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March 2, 2021

Senator Ned Claxton, Chair
Representative Michele Meyer, Chair
Members, Joint Standing Committee on Health and Human Services
100 State House Station
Augusta, ME 04333-0100

Re: LD 330 – An Act To Prevent Accidental Overdoses by Establishing a Protocol for Prescription Drug Recovery

Senator Claxton, Representative Meyer, and Members of the Joint Standing Committee on Health and Human Services:

This letter is to provide information on LD 330, An Act To Prevent Accidental Overdoses by Establishing a Protocol for Prescription Drug Recovery.

The bill would require a provider who provides in-home or community support long term care services and administers a controlled substance to an adult with long-term care needs, defined in the bill as an "administering provider" to document controlled substances prescribed/obtained for the "client-patient" and to report into the Prescription Monitoring Program (PMP). Administering providers includes an employee or contractor of a provider but does not include a family member of the client-patient. The bill would also require all controlled substances to be kept in a locked container to which only the administering provider, the client-patient, and, if there is one, designated caregiver have access. Finally, the bill would require the administering provider, upon the death of the client-patient, to collect any unused controlled substances (schedule II, III, and IV), properly dispose of them, and report strength, quantity, and manner of disposal into the PMP. The provider would need to develop a written policy for how administering provider will document, collect, and dispose of controlled substances in compliance with the bill and provide the policy to the Department for review.

Maine's PMP system is structured for use by two broad categories of medical professionals: clinicians who prescribe controlled substances (and thus have a Drug Enforcement Agency (DEA) number) and pharmacists who dispense controlled substances. Only these licensed prescribers and dispensers can access the protected health information contained within the PMP. This bill would require a new user role to be created within the PMP for in-home and community support workers. Requiring in-home and community support workers to report into the PMP would, by extension, allow these workers unfettered access to all patient records in the PMP database, not just their own patients. While licensed clinicians and pharmacists undergo extensive training on Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance with regard to use of the PMP, unlicensed in-home and community support workers are not currently subject to this training. Thus, if these workers are to be given access to the PMP

system for the purposes outlined in this bill, there will be a need (and commensurate administrative burden/cost) to train these workers on HIPAA compliance and use of the PMP. Additionally, allowing unlicensed workers to access the PMP will necessitate an increased level of system audit on behalf of the Office of Behavioral Health (OBH) PMP Team to ensure compliance of these new users.

This bill would require a new PMP module to be developed and implemented in order for administering providers to be given access to the system. Given the need for rulemaking and the current system implementations that must be completed prior to this new module being developed, we estimate that this work would require a minimum of 6-12 months to complete before administering providers would actually have this access. We estimate that the fiscal impact of implementing this module into the PMP is $75,000 with an annual maintenance fee of $30,000, for an estimated total amount of approximately $105,000 in year one and $30,000 each year after.

An alternative solution that could accomplish the same objective is to have a fillable form located on the PMP/OBH website for use by administering providers in the situation outlined in this bill. Administering providers would fill out the required information regarding controlled substances reclaimed and disposed, which would then be uploaded into the PMP Appriss AWARxE platform and connected to the decedent's record.

The containment section of the bill could create confusion regarding who has custody of a controlled substance. For example, as long as the administering provider had the controlled substance in a locked container, could they then take that container with them when they left the client-patient's home (especially if said client-patient did not have their own locked container)? There is a concern that this could potentially increase the risk for diversion.

Facilities, such as long-term care facilities, and Opioid Treatment Programs (OTPs) are already required to follow DEA regulations regarding disposal and take back of prescription medications. If this bill is intended only for services that take place in the home, defining the client-patient location may be helpful, otherwise this bill could cause confusion and/or conflict with current DEA diversion protocols and other regulations. As such, a definition for long-term care needs as well as in-home and community support services in this context could help to mitigate confusion as to what specific services are included in this bill.

This bill would require administering providers to develop written policies and submit them to the Department for compliance with this bill. Given that compliance would only be reviewed in accordance with this bill, there could be significant inconsistencies between providers and with DEA and other regulations.

According to the Maine Drug Death Report January – September, 2020, 26% of overdose fatalities mentioned pharmaceutical opioids, compared to remaining percentage of deaths caused by illicit, nonpharmaceutical causes or a combination of pharmaceutical and illicit,

nonpharmaceutical. Of the 26% of deaths caused by pharmaceutical opioids, almost all (96%) had at least one other substance mentioned as a cause of death.[1]

We wanted the Committee to be aware of the above information as it considers this bill moving forward. If you have any further questions, please feel free to contact me.

Sincerely,

Jessica Pollard, PhD, Director
Office of Behavioral Health

[1] Maine Drug Death Report January – September, 2020. Marcella H. Sorg, PhD.
https://www.maine.gov/tools/whatsnew/attach.php?id=3933388&an=1