SUMMARY OF PUBLIC COMMENTS, DEPARTMENT'S RESPONSES, AND LIST OF CHANGES MADE TO THE FINAL RULE

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10-144 C.M.R. CH. 113, REGULATIONS GOVERNING THE LICENSING AND FUNCTIONING OF ASSISTED HOUSING PROGRAMS

The Department of Health and Human Services, Division of Licensing and Certification (the Department), held a virtual public hearing via the Zoom platform on November 12, 2020 on a proposed amendment to 10-144 C.M.R. Ch. 113, Regulations Governing the Licensing and Functioning of Assisted Housing Programs. Written comments were accepted through November 22, 2020. Comments were received from the following people:

TABLE OF COMMENTERS

ID #	First Name	Last Name	Date	Representing	Format
1	Dale	Hamilton	11/12/20 and 11/19/20	Community Health and Counseling Services	Oral and Written
2	Paula	Clark	11/22/20	Maine Department of Environmental Protection	Written
3	Laura	Cordes	11/12/20 and 11/22/20	Maine Association of Community Service Providers	Oral and Written
4	Nadine	Grosso	11/12/20 and 11/22/20	Maine Health Care Association	Oral and Written
5	William	Nolton	11/12/20 and 11/22/20	Stericycle	Oral and Written
6	Paul	Dann	11/12/20	NFI	Oral
7	Michael	Parker	11/12/20	Maine Department of Environmental Protection	Oral

This summary include comments made in writing and oral comments made at the public hearing, and the Department's response to each comment. Commenters #1, 2, 4, and 5 provided oral and written comments. The Department's response follows each comment and explains whether the suggestions (if any) were followed by the Department or not. If the Department made no change in response to the comment, then an explanation of the reasons why no changes were made also is provided below. The summary list of changes following these comments identify new changes resulting from either public comment or Assistant Attorney General review of the Rule for form and legality.

1. **Comment:** Commenter 1 stated 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.

   Response: The Department thanks the commenter. The proposed Rule was drafted with broad flexibility to allow licensees to create a plan, policies, and procedures specific to their setting. The Department has responded to additional comments later in this document where commenters have raised issues specific to provisions of the proposed Rule. No changes were made to the Rule on the basis of this comment.

2. **Comment:** Commenter 1 stated: 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?

Response: The Department thanks the commenter. Comments regarding funding and reimbursement are outside the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

3. **Comment:** Regarding Section 2.A.1. "The facility must employ or contract with a person with certification or training in IPC to oversee the development and implementation of the IPCP." Commenter 1 asked: "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?"

   Response: The Department thanks the commenter. The Department, in the proposed Rule, identified the content areas the training must cover, but intentionally left any specific type of training program or source to the discretion of the licensed provider, to meet the needs of their specific setting and population. The Department did not require any pre-approval of the training program or source. No changes were made to the Rule on the basis of this comment.

4. **Comment:** Regarding Section 2.A.2.a.iii., "Review of current national or state standards and identification of any changes needed to meet those standards", Commenter 1 asked: "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?"

   Response: The Department thanks the commenter. The Department has clarified this requirement in the provisionally adopted Rule by adding a provision that the facility keep a log noting specifically what guidelines were utilized.

5. **Comment:** Regarding Section 2.A.3.f., "The IPCP must include policies and procedures for the prevention of the spread of any infectious disease, including: Documentation of random visual observations of staff use of PPE throughout an outbreak of an infectious disease", Commenter 1 stated "This is a very broad requirement. What type of documentation meets this requirement? What is the frequency associated with the term "random visual observations"?"

   Response: The Department thanks the commenter. This Rule provision is related to the required content of the licensed facility's policies and procedures, and therefore gives broad flexibility to each facility to determine how frequently visual observations are conducted and documented. No changes were made to the Rule on the basis of this comment.

6. **Comment:** Regarding Sections 2.A.4.a. ("Universal testing and resident cohorting, when applicable") and 2.A.4.d. ("Conditions and protocols for screening all full and part-time staff, all essential healthcare individuals who enter the facility (such as hospice staff, physicians, etc.), and any other individual entering the facility"), Commenter 1 stated that the Maine CDC may issue different requirements for universal testing and resident cohorting and/or conditions and protocols for screening to different types of facilities.

