Public Hearing Transcript

10-144 CMR Ch 113, Regulations Governing the Licensing and Functioning of Assisted Housing Programs: Infection Prevention and Control

11/12/20

Jonathan Leach: For people who have just joined the Zoom public hearing; I'd like you to open your chat and enter your name, your agency affiliation and your email address. And if you wish to speak today, we're going to call people in order, so please say if you wish to make public comments today. So, it's now about 10:05, I'm going to go ahead and start the formal public hearing.

Welcome everyone to the virtual public hearing on Regulations Governing the Licensing and Functioning of Assisted Housing Programs: Infection Prevention and Control. This is a rule administered by the Department of Health and Human Services, Division of Licensing and Certification. My name is Jonathan Leach, I'm the compliance analyst for the Division, and today's hearing will be slightly different than the typical in-person meeting.

On March 15th, 2020 the Governor proclaimed a State of Civil Emergency in Maine as the result of the substantial threat of the novel coronavirus, Covid-19. On March 18th, 2020 the Governor approved emergency legislation enacting Public Law 2020 Chapter 617, which among other things authorized state agencies to conduct public meetings through telephonic or electronic means during the State of Emergency and that is what we're doing today. As authorized by the newly adopted Title 1 Section 403A-Section 1 of the Maine Revised Statutes, we are conducting this rule making hearing through a video conference through the platform Zoom. Please bear with us in the event of any unforeseen technology problems, this is our first video public hearing, and hoping it goes smoothly but if it does not, I'd like to remind people you can always submit comments in writing to me by email or on the Division of Licensing and Certification rule making web page.

At this point in time please make sure you've entered your name, your program affiliation and your email address in the chat section, which is serving as our virtual sign-in sheet today, so we are able to include accurate information in response to your comments. You can open the chat section by clicking on the chat icon in the Zoom control bar.

We'd just like to inform people today that your microphones are turned off on this end. We will call on participants in the order that you signed in. When you hear your name, we'll turn on your microphone and you can begin to provide comments. This hearing is being recorded to allow the department to accurately respond to your comments. This hearing is scheduled to end at noon today.

If you have any questions about the rule making process itself, please enter those in the chat section and we will answer any questions after the comments are concluded. There is the possibility of inappropriate conduct, as the Zoom link to this hearing was available to the public. In the event of any offensive language or visual imagery, the speaker will be removed from the conference as quickly as we are able.

With me today are some other additional staff from the Division: Heather Hyatt, the Assistant Director of Community Health Care Programs is participating as is Diane Perry, the Assistant to the Director.
This public hearing can be found online, it was announced on the Secretary of State's Office website and advertised in 5 major newspapers. The Portland Press Herald, the Bangor Daily News, the Lewiston Sun Journal, the Morning Sentinel and the Kennebec Journal, on Wednesday October 21st, 2002. It was also posted on the Division's rule making page on that date.

At this point in time I would like to introduce Heather Hyatt, Assistant Director of Community Health Care Programs for the Division of Licensing and Certification, who will provide a brief background of the reason for these proposed changes.

Heather Hyatt: Morning everyone. This major substantive rulemaking institutes measures to improve and clarify infection surveillance control, mitigation and crisis staffing planning, in Maine's Assisted Housing facilities, including Assisted Living, Residential Care Facilities, and Private Non-Medical Institutions or PNMI's. This rulemaking revises 10-444 Chapter 113 regulations governing the licensing and functioning of Assisted Housing programs, which is published in 9 parts, by adding a new part. The provision related to the infection prevention and control will apply to all types of Assisted Housing program, subject to licensing under Title 22 Maine Revised Statutes Section 7801. These revisions are consistent with State and Federal Center for Disease Control Guidance, in response to the increased spread of the 2019 novel Coronavirus, Covid-19, and will help to mitigate any future outbreaks of novel contagious illnesses. In compliance with 22 M.R.S. Section 7853 (1), the Department developed this rule in consultation with the Long-Term Care Ombudsman Program. On June 25, 2020, the Department submitted draft rules to Brenda Gallant, Executive Director of the Long-Term Care Ombudsman Program, for her review and input. Department staff and Executive Director Gallant and staff discussed the rulemaking on or about June 26, 2020, at which time Executive Director Gallant expressed no concerns regarding the draft rule. The Department, through the Office of Aging and Developmental Services, has requested federal CARES Act Covid Relief Funding to hire an infection control consultant, who will work with facilities to help them develop an Infection Control and Prevention plan, which will be required by this rule. The Department received approval for the Covid Relief Funding at the end of September 2020. The Department anticipates that the facilities' plan development/infection control consultation costs will be defrayed though the CRF. The rule provides a requirement for PPE and supplies, but these measures should have been in place in the facilities in response to the Covid pandemic. This is a major substantive rulemaking, and this new rule will be provisionally adopted following public comment and review by the Office of the Attorney General. The provisionally adopted rule will not become effective until after Legislative review and approval.

