

ADMINISTRATIVE RULES FISCAL ESTIMATE AND ECONOMIC IMPACT ANALYSIS

Type of Estimate and Analysis

Original Updated Corrected

Administrative Rule Chapter, Title and Number

Ch. CSB 3, Special Use Authorization Permits (creating chapter)

Subject

Authorization from the controlled substances board for non-medicinal uses of controlled substances

Fund Sources Affected

Chapter 20 , Stats. Appropriations Affected

GPR FED PRO PRS SEG SEG-S

Fiscal Effect of Implementing the Rule

No Fiscal Effect

Indeterminate

Increase Existing Revenues

Decrease Existing Revenues

Increase Costs

Could Absorb Within Agency's Budget

Decrease Costs

The Rule Will Impact the Following (Check All That Apply)

State's Economy

Local Government Units

Specific Businesses/Sectors

Public Utility Rate Payers

Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

Policy Problem Addressed by the Rule

Under s. 961.335, Wis. Stats., the controlled substances board has the discretion to issue permits to persons who manufacture, possess, use, administer, or dispense controlled substances for non-medical purposes. Such purposes include scientific research, instructional activities, chemical analysis, and other special uses as approved by the board. The proposed rules will define the procedures associated with the board's exercise of its permitting authority, as allowed under s. 961.335 (9), Stats. In addition, under the authority granted by the statute, the board in these rules will set forth the acts constituting violations of a special use authorization permit, as well as the potential discipline the board may impose upon a finding of a violation.

Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

These proposed rules track legislation that has been in effect for several years. Any economic or fiscal impact experienced by private businesses or public entities due to the creation of s. 961.335, Stats., has long since been absorbed by such businesses and entities as a part of routine operations. The rules promulgated by this proposal will therefore have no current economic or fiscal impact on any of those entities.

Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The specification of acts constituting violations of special use authorization permits will provide permit holders and enforcement staff clearer notice of the acts that will garner board discipline. This will facilitate the board's ability to protect the public from injury caused by unlawful uses of such permits.

Long Range Implications of Implementing the Rule

Increased public safety through improved board oversight of the actions of permit holders, and decreased violations of permit provisions, both specific and general.

Compare With Approaches Being Used by Federal Government

The federal Controlled Substances Act, codified at ss. 21 U.S.C. 801- 971, is administered by the United States Department of Justice and its Drug Enforcement Administration (DEA). Subchapter I, pt. C of the those statutes contains comprehensive legislation for regulating the use of controlled substances, including a requirement that all persons using controlled substances for *any* purpose must obtain a registration from the U.S. attorney general. Sections 21 U.S.C. 821-831. The federal statutory registration requirements have served as a model for several of the states' versions of their controlled substances registration laws, whether in their statutes or administrative rules, either or both of which contain provisions substantially similar to those of the federal law. The DEA's rules regarding controlled substances registration are set forth at ss. 21 C.F.R. 1300-1399. It appears that the approach to registration for use of controlled substances in the Wisconsin statutes, and the approach taken by the Wisconsin controlled substances board in its rule-making proposal, is also substantially similar to the federal government's approach. Like several of the states neighboring Wisconsin though, the federal government does not separate registrations for non-medicinal-related uses from any other types of registration. That is because the federal government's regulation requirement applies to all persons using controlled substances in the course of their work, regardless whether they hold a state license or registration for use of controlled substances.

Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois:

Statutes: Under the Illinois Controlled Substances Act, all persons who manufacture, distribute, or dispense any controlled substance, or engage in chemical analysis or instructional activities using controlled substances, or who purchases, stores, or administers euthanasia drugs must obtain a registration issued by the Illinois Department of Financial and Professional Regulation. The Act requires the department to promulgate rules administering the registration function. Section 720 ILCS 570/301. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration and in conformity with the other provisions of the Act. Registration is site-specific, so persons operating at more than one site must have separate registration for each. Sections 720 ILCS 570/302 (a), (b), and (d). The department may deny, refuse to renew, suspend, or revoke a registration upon finding that the applicant or registrant has provided false information on an application, had his or her federal controlled substances registration suspended or revoked, been convicted of certain crimes, failed to take effective preventative measures against diversion, or violated any provision of the Illinois Controlled Substances Act or the Methamphetamine Precursor Control Act, or any of the rules promulgated under those Acts. Sections 720 ILCS 570/304 (a) and (b).

