ADMINISTRATIVE RULES REVIEW COMMITTEE

Meeting Dates: December 12, 2017

Purpose. *This compilation of briefings on legislative interim committee meetings and other meetings and topics of interest to the Iowa General Assembly, written by the Legal Services Division staff of the nonpartisan Legislative Services Agency, describes committee activities or topics. The briefings were originally distributed in the Iowa Legislative Interim Calendar and Briefing. Official minutes, reports, and other detailed information concerning the committee or topic addressed by a briefing can be obtained from the committee's Internet page listed above, from the Iowa General Assembly's Internet page at https://www.legis.iowa.gov/, or from the agency connected with the meeting or topic described.*

ADMINISTRATIVE RULES REVIEW COMMITTEE

December 12, 2017

Co-chairperson: Representative Dawn Pettengill

Co-chairperson: Senator Mark Chelgren

HUMAN SERVICES DEPARTMENT, *Special Population Nursing Facility Criteria—Increase in Age Limit, Inclusion of Residents in an Intermediate Care Facility For Persons With Medical Complexity,* 11/22/17 IAB, ARC 3459C, NOTICE.

Background. This rulemaking increases the age by which young adults with complex medical conditions are eligible for placement in a special population nursing facility from 21 years of age to 30. The rulemaking also modifies the definition of "special population nursing facility" to potentially increase the number of qualified providers available to meet the needs of young adults with complex medical conditions.

Commentary. Committee members questioned the department's authority to adopt this rule without specific legislative authorization. Committee members noted that the department had sought statutory authority to carry out this policy change during the 2017 Legislative Session, and the General Assembly declined to authorize the department to do so or to provide a line item on the department's budget to pay for such a change in policy. Committee members stated that this matter could be better handled through legislation. Ms. Deb Johnson and Ms. Nancy Freudenberg spoke on behalf of the department and explained that the affected population is already receiving these services through an exception to policy either at Childserve or through placement out of state. They explained that the department feels codifying this exception by rule would be a better approach than using an exception to policy. They apologized for the department not keeping the General Assembly better informed about this issue.

Committee members asked how such services are paid for without statutory authorization, and Ms. Johnson and Ms. Freudenberg explained that exceptions to policy are already covered in the Medicaid budget. Committee members asked how the fiscal analysis for this rulemaking was calculated given that these services are already being provided. They explained that the department's fiscal analysis treated this rulemaking as a new policy and included the cost of existing recipients, rather than only projecting the cost of new recipients. They were unsure how many new recipients not covered under the existing exception to policy there might be once the rules are in place.

Committee members asked why the age cutoff was set at 30, and Ms. Johnson and Ms. Freudenberg explained that the affected population generally does not survive to age 30. They further explained that any recipients that live to age 30 would be handled on a case-by-case basis, perhaps through another exception to policy.

Public comment was received from Mr. George Eichhorn on behalf of Childserve, who explained that Childserve had sought this rule change from the department because under current rules, the one or two recipients who reach age 21 under the exception to policy often have difficulty finding placement once they are no longer eligible at Childserve and end up at nursing facilities that are less equipped to provide them the complex care that they need. He said that Childserve has sought other providers that can offer the proper level of care and has been unsuccessful. He also said former Department Director Charles Palmer had told him changing this policy would have a negligible effect on the department's budget. He said he was not familiar with any discussions about this matter during the 2017 Legislative Session.

Committee members asked for information regarding the cost of providing this level of care at Childserve versus placement out of state, as well as the number of recipients being placed out of state each year in relation to the whole population of recipients. This information was not available at the meeting.

Action. No action taken.

PUBLIC HEALTH DEPARTMENT, *Medical Cannabidiol Program,* 10/25/17 IAB, ARC 3420C, NOTICE.

Background. This rulemaking is intended to implement 2017 Iowa Acts, HF 524, which repealed Iowa Code chapter 124D and enacted Iowa Code chapter 124E, the Medical Cannabidiol Act. The proposed rules establish operational requirements for medical cannabidiol manufacturers and dispensaries as well as operating procedures for the newly created Medical Cannabidiol Board (Board).

Commentary. Ms. Sara Reisetter, Deputy Director, Department of Public Health, presented proposed rules, detailed the public comments received in writing and at public hearing and described the department's ongoing conversation with MedPharm Iowa (MedPharm), the recently selected sole licensed manufacturer of medical cannabidiol, focusing on the proposed rules and how such rules may be amended prior to adoption due to feedback from MedPharm. Mr. Lucas Nelson appeared before the committee on behalf of MedPharm to share the company's perspective on the proposed administrative rules regulating the manufacturing and marketing of medical cannabidiol.

Ms. Reisetter provided an overview of MedPharm's concerns with the proposed administrative rules. The proposed rules require extensive security measures, including cameras and badges. She stated that the department is awaiting a proposal from MedPharm regarding security rules that are cost-effective and will also achieve the security goals of preventing diversion of product and, if the product is diverted, being able to determine how it was diverted.

Ms. Reisetter stated that MedPharm was concerned that the marketing and advertising rules were too restrictive. Additionally, she explained MedPharm's concerns with being required to transport returned product from the dispensaries back to the manufacturing facility. She further explained that the rules require such a policy because the law only provides an affirmative defense to the manufacturer for transportation. Ms. Reisetter indicated that MedPharm was concerned with the regulation that required the manufacturer to dispose of manufacturing waste product by composting. She stated that MedPharm has been invited to propose regulations that would save money in disposing of product but also meet security requirements, and indicated that she anticipates the State Board of Health will adopt final rules by early January.

Committee members inquired how many intent-to-apply letters were submitted to manufacture medical cannabidiol. Ms. Reisetter responded that nine letters of intent-to-apply for a manufacturing license application were submitted, but that only one completed application was received. Reasons for not submitting a completed application included high application and annual fees, short timeline to find a physical location for manufacturing, and other opportunities.

Mr. Nelson identified several concerns with the proposed rules. He indicated that the marketing and advertising restrictions were too strict and may not allow MedPharm to conduct necessary education in the form of pamphlets and presentations to doctors, law enforcement, and community members. He also indicated MedPharm was not contemplating billboards. Rather, the focus was on educational materials relating to the product accompanied by the manufacturer's logo, which may include some instruction on suggested dosage. Mr. Nelson expressed concern that the requirements for petitions to add medical conditions are too onerous for a petitioner and suggested that the board take on part of the research to determine if the medical condition should be added to the approved list. Additionally, Mr. Nelson indicated that composting was not a cost-effective or timely waste disposal method, instead suggesting a solvent-based approach, and indicated MedPharm had detailed questions about transportation, especially regarding enforcement of regulations on transportation issues. Finally, Mr. Nelson stated that it appeared that inventory would need to be reconciled on a daily basis under the proposed rules, but MedPharm would prefer to reconcile every two weeks.

Committee members inquired whether returned medical cannabidiol may be submitted to local law enforcement for disposal. Mr. Nelson indicated that the rules only allowed for the manufacturer to dispose of the product. Ms. Reisetter offered to determine if the law enforcement disposal method works for the deactivation of the product.

Committee members also inquired whether MedPharm's suggestions would hinder manufacturing applications by other companies in the future. Mr. Nelson responded that he thought MedPharm's suggestions would increase the interest in manufacturing by other companies, especially the suggestions regarding rules on security and marketing.

Action. No action taken.

Next meeting. The next committee meeting will be held in Room 116, Statehouse, on Friday, January 5, 2017, beginning at 9:00 a.m.

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