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Department of Licensing and Regulatory Affairs Bureau of Community and Health Systems

> Public Hearing Thursday, June 6, 2019 2:00 P.M.

Present From Department of Licensing and Regulator Affair

Ms. Karen Krzanowski

Ms. Tammy Bagby

Mr. Larry Horvath

Ms. Heather Hosey

MS. BAGBY: Good afternoon. My name is Tammy Bagby, and I am an analyst for the Bureau of Community and Health Systems in the Department of Licensing and Regulatory Affairs.

This hearing is being called to order at 2 p.m. on June 6, 2019 at the G. Mennen Williams
Building Auditorium located at 525 West Ottawa Street in Lansing, Michigan. The hearing is being conducted under the authority of the Administrative Procedures
Act, Public Act 306 of 1969.

The notice of public hearing was published in three newspapers. On May 14, 2019 it was published in the Jackson Citizen Patriot and the Grand Rapids Press; and on May 16th, it was published in the Marquette Mining Journal. The same notice was published in the Michigan Register on May 15, 2019.

As stated in the notice, the proposed new administrative rule set for licensing health facilities or agencies is replacing six individual rule sets for licensing health facilities and agencies. Those rule sets are: Complaints, public inspection of license records, hospice and hospice residents, minimum standards for hospitals, nursing homes and nursing care facilities, freestanding surgical outpatient facilities.

The proposed new single rule set has been updated to comport with the current practice standards; reflects the current organization of state licensing functions; harmonizes rules with current federal laws and regulations; eliminates duplicative rules and obsolete rules, meaning rules that pertain to subjects that are no longer practiced; is an improved comprehensive system of licensure and certification of health facilities or agencies that leads to improved patient care, safety and more effective and efficient uses of resources.

Regulatory impact statements are available for further explanation of these rule sets. Copies are available in the hall outside of the auditorium or they can be found on the Web site for the Michigan Office of Administrative Hearings and Rules, formerly known as the ORR, or Office of Performance and Transformation.

Pursuant to Section 45 of the

Administrative Procedures Act, MCL 24.245, this

public hearing is an opportunity for the public to

present data, views, questions and arguments in

regards to the proposed rules.

The Department will use the testimony and documents presented at this hearing to determine

if any changes should be made to the proposed rules before they are adopted. If you have comments, please make sure that they are related directly to the proposed rules. If you have questions regarding the rules, please submit your questions as part of your testimony for the Department's review. If you have suggested changes to the proposed rules, please include the specific reasons why the changes would be in the public interest.

If you wish to comment, please complete a white card that was available when you came in. This will help the Department prepare the hearing record. When you testify, please identify yourself by name and organization, if any, that you may be speaking for.

Written statements can be submitted directly to me. The Department will also accept written statements e-mailed or post -- e-mailed or delivered postmarked until 5 p.m. on Friday, June 7, 2019. Address information can be found in the notice of the public hearing that we have made available in the hall.

If you would like to testify and not have yet filled out a white card, you can do that now.

1	The Department staff from the Bureau
2	of Community and Health Systems includes myself,
3	Karen Krzanowski, Heather Hosey and Larry Horvath.
4	Before we start the public comments,
5	Larry Horvath is going to make a statement.
6	MR. HORVATH: So my name is Larry
7	Horvath; I'm with the Bureau of Community Health
8	Systems. I'm the Bureau Director.
9	I guess briefly, I want to make a
10	quick statement that I wanted to recognize the hard
11	work of the Department staff on promulgating these
12	rules.
13	I also want to thank all of those that
14	participated in providing us feedback working in our
15	informal work groups. We think we have a very good
16	product, and so we appreciate all of the hard work
17	and dedication of both our internal staff but also
18	the external providers and those of interest that
19	provided us feedback.
20	So, again, thank you very much for
21	your time and participation.
22	MS. HOSEY: Hi everybody. I'm just
23	going to go through some of the goals and the
24	projects that we worked with on the project and some
25	of the objectives that we had.

So today's hearing is on the proposed new rule set for licensing health facilities and agencies as a result of a project that was initiated by our Department two years ago. The purpose of the project is to identify the core principles and standards of health facility licensing and then conduct a comprehensive review and update of all health facility licensing rules.

The goal is to replace six different rule sets with a single new rule set for licensing health facilities and agencies that will accomplish the following objectives.

The first objective is to fulfill statutory requirements for rulemaking. That will enable the Department and health facilities to focus on a core set of principles and standards for health facility licensing and regulation; to comport with current practice standards; harmonize the rules with the federal laws and regulations; be uniform as reasonable, that is, the rules should be consistent across different types of health facilities and agencies, unless differences are necessary to fulfill statutory, medical or structural requirements; be free of unnecessary repetition of federal and state statutory and regulatory language; and be free of

obsolete and unnecessary rules; and, lastly, result in at least 25 percent fewer rules.

We think the proposed rule set accomplishes these objectives. The rule set is organized into ten parts. Nine parts apply to all types of health facilities and agencies. Part 10 is divided into four subparts that apply to specific facility types, including freestanding surgical outpatient facilities, hospice and hospice residences, hospitals and nursing care facilities.

rules for licensing health facilities and agencies.

The new rule set has 126 rules; in other words, 189

rules will be rescinded. This represents a 59%

reduction in the number of rules.

The project was designed to gather input from internal and external stakeholders from the very beginning of the process.

A steering committee was formed. It include at least 10 bureau personnel with expertise on different provider types and licensing functions. In addition, a team of 12 subject matter experts serve as consultants to the steering committee.

