VERMONT
DEPARTMENT OF HEALTH

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To: Representative Trevor Squirrell, Chair, Legislative Committee on Administrative Rules
From: Brendan Atwood, Policy Director, Vermont Department of Health
Re: Unused Drug Repository Program Rule
Date: June 19, 2024

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Following the filing of the Final Proposed Rule, the Department of Health made the following changes based on the recommendations received from the Legislative Counsel for the Legislative Committee on Administrative Rules:

1. Sec. 3.1 and Sec. 3.7 were updated to reference "long-term care facilities licensed under 33 V.S.A. chapter 71."
2. Sec. 3.8 was updated for clarity:
   "Drug" means both prescription and non-prescription (over-the-counter) drugs as defined in 26 V.S.A. § 2022(6), however, the term excludes compounded drugs in the context of Unused Drug Repositories.
3. Sec. 3.11 was updated to reference 18 V.S.A. § 4631a(15).
4. Sec. 4.10 was removed.
5. Sec. 8.3.2 was updated for clarity:
   "Is in unopened, tamper-evident packaging. A drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose or blister packaging, as applicable, remains intact;"
6. Sec. 8.3.5 was update to include reference to the FDA.
7. Sec. 8.3.8 was modified for clarity:
   "~~Is not subject to an FDA-managed risk evaluation and mitigation strategy (REMS) with an element to assure safe use, and/or an implementation system pursuant to 21 U.S.C. Section 355-1.~~ Is not subject to an FDA-managed risk evaluation and mitigation strategy (REMS) pursuant to 21 U.S.C. § 355-1 that includes an element to assure safe use and/or an implementation system.
8. Sec. 9.1 was updated to include reference to the appropriate subchapter.
9. Sec. 9.1.1 was updated to include "or."
10. Sec. 9.1.1 and 9.1.3 were updated to reference Title 18.



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