Jonathan Leach: Thank you, Heather. We're now going to begin to take comments from the public. We're going to call on each speaker in the order you stated that you wished to comment. If you have not done so, please comment 'I wish to comment today' in the chat section of this video conference. While you're speaking, we may ask you for comments in writing during the comment period just to assure we are able to adequately respond to your comments. Because of the review of comments and decisions to make changes to this proposed rule is a separate part of the process, we will not be responding to questions about the contents of the rule today, but we do understand that a question about a rule provision indicates that the commenter feels that the provision needs clarification. Time is limited today; we ask that you keep comments brief by not repeating what speakers before you have already stated. Please make sure your mic is unmuted at your computer when your name is called and you're welcome to provide your full comments in writing. Comments today will conclude today by 11:50 to allow time to answer questions and review the next steps in this rule making. At this point in time I'm going to turn control over to Diane to start announce speakers.

Diane Perry: The only one I see is D. Hamilton, and I have asked them to unmute.

Jonathan Leach: Okay. D, you are up.

Dale Hamilton: Hi, yeah this is Dale Hamilton Executive Director of Community Health and Counseling Services. So I guess my general theme of my comments all go under the area of needing further clarification, so I'll just go through that, those items. The first clarification would be, so we need to have the consultant the state is contracting with, to develop a plan, or are we able to utilize internal resources

for that? Along those lines, the certification and training that is mentioned, in terms that we must employee or contract with a person with certification and training. There's no criteria that is identified in terms of what that really entails. There are some areas that need to be included but without clarity on that it's impossible to know whether or not we're meeting that criteria. So further clarification on what that standard is around training, is that professional training, registered nurses, is that a specific program that your referencing. It's hard to know exactly what we need to meet to be able to have that in place.

Under the area of reviewing current national and state standards and identification so when we are putting the plan together, we're required to meet those, either national or state standards. Again, there is lack of clarity about, under this we're, you're lumping together various types of programs that operate very differently under federal and stated regulations, and so, for example under CDC they have guidelines for shared and congregate living, which is different than for guideline they would have funder for Assisted Living programs. So this rule is written with putting everything together, and requiring that, and the standards are different, and they vary at those national levels, so without that kind of distinction, it seems that the rule implies that PNMI's will have to meet a standard that exists at the federal level or at the state level that doesn't really meet what our programs do. So again, being able to distinguish the types of programs that you're putting together, and then when we try to link back to have our plans match, those national standard we may have matching them under the criteria that we have for our programs, but under this rule it would conflict with that. So further clarification of what those guidelines relate to program type would be helpful.

Then under the category of just documentation of random visual observations through on outbreak, that just seems really broad in terms of what does that really mean? Do you have a standard, is there a particular process that entails how frequent is that? There's just some very broad statements in this, and I'm concerned from the perspective of the accountability, of being able to meet the requirements when there's such broad statements.

The facility must implement recommendations from the Maine CDC, then it includes Universal testing and resident cohorting, again, different types of programs operate very differently in terms of what's possible and what isn't. Also the idea of universal testing, exactly what does that mean? PNMIs for example, they don't administer tests, is that contracting, is that sending people to be tested, what does that entail, also address the issues related to availability of testing. When there is limitations on testing, as we're experiencing now. It's very difficult for asymptomatic people to be tested, so putting a requirement on a provider without detailing how that works, could make that challenging. So that partnership that exists with the CDC and the state, in terms of meeting some of those requirements would be helpful.

Then there's conditions protocols for screening, again what does that mean in terms of definition of screening. Is that just the symptom checklist that has been provided by the CDC or does that mean something different? For example, I know in-home health services and in some of the facilities they have required testing to have been taken by providers. What does that mean as it relates to different programs in terms of screening?

Then just in terms of the training protocol, in going back to the overall plan, the internal training that we provide are there any specific criteria or is it just noting that the person has received training or are you looking to have detailed information about what the content of the training was and are there specific content that must be checked off exist in the personnel record to capture what will be reviewed to be sure we're in compliance with the requirement. That's the extent of my comments.