Response: The Department thanks the commenter. The Department finds that the rule requires that each licensed facility must implement any recommendations of the MeCDC. Such recommendations would be issued to the affected types/levels of facilities, specific to the needs of the size of the facility and the population served. No changes were made to the Rule on the basis of this comment.

7. **Comment:** Commenter 2 stated that the "Maine Department of Environmental Protection has the statutory authority under PL 1989, c. 124 § 3 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" and the DEP initiated rulemaking as directed by 38 M.R.S. § 1319-O(3), 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.)" Commenter 2 also provided additional information regarding commercial biomedical waste disposal or treatment facilities. Commenter 2 noted that several discrepancies or areas of potential confusion between DEP's Chapter 900 and the DHHS's Chapter 113 were noted. Commenter 2 provided individual comments regarding each of the discrepancies.

   Response: The Department thanks the commenter. The Department has deleted Section 2.B. of the proposed Rule in its entirety from the provisionally adopted Rule, and added the following to Section 1.A. Purpose: Facilities governed under this regulation may be required to register as generators of biomedical waste under the provisions of the Department of Environmental Protection rule 06-096 CMR Ch. 900, Biomedical Waste Management Rules.

8. **Comment:** Commenter 2 noted that facilities regulated under the proposed rule may be required to register as generators of biomedical waste under the provisions of 06-096 C.M.R. Ch. 900, § 11, and recommended that a reference to this requirement be added to the proposed rule.

   Response: The Department thanks the commenter. See the response to comment 7.

9. **Comment:** Section 1.B.1: Commenter 2 stated that 06-096 C.M.R. 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 the proposed rule.

   Response: The Department thanks the commenter. The Department has deleted the definition of "biomedical waste", as it is no longer relevant to the Rule given the deletion of Section 2.B.

10. **Comment:** Regarding Section 2.B.2., Containment procedures, Commenter 2 stated that 06-096 C.M.R. 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 06-096 C.M.R. Ch. 900 and the proposed rule, the two chapters are generally consistent in the containment procedures for biomedical waste. However, the DEP offers to discuss with DHHS some suggestions for additional storage and handling provisions to enhance what is included in the proposed rule and to more fully align it with 06-096 C.M.R. Ch. 900 requirements.

Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule.

11. **Comment:** Regarding Section 2.B.3. "Contract for disposal. Biomedical waste shall be incinerated (or interred) per contract with a licensed biomedical waste contractor", Commenter 2 stated that Ch. 900 allows biomedical waste, if treated by an approved technology, to be disposed of in Maine as a "special waste". Section 9 of 06-096 C.M.R. Ch. 900 prohibits the disposal of untreated biomedical waste in Maine; thus, "interring" biomedical waste (in Maine) as described in the proposed rule would be prohibited under 06-096 C.M.R. Ch. 900. Commenter 2 stated: "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."

    Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule.

12. **Comment:** Regarding Section 2.A.1, "The facility must employ or contract with a person with certification or training in IPC to oversee the development and implementation of the IPCP", Commenter 3 stated the proposed rule requires facilities to employ or contract with a person with certification or training in Infection Prevention and Control (IPC) not only to oversee the development of the IPCP but the implementation as well. The commenter stated that "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. 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."

    Response: The Department thanks the commenter. The Department drafted the Rule to give broad discretion to licensed providers in identifying the person to oversee and conduct the implementation of the Infection Control Plan, given the varying size and needs of the programs licensed. The proposed Rule does not call for that person to have nursing credentials, but to have received training, based on the needs of the setting, in the specific content areas outlined. Comments regarding funding and reimbursement are outside the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

13. **Comment:** Regarding Section 2.A.1. (see above), Commenter 3 asked for clarification on how the state defines "implementation" and stated that "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?" The commenter added: "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."

