs from a patient sign in sheet because it discloses qualitative patient health care information including the substance purchased and amount. The incidental disclosure exception for a patient sign in sheet allowed under HIPAA can not be readily extended to a controlled substances log listing patients and containing additional information required by Wis. Stat. § 961.23 (4).

The use of such a chronological log if subject to viewing by each subsequent patient listed therein would also violate Wis. Stat. § 146.82 (1) and (2), even were it to pass muster under HIPAA.

Effect on pharmacy practice-

1. If the use of a chronological log were anticipated, patient consent should be obtained under Wis. Stat. Ch. 146, if patient specific information could not be readily obscured.¹²
2. Individual patient specific pages could also be utilized.
3. Any other option for recordkeeping would be possible if it prevents the disclosing of patient identification information.¹³
4. The pharmacy’s prescription order and patient profile system could also be used with appropriate coding and combined with a device to electronically capture a patient’s signature for storage in the electronic records of the pharmacy.

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¹¹ Wis. Stat. § 961.23 (4)

¹² Patient authorization under HIPAA should also be obtained.

¹³ Either electronically based or hard copy based, with individual record pages for each patient, or utilizing a means of obscuring.