Jonathan Leach: Thank you Dale. Hopefully everyone can see that the directions on how to provide written comments are up on the PowerPoint slide. Would you be able to provide these to us in writing?

Dale Hamilton: Yes I can.

Jonathan Leach: OK. Thank you very much. Diane, do we have anyone else who has stated that they wish to comment today?

Diane Perry: Not that I can see.

Jonathan Leach: I can see that Nadine Grosso is raising her hand.

Nadine Grosso: Sorry. Thank you so much. I joined a little bit late I was having some issues with my links. My name is Nadine Grosso. I'm the vice president and director of the communications for the Maine Health Care Association. Really I don't want to reiterate; I just heard the last gentleman's comments and we actually have a lot of this those similar questions as it pertains to how this rule is going to affect providers of different size, different type, different resources, different infrastructures, abilities so I'd really like to say today as we appreciate the opportunity for you to have this public hearing in this covid environment. I know Zoom is fairly normal now but still not quite normal period.

From our sort of initial review of this rule proposal, we certainly recognize some of the requirements are best practices some of what's in your proposal is already OSHA mandates. So those things will deal with in we will submit written comments as well. We do have a couple questions and want some clear definitions, but the previous speaker really addressed a lot of those.

I would also just add the Maine Health Care Association does have an infection control program that we developed specifically for assisted living during this time period we believe our program can help with a lot of these rule proposals but I think overarching all of this it does come back to the idea that assisted living certainly has fewer resources than the nursing homes. So, when I look at these rules, I say 'these might be more achievable in the nursing home setting' from a resource perspective. So we would like more confirmation that the Department is going to be able to go ahead and hire that infection control consultant and that that person will be available to help assisted housing providers with their plan development and consultation and we would just like to add that the on-going, these are going to be costs that once, these rules are hammered and implemented are going to be costs that are going to be significant to some of our providers, so particularly to the extent that they rely on Medicaid for majority of their funding. Again, those resources are very different than those of nursing homes so we just kind of wanted to be on record as commenting on that and we will do some more written comments, so thank you.

Jonathan Leach: Thank you Nadine. I did see W. Nolton raised their hands a couple moments ago.

William Nolton: Can you hear me?

Jonathan Leach: Yes, I can hear you.

William Nolton: Yes my name is Bill Nolton I work for Stericycle, so we're kinda on the back end of this regulation and I apologize, we just kinda found out about this new regulation coming out, a few days ago, so I don't have a fully prepared statement to make but I think the biggest thing that Stericycle is a waste handler and the back end of this.

Our largest concern is this regulation is kind of duplicative as well as a little bit different than the deep regulations that are currently in place which is 06-096 Chapter 900. The definition of medical waste is a little bit different, as well as how medical waste needs to be handled and I feel by having different definitions as well as how the waste has to be handles is just going to create a lot of confusion with generators as to what needs to be handled.

I guess one of the largest examples is that you guys are requiring that this waste be incinerated, and incineration costs are probably three to four times higher than autoclave treatment costs. So, if this stays in effect obviously we're going to have to raise our prices to transport this material all the way down to a medical waste facility which for Stericycle is in Haw River North Carolina, that's quite a haul from Maine. So that's probably the biggest that we see with this. The incineration costs will be higher so now you're changing the definition of personal protection equipment so compared to the OSHA requirements so that will increase the waste stream which will obviously increase cost to the customers, our customers. So with that being said I just feel that this rulemaking , I don't really have an issue per se with the rulemaking, but I think it needs to be more in line with the current DEP regulations, which have been in effect for quite some time period so I think already handle a lot of the requirements that you guys are proposing here.

Jonathan Leach: Bill, thank you very much. Would you be able to provide those comments to me in writing?

William Nolton: Yes, I believe we plan on putting our things in writing. I've been talking with our regulatory affairs Department, and they plan on putting together a letter for you.

Jonathan Leach: OK, thank you very much. If there is anyone else who wishes to speak? OK, I've seen two people who have raised their hand. I'm going to call on my cohost to see who these people are I'm not able to.

Diane Perry: You have W. Nolton and Paul Dann.

Jonathan Leach: Paul Dann, okay. That was Bill Nolton we just heard from, so Paul Dann.

Paul Dann: Morning everyone. Thanks for the Opportunity to comment period most of us are credited by external accredited organizations and word joint accredited and would we would appreciate having the ability in the rule to say that there is a deemed status with current and active accreditation. Thank you.