Response: The Department thanks the commenter. As the commenter states, the provisionally adopted rule requires each licensed program to employ or contract with to develop and oversee implementation of the Infection Prevention and Control Plan. The specific duties of that person would be contained in the licensed provider's specific plan, policies, and procedures, contingent upon the needs of the facility. Comments regarding funding and reimbursement are outside the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

14. **Comment:** Commenter 4 stated that the Maine Health Care Association (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."

    Response: The Department thanks the commenter. The request for the Department to reconsider an approach to grant-funded IPC consultation services offered by the Office of Aging and Disability Services falls outside of the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

15. **Comment:** Commenter 4 urged 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 and adds MHCA stands ready to assist providers in meeting the goals of this proposal and asks the Department to do the same.

    Response: The Department thanks the commenter. The proposed Rule was drafted with great flexibility, and requires licensees to create an Infection Control Plan, and polices and procedures to implement that plan, based on the unique characteristics and needs of their setting and the population serviced. No changes were made to the Rule on the basis of this comment.

16. **Comment:** Commenter 4 urged 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.

    Response: The Department thanks the commenter. The proposed Rule will be provisionally adopted prior to being submitted for review by the Maine State Legislature, and final adoption will occur following that review. While the Rule is provisionally adopted, the Department intends to provide support and education to licensed providers aimed at achieving compliance. Enforcement measures may be pursued after the Rule is finally adopted. No changes were made to the Rule on the basis of this comment.

17. **Comment:** Commenter 4 stated "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."

    Response: The Department thanks the commenter. The Department drafted the Rule to give broad discretion to licensed providers in identifying the person to oversee and conduct the implementation of the Infection Control Plan, given the varying size and needs of the programs licensed. The proposed Rule does not call for that person to have nursing credentials, but to have received training, based on the needs of the setting, in the specific content areas outlined. Comments regarding funding and reimbursement are outside the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

18. **Comment:** Regarding Section 2.A.3.c. "The IPCP must include policies and procedures for the prevention of the spread of any infectious disease, including: c. A respiratory protection program", Commenter 4 stated "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."

    Response: The Department thanks the commenter. Comments regarding funding and reimbursement are outside the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

19. **Comment:** Regarding Section 2.B.3: "Contract for disposal. Biomedical waste shall be incinerated (or interred) per contract with a licensed biomedical waste contractor", Commenter 4 stated that "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."

Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule.

20. **Comment:** Commenter 5 stated that several parts are duplicative of the State of Maine Department of Environmental Protection (DEP) 06-096 C.M.R. Ch. 900 regulations. Commenter 5 adds that the proposed rule 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 proposed rule specifies.

    Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule.

21. **Comment:** Commenter 5 stated: "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.*
    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."

    Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule. The commenter's suggestion that the Departments of Environmental Protection and Health and Human Services work together to create guidance falls outside of the scope of this rulemaking. No changes were made to the Rule on the basis of this comment.

22. **Comment:** Regarding Section 1.B.1. Identification of materials that constitute biomedical waste, Commenter 5 stated that 06-096 C.M.R. Ch. 900 §7 includes a much more detailed definition of "biomedical waste" 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, and recommended that the Department not adopt a separate definition but rather refer back to the DEP regulation for definitions.

    Response: The Department thanks the commenter. The Department has changed the deleted the definition of "biomedical waste" from the provisionally adopted Rule.

23. **Comment:** Regarding Section 2.A.3.f., "The IPCP must include policies and procedures for the prevention of the spread of any infectious disease, including: Documentation of random visual observations of staff use of PPE throughout an outbreak of an infectious disease", Commenter 5 asked "Who determines the timing of an outbreak? The CDC? Rules should clarify this point."

    Response: The Department thanks the commenter. The Department has changed the definition of an outbreak, for the purposes of this Rule, to "the diagnosis of a notifiable disease in any resident, or any employee who has direct care of residents, of an Assisted Living Program, Residential Care Facility or Private Non-Medical Institution governed by 10-144 CMR Chapter 113." This is consistent with the CDC definition of "outbreak", which includes "A single case of a disease long absent from a population is also reportable and may require immediate investigation."