The rules apply to four different provider types, including approximately 1,000

1 facilities and agencies. In order to have input from 2 these providers, the Department identified 30 3 stakeholders, such as professional associations that represent these types of providers and invited them to participate in the project. 5 The Department held five meetings with 6 the stakeholders. 7 In addition, during the summer of 8 9 2017, more than 60 individuals who represented 10 providers and consumers participated in five 11 different work groups to review the existing rules 12 and determine which rules were obsolete, which ones 13 should be retained, and which rules should be 14 revised, and which rules should be added. Five versions of the draft rules were 15 16 circulated for stakeholders to review and comment on. 17 The proposed rules reflect their input. 18 We look forward to hearing from -- or 19 your comments today; and thank you for your 20 participation. 21 MS. BAGBY: Okay. We will now begin 22 the public comment time frame. If you're handing in written comments, feel free to summarize and add to 23 24 your comments. You do not need to read them as they

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will become part of the official record.

1	Our first person is Margaret
2	Chamberlain. If you want to come up to the
3	microphone.
4	MS. CHAMBERLAIN: Hello. Margaret
5	Chamberlain, and I have two comments with respect to
6	surgery. The first is for the general provisions
7	relating to surgery. Would the Department consider
8	acknowledging past physical plant waivers and
9	allowing those waivers to remain in effect? That's
10	my first comment.
11	And then the second one is, would the
12	Department also consider adding language with respect
13	to surgical, that the location of the surgical
14	procedure is decided by the physician based on the
15	procedure and the medical condition of the patient?
16	MS. BAGBY: Thank you. We will take
17	those back to the Department and consider them.
18	I don't have any more cards. Does
19	anybody else want to speak in support or against?
20	(No response.)
21	MS. BAGBY: Okay. We will recess for
22	10 minutes just to allow other people to come, and
23	then if nobody else comes, we will end.
24	(Recess taken.)
25	MS. BAGBY: Okay. It's 2:15, and we

1 have two more people that would like to speak. 2 Dann Holmes, if you would like to come 3 up and speak in the microphone. Yes, hi. Dann Holmes, 4 MR. HOLMES: 5 I'm with NSF International. First of all, we want to 6 applaud the State for moving forward with the 7 proposals. There was some additional changes that 8 9 we would recommend in some of the language; we can 10 follow up with copies with you on this. 11 Basically we're in section, bear with 12 me, under the healthcare section, Chapter 9, Section 13 (8), we would like to see language, "A healthcare 14 facility must develop a water management program 15 consistent with Centers for Medicaid care and 16 Medicaid Services (CMS) requirements in QSO-17-30. 17 Facilities must have a water management plan and 18 documentation that, at a minimum, ensure each 19 facility: Conducts a facility risk assessment to 20 identify what --21 (Interruption.) 22 MR. HOLMES: -- so identify where 23 Legionella and other opportunistic waterborne 24 pathogens, for example, Pseudomonas, Acinetobacter,

Burkholderia, Trophomonas, and other pathogens that

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1	grow and spread in the facility water system.
2	This is consistent with the message
3	that CMS has come out with that develops and
4	implements a water management program that considers
5	the ASHRAE industry standard and the CBC toolkit.
6	Specified testing protocols and
7	acceptable ranges for control measures and document
8	the results of testing and corrective actions taken
9	when control limits are not maintained.
10	Maintains a compliance with other
11	Federal and State and local requirements.
12	A health facility must update their
13	water management program for new additions and
14	renovations to the facility.
15	A healthcare facility shall conduct a
16	water risk assessment at least once per year.
17	In addition, in Section (10) (sic),
18	we're looking at: A water management program shall
19	include all water systems, including medical devices
20	that use water.
21	And the health facility must have a
22	copy of their water management program on site.
23	MS. BAGBY: Thank you. Do you have
24	those written with your specific language?
25	MR. HOLMES: Yes, we do. And as

1	following up today, we're going to file an actual
2	follow-up by 5 o'clock tomorrow.
3	MS. BAGBY: Okay, perfect.
4	MR. HOLMES: I can leave this with you
5	if you'd like.
6	MS. BAGBY: That would be great.
7	Thank you.
8	And then, Andrew, are you also
9	speaking?
10	MR. WARD: Sure.
11	MS. BAGBY: Welcome.
12	MR. WARD: Thank you. My name is
13	Andrew Ward with the NSF International. Everyone can
14	hear clearly?
15	Just to follow up on Dann's statement
16	and recommendations for the proposed changes to the
17	rules, we just encourage the State of Michigan
18	address the CMS requirements that came out on June
19	2nd of 2017 and then updated the next year.
20	They are looking for additional
21	components of a water management program, not looking
22	at just Legionella, because healthcare facilities are
23	concerned with more pathogens, more hazards in their
24	water systems other than Legionella. It's getting a
25	lot of attention, but there's a lot of other

1 pathogens, a lot of other hazards that need to be considered. 2 3 So we strongly encourage that the 4 State of Michigan address, you know, these things, 5 make sure that the requirements are consistent at 6 least with CMS since they are targeting and expecting 7 these programs to look at other hazards. 8 So our recommendations for changes in 9 the code have been submitted, and so we just 10 encourage there to be a little bit more specificity for what should be included in these plans. 11 12 In general, there should be an 13 expectation by the State Health Department by various 14 regulatory affairs to address these things, to look 15 through these plans and make sure that they are 16 sufficient in nature. 17 MS. BAGBY: Thank you. I have no 18 other comment cards. Thank you everybody for coming. Each comment will be reviewed and evaluated by the 19 20 bureau, as well as the comments that we received 21 electronically. 22 We will now adjourn. It is 2:25. 23 (Hearing concluded at 24 2:25 p.m.) 25 (END OF RECORD)