Jonathan Leach: If there is anyone else who wishes to comment today, if you could raise your hand or enter a comment in the group chat. Michael Parker. Mr. Parker you have the mic.

Michael Parker: Since the comment period closes the 22nd of November, that's a Sunday, will that be rolled over the next business day?

Jonathan Leach: Yes, I'll accept comments if they come in on Monday morning.

Michael Parker: Oh, Okay thank you.

Jonathan Leach: Okay, last call, is there anyone else who wishes to speak today? You can either raise your hand or make a comment in the group chat. To submit written comments, I have the screen still up. You can send those to me via Mail US Postal service or you can send them to me by email at Jonathan.H.Leach@maine.gov. The deadline for written comments is the 22nd. During formal rulemaking, no members of the Department can make any comment, or answer any questions about the content of the proposed rule, but the Department will be responding to all comments including all written comments during the period of the public comment, in a single summary of comments and responses that will be made available at the time the rule is provisionally adopted, and because this is an addition to a major substantive Rule, we will first provisionally adopt the rule and then submit that provisionally adopted rule to the Legislator for consideration in final adoption. Does anyone have any comments or

questions about the rulemaking process? You can either raise your hand or enter those in the comment chat.

Nadine Grosso: I was just going to ask the other folks on the call, will you remind us during the provisional process when you submit it to the Legislature if there is another opportunity for public comment at that point?

Jonathan Leach: That is determined by the legislature and they could hold another public hearing similar to this one at its discretion after it's assigned to committee, and I'm sure this will be assigned to Health and Human Services.

Nadine Grosso: Thank you.

Jonathan Leach: If there are no further questions or comments today, I'm going to allow people to go ahead and exit the public hearing and if you do have any questions or comments you can certainly send those to me at my email address as well or call me at 207-287-5825. I'm also working remotely most of the time now, so my work cell phone is 441-4998. Thank you all.

Transcribed by Rebecca Stenger, Division of Licensing and Certification

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November 19, 2020

Jonathan Leach, Compliance Analyst
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41 Anthony Ave., SHS #11
Augusta, ME 04333

RE: Comments on Proposed Rule Changes for 10-144 CMR Ch. 113, Regulations Governing the Licensing and Functioning of Assisted Housing Programs

Dear Mr. Leach:

Thank you for the opportunity to provide comments on the proposed rule changes to address standards for infection prevention and control. I appreciate and support the goal of establishing consistent standards and processes to guide programs in their management of infection control practices. My general comment is that there are portions of the rule that lack sufficient specificity to adequately guide programs. The lack of specificity could result in the failure of the program to meet a requirement based on a misinterpretation or misunderstanding of the rule statement.

Section 2 A.1:
The rule states, "The facility must employ or contract with a person with certification or training in IPC to oversee the development and implementation of the IPCP. While the rule identifies some content that is required in the training, it does not provide guidance as to what type of certification or training is appropriate. Do programs need to receive approval regarding the background of the employee/contractor or do programs have the independent authority to approve the certification and/or training?

Section 2 A.2 a iii:
Is the program required to document which national or state standards were reviewed? There are numerous national and state entities that provide standards regarding infection control practices. Do programs maintain the independent authority to choose the national and state standards that they review? If not, will the rule provide more specificity as to the entities that are deemed appropriate for review?

Section 2 A.3 f:
This is a very broad requirement. What type of documentation meets this requirement? What is the frequency associated with the term "random visual observations"?

The Department states that "there will be no additional costs to the Department as a result of this rulemaking". Several requirements of this rule will likely result in increased costs to the programs. Will the Department allow expenses associated with compliance of these rules to be included in cost reports? Will the Department adjust program caps in instances when the expenses exceed current approved budgets?

STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION

JANET T. MILLS
GOVERNOR

MELANIE LOYZIM
ACTING COMMISSIONER

November 22, 2020

Jonathan Leach, Compliance Analyst
Division of Licensing and Certification
Maine Dept. of Health and Human Services
11 State House Station
Augusta, Maine 04333

RE: Comments on Draft Revisions to 10-144 C.M.R. ch. 113, *Regulations Governing the Licensing and Functioning of Assisted Housing Programs; Infection Prevention and Control*

Dear Mr. Leach:

The Maine Department of Environmental Protection (DEP) appreciates the opportunity to offer the following comments on the proposed modifications to 10-144 C.M.R. ch. 113.

