

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date December 9, 2019</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 3</p>	
<p>4. Subject Special use permits</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected 20.165(1)(g) and (hg)</p>
<p>7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input checked="" type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0.00</p>	
<p>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule This chapter was created in 2012. This proposed rule is a clean-up to clarify provisions based upon feedback received from stakeholders since the creation of the chapter. In addition, in consideration of the opioid epidemic, the Board reviewed provisions to ensure adequate access to controlled substances is balanced with public welfare and safety.</p>	
<p>12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. This proposed rule was posted for economic impact comments and none were received.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None</p>	
<p>14. 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) This rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units and the state's economy as a whole.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule Updates to the rule ensures the chapter is statutorily compliant and current with professional standards and practices.</p>	
<p>16. Long Range Implications of Implementing the Rule The long range benefit is creating clarity regarding the special use authorizations.</p>	
<p>17. Compare With Approaches Being Used by Federal Government The federal government requires security controls for non-practitioners storing controlled substances. Our security provisions match the Drug Enforcement Administration's requirements.</p>	
<p>18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota) Illinois: In Illinois, every person who, or proposes to, manufacture, distribute, or dispense any controlled substances;</p>	

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engages in chemical analysis, research, or instructional activities which utilize controlled substances; purchases, stores, or administers euthanasia drugs, provides canine odor detection services; must obtain a registration issued by the Department of Financial and Professional Regulation. Registered persons may possess, manufacture, distribute, or dispense controlled substances, or administer euthanasia drugs to the extent authorized by their registration, Registration is site-specific, so persons operating at more than one site must have a separate registration for each.

Iowa: In Iowa, researchers, analytical laboratories, animal shelters, dog training facilities, and teaching institutions are required to apply for a controlled substances registration permit with the Pharmacy Board. 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. A registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities or conduct chemical analysis with controlled substances may be denied if the board determines that the issuance of the registration would be inconsistent with the public interest.

Michigan: In Michigan, an individual in charge of a licensed dog pound or animal shelter, must obtain both a Drug Enforcement Agency (DEA) controlled substance registration and a Michigan controlled substance license for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals. Michigan officers or state employees are exempted from licensure if that person is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties. Licensed researchers and manufacturers of a controlled substance may conduct research with those substances, perform chemical analysis, manufacture the substance, distribute the substance to other persons who are licensed or authorized, and conduct instructional activities with the substances. Certain activities involving schedule 1 controlled substances may require a separate license.

Minnesota: In Minnesota, any qualified person may use controlled substances in the course of a bona fide research project but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed and administered by a person lawfully authorized to do so. Researchers involved in the use of controlled substances must apply annually for registration with the state Board of Pharmacy. 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.

19. Contact Name

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20. Contact Phone Number

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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