24. **Comment:** Regarding Section 2.A.3.j., "The IPCP must include policies and procedures for the prevention of the spread of any infectious disease, including: An exposure control plan to address potential hazards posed by blood and body fluids and other potentially infectious material (OPIM) or infectious diseases", Commenter 5 asked: "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?"

    Response: The Department thanks the commenter. The Department refrained from including specific existing rules or standards when drafting the requirement for a exposure control plan that meets the needs of the specific licensed setting and the population served. Any such plan must comply with all existing State and federal rules and regulations. The entities the commenter names may be useful resources in the development of such a plan. No changes were made to the Rule on the basis of this comment.

25. **Comment:** Regarding Section 2.A.5.c., "In the event of an outbreak of an infectious disease, the facility must provide a refresher training to all employees", Commenter 5 asked: "What constitutes refresher training? Will facilities have flexibility in how this is carried out?"

    Response: The Department thanks the commenter. The Department finds that the nature and content of the refresher training should be specific to the nature of the emergent outbreak, and phrased the Rule provision broadly to allow flexibility for the licensed provider to determine the necessary content of such training. No changes were made to the Rule on the basis of this comment.

26. **Comment:** Regarding Section 2.B.3., "Contract for disposal. Biomedical waste shall be incinerated (or interred) per contract with a licensed biomedical waste contractor", Commenter 5 stated that

DEP 06-096 Chapter 900 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, and added that requiring incineration of all biomedical waste at assisted living facilities would be burdensome, costly and create logistical issues."

Response: The Department thanks the commenter. As stated previously, the Department has deleted Section 2.B. of the proposed Rule from the provisionally adopted Rule.

27. **Comment:** Commenter 6 asked that the Department include deemed status in the Rule for licensed facilities who have achieved accreditation.

    Response: The Department thanks the commenter. The Department finds that this request falls outside of the scope of this rulemaking, and will consider this request when a broader revision of 10-144 CMR Ch 113 is undertaken. No changes were made to the Rule on the basis of this comment.

28. **Comment:** Commenter 7 pointed out that the close of the period of public comment falls on a Sunday, and asked if the Department would accept written comments submitted on Monday, November 23, 2020.

    Response: The Department thanks the commenter. The Department agreed to accept written comments submitted on Monday, November 23, 2020. No changes were made to the Rule on the basis of this comment.

SUMMARY OF CHANGES RESULTING FROM PUBLIC COMMENTS & AAG REVIEW:

Header:

- The phrase "Provisionally Adopted Rule" and the date was added.

Table of Contents:

- Section 2.B. "Biomedical Waste Management" was deleted.

Section 1. Purpose and Definitions

- Page 1, Section 1.A: Added the following sentence: "Facilities governed under this regulation may be required to register as generators of biomedical waste under the provisions of the Department of Environmental Protection rule 06-096 CMR Ch. 900, Biomedical Waste Management Rules."

- Page 1, Section 1.B.1: The definition of "biomedical waste" was deleted, and the following definitions were renumbered accordingly.

- Page 1, Section 1.B.7: The definition of "outbreak" was revised to read "Outbreak means the diagnosis of a notifiable disease in any resident, or any employee who has direct care of residents, of an Assisted Living Program, Residential Care Facility or Private Non-Medical Institution governed by 10-144 CMR Chapter 113."

Section 2. Infection Prevention and Control

- Page 3, Section 2.A.2.a.iii: The phrase "current national or state standards" was replaced with "current Maine Center for Disease Control and Prevention (MeCDC) standards and federal Center for Disease Control (CDC) guidelines." and the phrase "The facility should keep a log noting specifically what guidelines were utilized" was added to the following sentence.

- Page 3, Section 2.A.2.c: The sentence "The facility should keep a log noting specifically what guidelines were utilized, and identification of any changes needed to meet those standards." was added.

- Page 5, Section 2.B: This section was deleted in its entirety.

Statutory Authority:

- 22 M.R.S. §§ 42 and 3173 were added.

Regulatory History:

- The sentence "This is a major substantive rule pursuant to 22 M.R.S. § 7853" was added, and the phrase "[major substantive rulemaking process]" was deleted.