DEP's interest in this rulemaking stems from its statutory obligation to regulate biomedical waste activities and facilities. Through PL 1989, c. 124 § 3, the Maine Legislature directed the DEP to adopt rules relating to the "packaging, labeling, handling, storage, collection, transportation, treatment and disposal of biomedical waste, including infectious and pathogenic waste, to protect public health, safety and welfare and the environment." The law further required that the rules include: registration of biomedical waste generators; handling of biomedical waste by generators; licensing of biomedical waste transporters and the conveyances used for the transportation of biomedical waste; implementation of a biomedical waste tracking or manifest system; establishment of treatment and disposal standards; categories of biomedical waste subject to the regulation; and, siting, licensing, operational and record-keeping requirements for biomedical waste treatment, storage, and disposal facilities (see 38 M.R.S. § 1319-O(3)). As directed by 38 M.R.S. § 1319-O(3), the DEP initiated rulemaking and the DEP's 06-096 C.M.R. ch. 900, *Biomedical Waste Management Rules*, became effective on January 1, 1991. (This rule was subsequently amended on August 4, 2008 and August 13, 2011.)

Any new or substantially modified biomedical waste treatment or disposal facility is also subject to 38 M.R.S. § 1310-X and § 1319-X. Section 1319-X, in part, establishes criteria for the development of biomedical waste facilities. Among other provisions, § 1310-X prohibits approval of new commercial biomedical waste disposal or treatment facilities after September

30, 1989, except for an exemption that allows processing of an application for a commercial biomedical waste disposal or treatment facility, if at least 51% of the facility is owned by a licensed hospital or hospitals as defined in 22 M.R.S. § 328, sub-§ 14, or a group of hospitals that are licensed under 22 M.R.S. acting through a statewide association of Maine hospitals or a wholly owned affiliate of the association. Since this provision was established under PL 2003, c. 551, § 17, only one application for a treatment facility has been submitted to the DEP. This was for the Stericycle treatment facility located in Pittsfield; this facility is no longer in operation. No applications for a biomedical waste disposal facility have been submitted to the DEP.

In our review of the proposed modifications to 10-144 C.M.R. ch.113, several discrepancies or areas of potential confusion between DEP's Chapter 900 and the DHHS's Chapter 113 were noted. These discrepancies or areas of potential confusion are summarized below:

- Ch. 900, § 7 includes a detailed definition of "biomedical waste", based on the definition in 38 M.R.S. § 1303-C. The definition in draft ch.113, § 1(B) differs from that in the DEP rule. The DEP comments that this difference may cause confusion among the regulated community and suggests that ch.113 either reference the DEP definition or specifically include it in ch. 113.

- Ch. 900, § 6 includes definitions of "infection" and "infectious agent", and the rule subsequently addresses the standards and licensing and registration requirements for all types of biomedical waste generators and facilities, including those for infection prevention and control. The DEP comments that while there are some subtle differences between the ch. 900 and the draft ch. 113, § (B)(2) containment procedures for biomedical waste, the two chapters are generally consistent in this regard. However, the DEP offers to discuss with DHHS some suggestions for additional storage and handling provisions to enhance what is included in the draft ch. 113 rule and to more fully align it with ch. 900 requirements.

- As noted above, there are currently no licensed biomedical waste treatment facilities in Maine. Section 9 of ch. 900 prohibits the disposal of untreated biomedical waste in Maine; thus, "interring" biomedical waste (in Maine) as described in the proposed ch. 113 rule would be prohibited under ch. 900. Ch. 900 allows biomedical waste, if treated by an approved technology, to be disposed of in Maine as a "special waste". While incineration of biomedical waste is recognized in ch. 900 as a method of treating biomedical waste to minimize the levels of infectious agents contained in the waste, the DEP Bureaus of Remediation and Waste Management and Air Quality have encouraged the use of alternative non-incineration technologies in order to reduce the discharge of air pollutants associated with incineration of this waste. There are currently no incineration facilities located in Maine that are licensed by the DEP to accept and treat biomedical

waste. Restricting the treatment of biomedical waste generated by the facilities regulated under the provisions of the draft ch.113 rule to incineration would limit the management options for these facilities and potentially increase their costs. DEP recommends that the wording of draft ch.113 be modified to make it consistent with ch. 900.

- DEP comments that facilities regulated under the draft ch. 113 rule may be required to register as generators of biomedical waste under the provisions of ch. 900, § 11. The DEP recommends that a reference to this requirement be added to the draft ch. 113.

The following is a link to DEP's Chapter 900 rule for your reference:
https://www.maine.gov/dep/waste/rules/index.html

Thank you for your consideration of our comments on this draft rule. We would be happy to work with you to discuss options for resolution of the issues outlined above. Please contact me if you would like to arrange such a discussion or if I can provide anything further at this time.

