

Comparison of DRAFT Proposed Snohomish Secure Medicine Return Regulation for First Reading to King County Secure Medicine Return Regulations

05/02/2016

Section in Snohomish Draft Ordinance	Substantive Changes from King County Secure Medicine Return Regulations Section in King Co. BOH Code	Explanation
1. Findings 2. Codification instruction 3. Short title 4. Authority, purpose and scope	11.50.010 No significant differences. 11.50.020	Sections are tailored for each county's needs and practices.
5. Definitions	11.50.030 <u>Definitions added for:</u> "Authorized Collector"; "Drop-off Site"; "Long-term Care Facility"; and "Potential Authorized Collector" <u>Definition modified for:</u> "Covered Drugs" – modification explicitly includes vet drugs, drugs in medical devices or combination products, and pre-filled injector products with a retractable or otherwise securely covered needle. Modification in subpart f. clarifies exemption for injector products or medical devices that do not contain a covered drug or that contain no more than trace residues of a covered drug. <u>Definitions removed:</u> "Collector" and "Unincorporated community service area"	New definitions align with the DEA's 2014 Rule for Disposal of Controlled Substances, which was only available in draft form when King County regulation was developed. Other changes clarify intent and/or align to Snohomish County.
6. Stewardship plans – participation	11.50.040 <u>Timing of deadlines after Date of Adoption adjusted:</u> <i>2 months:</i> each medicine producer must notify SHD of their intent to participate in a stewardship plan; retailers with a store label drug must notify SHD that their manufacturer intends to participate. <i>4 months:</i> producers must notify SHD of name/contact for their stewardship plan operator. <i>4 months:</i> producers/stewardship organizations must notify all authorized collectors of opportunity to participate as collector. <i>6 months:</i> producers must submit a proposed stewardship plan for SHD review; <i>3 months after approval:</i> stewardship plan(s) must begin operations. 6 C modified to clarify timing of required notifications from producers who begin new sales of covered drugs in or into the county.	Implementation timeline is shortened given producers' experience with development of stewardship plans for King County and similar local ordinances in CA.

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	<p>D 2 modified to include in (2) a requirement on timing of good faith negotiations between interested potential authorized collectors and producers, and in (4) a requirement for documentation that authorized collectors have amended their registrations with DEA.</p> <p>Moved language from 11.50.120 A in King SMR law to subsection H stating that the Director may provide consultation/technical assistance to producers/stewardship organizations in development of their plan(s).</p>	<p>Modifications to 6 D facilitate timely recruitment of collectors and reflect DEA Regulation requirements for authorized collectors.</p>
<p>7. Stewardship plans – components</p>	<p>11.50.050 In 7 B, language added requiring explanation why an interested potential authorized collector was not included in a stewardship plan.</p> <p>In 7 G, language on goals changed from “education and promotion” to “public awareness”.</p>	<p>Modifications made to clarify intent and adjust language for new definitions.</p>
<p>8. Stewardship plans – collection of covered drugs</p>	<p>11.50.060 In 8 A and 8 D, modifications to utilize “authorized collectors” term appropriately and to include potential collection receptacles for residents of long-term care facilities.</p> <p>In 8 A, changed the phrase “in exchange for incentives or payments” to “in exchange for compensation”.</p> <p>In 8 D 2., “hospitals/clinics with on-site pharmacy” added to types of drop-off sites that producers must give preference to, and requires stewardship plans to accept as collectors, “any retail pharmacy, hospital/clinic with on-site pharmacy or any law enforcement agency willing voluntarily to participate...”</p> <p>In 8 E and F, modifications to 11.50.060 E in King SMR law to clarify acceptance of drugs at long-term care facilities per DEA Regulation. Split language on some secure drop box requirements into 8 F, and added new language on required contact information on the secure drop box.</p>	<p>Modifications made to clarify intent and adjust language for new definitions.</p> <p>Adjusted service convenience goal in 8D to include convenient drop-off sites at authorized hospitals/clinics.</p>
<p>9. Stewardship plans – promotion</p>	<p>11.50.070 In 9A 2 and 5, new requirements for education on Snohomish County Code that prohibits acceptance of pharmaceutical wastes at county solid waste disposal sites.</p> <p>In 9 A 6, survey of health practitioners must include veterinarians. Surveys to be conducted after first program year, and biennially thereafter.</p>	<p>Modifications clarify intent and adjust for Snohomish County, including aligning education with</p>

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	<p>In 9 B, clarification that coordination of educational activities if more than one stewardship plan is approved must include a single phone number and single website for consumer access to information.</p> <p>In 9 C, new provision that pharmacies selling medicines are encouraged to promote the medicine take-back program and must provide materials to customers upon request.</p> <p>In 9 D, adjusted requirements for local government promotion of the stewardship program for Snohomish County.</p>	<p>Snohomish County Code 7.41.050(7).</p> <p>Added requirement that pharmacies distribute program materials upon request by customers.</p>
10. Stewardship plans – disposal of covered drugs	11.50.080 No changes.	
11. Stewardship plans – administrative and operational costs and fees	11.50.090 In 11 A 8, language added that program promotion costs include costs of materials that pharmacies must provide to consumers upon request. Removed requirement in King County regulation that the local agency purchase secure drop boxes for the standard stewardship plan.	Adjusted language for Snohomish County.
12. Stewardship plans – reporting requirements	11.50.100 No substantive changes, only small wording clarifications.	
13. Stewardship plans – identification of producers of covered drugs	11.50.110 In 13 A, the requirement on wholesalers to provide a list of producers to the oversight agency is changed from a “must” in King County law to a must provide if requested by the Director. In 13 B, requirement is added that a potential producer must respond within 60 days of receipt of a letter of inquiry from the Director.	Modified these requirements to reflect improved availability of producer information.
14. Stewardship plans – review of proposed plans	11.50.120 In 14 A, language added to clarify process for stewardship plans to propose to be the standard plan or an independent plan; and to clarify how Director shall designate the standard plan if necessary. In 14 G, language added to clarify there will be a written public comment period on each stewardship plan, to further clarify the provision in 14 B.	Modified language to clarify intent and process.

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15. Stewardship plans – prior approval for change	11.50.130 15 D added to clarify timing of notifications to the Director when there are changes in contact information for plan operators or participating producers.	Modified to improve agency's ability to contact stewardship organizations and participating producers.
16. Stewardship plans – enforcement – penalties	11.50.140 Rewritten to reflect standard compliance and enforcement practices for Snohomish Health District.	Adjusted language for Snohomish County.
17. Stewardship plans – regulations, performance standards and report	11.50.150 Rewritten to reflect standard compliance and enforcement practices for Snohomish Health District, and to match modified language on plan goals in 7.	Adjusted language for Snohomish County.
18. Stewardship plans – plan review and annual operating fees	11.50.160 18 D on the fee schedule was modified to reflect standard practice for fees for service collected by Snohomish Health District.	Adjusted language for Snohomish County.
19. Severability 20. Effective date	No changes.	