<http://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=072005700HArt%2E+III&ActID=1941&ChapterID=53&SeqStart=2600000&SeqEnd=5000000>.

Administrative rules: The Illinois Administrative Code sets forth rules promulgated by the Department of Financial and Professional Regulation for implementing the provisions of the Controlled Substances Act. Title 77, ch. XV, pt. 3100, Ill. Admin. Code. Among other things, these rules require separate registrations for any of six different types of controlled substances activities deemed independent of each other. The independent-activities rule also describes several exceptions thereto. For instance, the first two of the different types of activities are 1) manufacturing controlled substances, and 2) distributing controlled substances. However, persons registered to manufacture a basic class of controlled substances, or one substance in particular, may distribute the same without a separate distribution registration. Sections 3100.50 a), b), Title 77, Ill. Admin. Code. Other rules provide instructions for registration applicants, and authorize the department to deny, limit, suspend, or revoke any registration upon finding the registrant in violation of any of the statutes or rules regarding controlled substances.

Sections 3100.100, .160, Title 77, Ill. Admin. Code.

<http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html>.

Comparison of approaches: The Illinois laws regarding registration for use of controlled substances do not address “special uses” in a separate, or stand-alone, section as Wisconsin law does. Similar to Wisconsin though, the Illinois Controlled Substances Act includes a registration requirement, and charges a state agency with the administration of that requirement. The Illinois statutes and rules also contain provisions for certain non-medicinal-related uses that are substantially similar to the provisions of Wisconsin’s special use authorization law, s. 961.335, Stats. One exception to the similarity is that, unlike the proposed Wisconsin rules, Illinois law does not specifically reference narcotic dog trainers in either its Controlled Substances Act or administrative code.

While Illinois’s approach to controlled substances user registration differs in part from the approach taken by the Wisconsin controlled substances board’s proposed rules, the fundamental policy of regulating uses of controlled substances not related to medical treatment is the same. Unlike Wisconsin’s controlled substances law, the Illinois law is silent regarding the use of controlled substances for training narcotic dogs. That silence may cause confusion for persons using controlled substances for that purpose. Wisconsin’s special use authorization statute provides for uses not specified in the statute by permitting the controlled substances board to approve “other special uses, without restriction because of enumeration.” s. 961.335 (1), Stats. Accordingly, in addition to the special uses the Wisconsin statute does specify, the board’s proposed rules address other “special,” but well-known purposes, such as euthanasia at humane shelters or under municipal animal control laws, and the training of narcotic dogs. The board believes increased clarity will result in less confusion for both permit applicants and administrators.

Iowa:

Statutes: The Iowa statutes require that all persons who manufacture, distribute, or dispense any controlled substance, or who propose to engage in the manufacture, distribution, or dispensing of any controlled substance, obtain and maintain a biennial registration from the Iowa Board of Pharmacy. Registration applies to one site only, so persons operating at more than one site must have separate registrations for each. Registered persons may possess, manufacture, distribute, dispense, or conduct research using controlled substances to the extent authorized by their registration only and in conformity with the other provisions of Iowa’s controlled substances registration law. Sections 124.302, 1., 2., 4., Iowa Code. The pharmacy board may suspend, revoke, or restrict a registration to manufacture, distribute, or dispense a controlled substance upon certain findings, including that the registrant has committed such acts as would render the registrant’s registration inconsistent with the public interest as determined under s. 124.304 1.d., Iowa Code. <http://www.state.ia.us/ibpe/pdf/IC124.pdf>

Administrative rules: Iowa’s administrative code contains rules implementing the statutes regarding the use of controlled substances. The rules establish further specifications of who or what entities must register, and seven different types of activities, each of which requires separate registration. In addition, the rules include application instructions and procedures; specific requirements for the approved uses of controlled substances; descriptions of, and requirements for separate registrations of separate sites; requirements and procedures for modifying or terminating a current registration based on several different types of changes; and registration enforcement provisions. Beyond requiring “[m]anufacturers, distributors, reverse distributors, importers and exporters,” of controlled substances to register, the list of persons and entities that must register includes all individual medical practitioners, pharmacies, hospitals, animal shelters, care facilities, researchers, dog trainers, analytical laboratories, and teaching institutions. Rules 657—10.1-.12, IAC.