Sincerely,

Paula M. Clark

Paula M. Clark, Director
Division of Materials Management
Bureau of Remediation and Waste Management

MACSP
Maine Association For Community Service Providers

November 22, 2020

Jonathan Leach
Compliance Analyst Division of Licensing and Certification
41 Anthony Ave., SHS #11
Augusta, ME 04333

RE: Proposed Rule: Infection Prevention and Control/10-144 CMR, Chapter 113

Sent via email: Jonathan.h.leach@maine.gov

Dear Mr. Leach,

On behalf of the Maine Association for Community Service Providers (MACSP), thank you for the opportunity to provide comments on Proposed Rule 10-144 CMR, Chapter 113 regarding infection and prevention control.

MACSP is the statewide association of more than 70 organizations providing services and support to children and adults with intellectual and developmental disabilities (I/DD) to live and thrive in Maine communities. The majority of our members provide residential services and supports to people with intellectual and developmental disabilities.

This rule establishes minimum standards for infection prevention and control for assisted living, residential care facilities and private non-medical institutions. Our concerns and questions are outlined below.

Section 2. Infection Prevention and Control Plan (Pg. 2)
The majority of the several hundred "residential care facilities" supported by MACSP providers are 1-4 person homes in communities throughout the state. The supports that are received by MaineCare members in these small residential settings, while essential for daily living and community integration, are not typically provided by nursing level staff, nor are nurses on-site 24/7 like other settings this rule may apply to.

Unlike larger settings, these organizations do not employ or contract with a person who is an infection control specialist.

MACSP appreciates that the Department, through OADS, is currently offering infection control consultants through the end of 2020 to work with facilities to help them develop an Infection Control and Prevention plan, required by this rule. Many of our members, especially organizations that provide support in residential settings described above, utilize these consultants under this program. The proposed rule, however, requires facilities to employ or contract with a person with certification or training in IPC not only to oversee the development of the IPCP but the implementation as well. **(A.1)**

We are not familiar with another state program that would offer this support. The requirements under this rule, therefore, without additional funding, become unfunded mandates for providers after 2020. This is worrisome for an already strapped and underfunded sector.

Also, we wish to know how the state defines " implementation". It is unclear how frequently agencies without a person with certification or training in IPC, would need to employ or contract someone to implement the plan after it is developed. Is such a person needed for periodic review; during a public health emergency; during the onset of an outbreak; when updating the plan, or required to be always on staff or under contract?

Whether a staff member consultant is needed full time or not, maintaining and documenting the training and implementation requirements will require additional staff time and costs. MACSP urges the State to amend rates tied to these licensed services to reflect these costs more adequately and to develop additional supports through an ongoing system-wide IPC training to ensure the successful implementation of the rule.

Thank you again for the opportunity to provide comments. Please contact me if you have any questions or would like additional information.

Sincerely,

Laura Cordes
Executive Director

MHCA

Maine Health Care Association

Comments on behalf of the Maine Health Care Association

REGULATIONS GOVERNING THE LICENSING AND FUNCTIONING

OF ASSISTED HOUSING PROGRAMS:

Infection Prevention and Control

10-144 C.M.R. Chapter 113

Nadine L. Grosso

Vice President & Director of Communications

November 20, 2020

On behalf of the Maine Health Care Association (MHCA), an organization representing over 200 nursing homes and assisted living/residential care facilities, we submit the following comments and questions regarding the Maine DHHS Division of Licensing and Certification proposal to amend the regulations for assisted housing, specifically to add an infection prevention and control (IPC) section.

MHCA fully appreciates the importance of IPC in long term care and is generally supportive of the Department's efforts to ensure that our Assisted Housing providers are afforded critical IPC training, education and resources necessary to care for their residents. We also think these rules will provide IPC continuity across the long term care continuum, which is good for providers and consumers alike.

In the announcement of this proposal, the Department reminds us of the free IPC consultation services currently available to Assisted Housing providers through a State/Home Health Agency partnership that is funded by $1 Million of CARES Acts money. The feedback we've received on this program has been favorable in terms of the caliber and expertise of the agencies involved, however, there is a perennial challenge that our assisted housing providers have faced throughout the COVID-19 pandemic – they are trying to limit non-essential visitors into their homes.

We are aware of several instances where our assisted housing providers have requested ZOOM review/consultation of their IPC plans vs. in-person meetings and have been advised that the Department is recommending in-person contact for these consulting services. MHCA remains concerned about the imposition of risk this poses for COIVD-19 to enter our facilities especially during this time when cases are on the rise. We respectfully ask the Department to review its recommendations for in-person vs. remote IPC consultation and err on the side of caution by supporting remote options. It only makes sense for the duration of this public health emergency.

MHCA has the following specific comments/questions by proposed section:

Section 2 A-1: Requiring assisted housing facilities to employ or contract with a person with certification or training in IPC to oversee the development and implementation of the IPCP.

- Many Assisted Housing providers don't have the federal or state funding sources to support staff of this nature. While Assisted Housing providers have RN consultants, not all have RNs on staff and many don't have access to an RN certified in IPC. It is not clear from the proposal if the

Department intends this position to be full time, part time or other and we seek clarification. Also, at this time, there is no standard infection prevention training program designed for assisted housing nationally or within the State. While we believe MHCA's IPC program can meet most of what is required for IPC plan development, the costs for certifying and training an IPC professional are expensive and we ask the Department to consider this, along with the ongoing expense of maintaining such a position within the context of current MaineCare rate setting analysis.

Section 2 A-3c: Plan must include a respiratory protection program

- Many long term care facilities have developed respiratory protection programs in response to the current pandemic. It is worth noting that Maine has been able to assist providers through this process but that is largely because of the work of the national guard and community fire departments. If these resources were no longer available, the financial and resource burden to assisted housing providers will increase.

Section A-3f: Documentation of random visual observations of staff use of PPE throughout an outbreak of an infectious disease;

- Who determines the timing of an outbreak? The CDC? Rules should clarify this point.

Section A-3j: An exposure control plan to address potential hazards posed by blood and body fluids and other potentially infectious material (OPIM) or infectious diseases.

- What existing rules or standards apply to this plan? Is this proposal consistent with existing OSHA and/or DEP requirements or will it pose conflicts?

Section A-5c: In the event of an outbreak of an infectious disease, the facility must provide a refresher training to all employees.

- What constitutes refresher training? Will facilities have flexibility in how this is carried out?

Section B-3: Contract for disposal. Biomedical waste shall be incinerated (or interred) per contract with a licensed biomedical waste contractor.

- This provision will be very costly and as a commenter mentioned at the public hearing may be in conflict with existing OSHA and/or DEP requirements. MHCA seeks clarification on this point.

As noted at the public hearing, MHCA urges the Department to recognize the wide variety of assisted housing provider types. Their size, ownership, financial resources, etc. will dictate how successful they will be in implementing this IPC rule. MHCA stands ready to assist providers in meeting the goals of this proposal and asks the Department to do the same.

Lastly, we urge DHHS to be sensitive to the timing for compliance with these new rules, especially for any provider who may be struggling with viability during the pandemic or after.

Thank you for the opportunity to comment and we look forward to the Department's response.

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November 22, 2020

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State House Station 11
41 Anthony Ave
Augusta, ME 04333-0011

Attn: Jonathan Leach, Compliance Analyst of Licensing and Certification

Submitted via e-mail: Jonathan.H.Leach@Maine.gov .

RE: Comments on Regulations Governing the Licensing and Functioning of Assisted Housing Programs: Infection Prevention and Control Part of 10-144 C.M.R. Chapter 113

Dear Mr. Leach:

Stericycle, Inc. (Stericycle) appreciates the opportunity to submit comments on the Maine Department of Health and Human Services (DOH), Division of Licensing and Certification (DLC) draft Infection Prevention and Control Rule, 10-144 C.M.R. Chapter 113 (the Regulation). Stericycle is a publicly traded corporation (NASDAQ: SRCL) based in Bannockburn, Illinois. In 2019, we had estimated revenues of approximately $3.3B. Our services include compliant collection, transportation and treatment of medical waste, collection/disposal of pharmaceutical waste, secure document destruction, and consulting/training programs to help educate our customers on the proper handling of these waste streams. In the State of Maine, Stericycle operates a medical waste transfer station in Pittsfield, ME, our corporate vision is to be leaders in "Protecting What Matters".

Stericycle has conducted a review of the regulation and respectfully submits the general comments outlined below.