<http://www.legis.state.ia.us/asp/ACODocs/ruleList.aspx?agency=657&chapter=10>

Comparison of approaches: Like Illinois, and unlike Wisconsin, Iowa takes an approach to registration for controlled substances use that does not treat non-medicinal-related uses separately. Nevertheless, Iowa’s controlled substances laws do require registration of persons using controlled substances for non-medicinal-related purposes, and charges a state agency with administering that requirement. Iowa sets forth comprehensive registration provisions in its administrative rules that are substantially similar to Wisconsin’s special use authorization statute.

In addition, the scope of Iowa's rules is more consistent with the Wisconsin board's proposed rules than not. Thus, Iowa's approach to administering its "special use" laws is essentially the same as the approach the Wisconsin controlled substances board contemplates in the instant rule-making proposal.

Michigan

Statutes: Michigan's controlled substances law is set forth in that state's public health code, Act 368 of 1979, Art. 7. The statutes require any person who manufactures, distributes, prescribes, or dispenses a controlled substance in Michigan to obtain a license for such purposes issued by the Michigan Board of Pharmacy or its Administrator. Sections 333.7303, Art. 7, Michigan Compiled Laws (MCL). The administrator is authorized to promulgate rules for controlled substances licensure and the enforcement thereof. Section 333.7301, MCL. License holders may possess, manufacture, distribute, prescribe, dispense, or conduct research with the specified controlled substances to the extent authorized only, and as is consistent with all other provisions of Article 7. Licenses apply to specific sites, so persons operating at more than one site must have separate registrations for each. Persons licensed as pharmacists must also obtain a separate controlled substances license. Sections 333.7303 (1), (2), (5), MCL. The pharmacy board's disciplinary subcommittee may deny, limit, suspend, or revoke a license, or fine or reprimand a licensee, or order the licensee to perform community service or make restitution upon certain specified findings, including that the applicant or licensee has violated, or attempted to violate, any of the statutes in Article 7, or any of the rules promulgated thereunder. Section 333.7311 (1), MCL. The statutes require licensees to keep records of, and to annually inventory all stocked Schedule II-V controlled substances. Licensees must report their annual inventory to the Administrator. Section 333.7321 (2), MCL.

[http://www.legislature.mi.gov/\(S\(nmvaabic1r5tk45u0orwga0\)\)/mileg.aspx?page=McIPASearch](http://www.legislature.mi.gov/(S(nmvaabic1r5tk45u0orwga0))/mileg.aspx?page=McIPASearch)

Administrative rules: Michigan's administrative code specifies the particular type of activities a controlled substances license authorizes. There are six types of activities, and persons engaging in more than one type must obtain separate licenses for each. The list of activity types briefly describes the permissible practices under each license. Rules 338.3132 (1), Mich. Admin. Code. Other rules include provisions regarding the use of controlled substances for animal euthanasia, theft and diversion of controlled substances, storage, record-keeping obligations, and exceptions to the licensure requirement. Rules 338.3137 - .3143, and .3151 - .3153, Mich. Admin. Code.
http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33803101&Dpt=&RngHigh=33923405

Comparison of approaches: Similar to the controlled substances laws of Illinois, Iowa, and Wisconsin, Michigan's laws require that any person who uses controlled substances for purposes not related to medical treatment must obtain a license for such purposes from a state agency, in Michigan's case, the Michigan Board of Pharmacy. Unlike Illinois, Iowa, and Wisconsin, Michigan law compels licensed pharmacists to hold a separate license for the use of controlled substances within the scope of their practice. Moreover, Michigan's controlled substances statutes are far more comprehensive with respect to the licensing requirement than the Wisconsin special use authorization statute. The Michigan statutes contain many of the provisions that the Wisconsin controlled substances board proposes to codify as administrative rules. Michigan's approach to regulating controlled substances use thus differs significantly from Wisconsin's, and may ultimately be more onerous to its pharmacists than Wisconsin's approach.

Minnesota:

Statutes: Chapter 151, Minn. Stats., authorizes the Minnesota Board of Pharmacy to regulate the practice of pharmacy, the manufacture, wholesale, and retail sale of drugs within that state, and to license wholesale drug distributors. The pharmacy board is also charged with administering ch. 152, Minn. Stats., which regards scheduling and regulation of controlled substances. Section 152.02, subd. 7, Minn. Stats. Pursuant to s. 151.06, subds. 1. (a) (1), (2), (6), (7), (10), 1. (c), Minn. Stats., the board must promulgate uniform rules for carrying out and enforcing the governing statutes. The statutes require the board to register, on an annual basis, every person engaged in manufacturing drugs, medicines, chemicals, or poisons for medicinal purposes. Section 151.25, Minn. Stats. The Minnesota pharmacy and controlled substances statutes do not specifically address uses that are not directly or indirectly related to medical treatment of patients. The pharmacy board may deny, suspend, revoke, or

refuse to renew any required registration or license on grounds such as fraud or deception in securing a registration or license, unprofessional conduct or conduct endangering public health, and gross immorality.

<https://www.revisor.mn.gov/statutes/?id=151>

Administrative rules: Chapter 6800 of Minnesota's administrative code pertains to the state's board of pharmacy and its oversight of pharmacists and pharmacies. The code provides for four general types of licenses: pharmacists, pharmacies, drug manufacturers and wholesalers, and controlled substances researchers. Any person engaging in research, teaching, or educational projects involving the use of controlled substances must obtain registration for these uses, renewable annually, from the board. Section 6800.4400, subp. 1., Minn. Admin. Code. Registration requires that the registrant have policies and procedures for effective controls against theft and diversion of all stocked inventory, unauthorized access, substance waste, and returns. Further, registrants must maintain adequate records showing purchases and purchase receipts, use, transfer, and disposal of the controlled substances specified in the registration. To track the effectiveness of the required controls, registrants must inventory stocked controlled substances annually. Section 6800.4400, subpt. 3., Minn. Admin. Code. Disciplinary proceedings against any pharmacy board licensee or registrant are governed by ss. 6800.9100 - .9700, Minn. Admin. Code.

<https://www.revisor.mn.gov/rules/?id=6800>

Comparison of approaches: By administrative rule, Minnesota registers persons using controlled substances for research or instructional purposes separately from pharmacists and pharmacies. Minnesota's approach to regulating non-medicinal-related uses is, in that sense, similar to Wisconsin's. However, unlike Wisconsin, neither Minnesota's pharmacy or controlled substances statutes, nor its administrative rules address the use of controlled substances in humane shelters or for training narcotic dogs. Moreover, the law regarding research or educational use of controlled substances appears only in Minnesota's administrative code, and not in its statutes. The administrative rule specific to such uses references only persons involved in research or teaching. Finally, the enforcement procedures applicable to alternative use registration are subsumed within the pharmacy board's general enforcement authority, rather than set forth within the context of research or teaching use registration.

Minnesota's rules on controlled substances licensure thus appear to provide very little guidance to persons involved in research or teaching activities. For instance, there are no rules establishing the precise requirements and procedures for registration applications or record-keeping, and none defining violations warranting disciplinary action. The absence of such written requirements and procedures would seem to promote a lack of clarity, and generate numerous inquiries from applicants and current registrants. Inadequate clarity with respect to registration requirements and procedures could also permit more challenges to board decisions on registration issues than may otherwise occur. The rules proposed by the Wisconsin controlled substances board would serve to avoid such potentialities, and in doing so, conserve scarce state resources.

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