General Comments

The DOH Regulation in several parts is duplicative to the State of Maine Department of Environmental Protection (DEP) 06-096 Chapter 900 regulations, The DOH Regulation states that it applies to all types of assisted living programs, residential care facilities, and private non-medical institutions. However, the DEP regulations already apply to all persons engaged in biomedical waste activity and thus already include the facility types that the DOH Regulation specifies. Each regulation defines the term "biomedical waste", however, the DEP regulations found in 06-096 Chapter 900 Section 7 include a much more detailed definition in that it discusses many types of biomedical waste including discarded human blood, blood products, and

body fluids, waste saturated with human blood, blood products, or body fluids, pathological waste, chemotherapeutic waste, sharps waste, and cultures and stocks. Having multiple definitions which may not be consistent creates confusion and creates a potential compliance risk for the regulated entity. Thus, we would recommend that the DOH not adopt a separate definition but rather refer back to the DEP regulation for definitions.

Biomedical Waste Management

DOH Regulation Section 2, "Biomedical Waste Management" contradicts the current DEP 06-096 Chapter 900 regulations. As stated above, the DEP regulations apply to all businesses that generate biomedical waste today. Additionally, the DEP regulations detail how biomedical waste is to be packaged, labeled and disposed. They also detail how waste should be treated, (06-096 Chapter 900, Section 10) with multiple options are provided for treatment of biomedical waste. However, DOH Regulation Section 2, B.3, of the Regulation states that biomedical waste shall be incinerated (or interred) per contract with a licensed biomedical waste contractor. Incineration being the only option provided is not feasible or necessary, and would be much more costly for generators, as there are no medical waste incinerators in the state or in close proximity (i.e. Stericycle's closes locations are in Ohio or North Carolina). There are very few incinerators across the country due to the stringent operating conditions and thus use of incineration should be limited to those things that truly need incineration, such as pathological wastes or other drug wastes such as trace chemotherapies or pharmaceuticals. Alternatively, autoclaving biomedical waste is a proven technology and an accepted technology by the DEP as well as the United States Centers for Disease Control and Prevention (CDC) and all other states across the country for this type of waste generated. Autoclaving is more readily available (more facilities employ autoclaving for treatment of biomedical waste and it is much less expensive). Requiring incineration of all biomedical waste at assisted living facilities would be burdensome, costly and create logistical issues.

Recommendation

The COVID-19 pandemic has raised much awareness on the topic of proper biomedical waste management. We mention this as we suspect that is the genesis of this regulation. As a company that provides biomedical waste transport and treatment, we have constantly been asked questions regarding the proper disposal of biomedical waste contaminated with COVID-19 or generated during the care of a COVID-19 patient. The audience that this rule was written for, assisted housing programs, typically generates very little biomedical waste. However, we have seen numerous assisted living facilities being more conservative and managing all waste generated from their COVID-19 patients as biomedical waste, which is unnecessary. Early on, in the pandemic the CDC made it clear that waste generated in the care of COVID-19 patients does not need to be managed any differently than it was before the pandemic in stating on their website:

Medical waste (trash) coming from healthcare facilities treating COVID-2019 patients is no different than waste coming from facilities without COVID-19 patients. CDC's guidance states that management of laundry, food service utensils, and medical waste should be performed in accordance with routine procedures. There is no evidence to suggest that facility waste needs any additional disinfection.
Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Waste-Management

Separate and more stringent management of biomedical wastes is unnecessary. While some states have provided additional guidance on COVID-19 related biomedical waste to further assist the regulated community, none are going so far as to implement true regulation. Instead of writing a separate set of biomedical waste regulations, we would strongly recommend that DOH work with the DEP to produce biomedical waste management guidance documents. These documents could be specific to healthcare facility types, such as assisted housing, or more general to give overarching guidance on COVID-19 waste management to all regulated entities. Stericycle shares information from other State regulatory agencies on COVID-19 waste management on our website at: https://www.stericycle.com/covid-hub/external-resources. We think that the sharing of information on this waste stream is key and we would be happy to share any guidance that your agency or DEP puts together as well.

Ultimately, COVID-19 will soon become a virus much like the common flue we will all have to manage through. Additional rulemaking that is redundant to existing DEP regulations, will be unnecessary and overly burdensome for the already taxed assisted housing industry.

Stericycle appreciates this opportunity to submit comments and work with the Department on this rulemaking.

In the meantime, if you have any questions or comments for us, please feel free to contact me at 401-641-5878 or via email at wnolton@stericycle.com or Cara Simaga via email at csimaga@stericycle.com.

Sincerely,

William Nolton

William Nolton OHST
Regional Permit Manager
Stericycle, Inc.

CC: – Cara Simaga, Director, Regulatory Affairs, Stericycle, Inc.

Enclosures