



## KING COUNTY

1200 King County Courthouse  
516 Third Avenue  
Seattle, WA 98104

### Signature Report

June 21, 2013

R&R BOH13-03

Proposed No. BOH13-03.1

Sponsors

1 A RULE AND REGULATION relating to providing safe  
2 collection and disposal of unwanted drugs from residential  
3 sources through producer provided and funded product  
4 stewardship plans by amending R&R 66, Section 1 (part), as  
5 amended, and BOH 2.08.085, adding a new chapter to BOH  
6 Title 11, and prescribing penalties; enacted pursuant to RCW  
7 70.05.060, including the latest amendments or revisions  
8 thereto.

9 BE IT ADOPTED BY THE KING COUNTY BOARD OF HEALTH:

10 SECTION 1. Findings:

11 A. Residents of King County benefit from the authorized use of prescription and  
12 nonprescription, or over-the-counter, medicines. However abuse, fatal overdoses and  
13 poisonings from prescription and nonprescription medicines used in the home have  
14 emerged as an epidemic in recent years.

15 B. More people die from prescription medicines than from heroin and cocaine  
16 combined. Drug overdoses in King County have surpassed car crashes as a leading cause  
17 of preventable deaths, with the majority of overdoses involving prescription opiates.

18 C. Prescription and nonprescription medicines used in the home are the leading  
19 cause of poisonings reported to the Washington Poison Center, and preventable

poisonings from medicines have been rising rapidly, especially among children and seniors.

D. Unused, expired and leftover drugs that accumulate in homes increase risks of drug abuse, overdoses, and preventable poisonings. A system for the proper disposal of unneeded drugs is an element of a comprehensive strategy to prevent prescription drug abuse.

E. Flushing medicines down toilets and sinks is an inappropriate disposal practice because wastewater treatment facilities cannot effectively remove or degrade all pharmaceutical compounds. Trash disposal of medicines is an undesirable disposal option because trash cans are not secure and mixed pharmaceutical wastes are household hazardous wastes that should not be disposed of in the solid waste stream.

F. Medicine take-back programs provide secure collection and environmentally sound destruction of unwanted medicines to protect public health.

G. Voluntary medicine take-back programs in the county are insufficient to protect the public, so local action is warranted to reduce risks of abuse, overdoses and poisoning.

H. The Board of Health finds it in the interest of public health to establish a county-wide secure medicine return program providing equitable access for all of the county's residents that is financed and operated by drug producers selling medicines in or into King County for residential use. Although producers may not charge a specific point-of-sale or point-of-collection fee, the board does not otherwise intend to preclude producers from recouping the costs of their program through other means, including allocating costs to the prices of their covered drugs in King County.

43 I. The Board of Health approved the Local Hazardous Waste Management  
44 Program's plan, on April 15, 2010, which states support for product stewardship  
45 approaches for waste pharmaceuticals from residential sources. The plan states that  
46 product stewardship provides a means "to shift from a system focused on government-  
47 funded and ratepayer-financed waste disposal and diversion, to one that relies on  
48 producer responsibility in order to reduce public costs, increase accessibility to services,  
49 attain higher environmental benefits, and drive improvements in product design that  
50 promotes environmental sustainability."

51 J. Drug producers are well-positioned to efficiently develop and operate the  
52 medicine take-back system, working with other stakeholders such as pharmacies and law  
53 enforcement, within standards prescribed by the board to ensure safety and security of the  
54 system, and in compliance with pertinent federal and state laws, regulations, and  
55 guidelines.

56 K. The Board of Health encourages pharmacies, health care providers, health  
57 professionals, government agencies responsible for solid waste management, wastewater  
58 treatment and health and community organizations in the county to inform residents  
59 through all their standard communication methods about safe storage of medicines and  
60 the use of collection services for unwanted medicines provided through the drug  
61 producers' stewardship program.

62 SECTION 2. Sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 of  
63 this rule should constitute a new chapter on secure medicine return in BOH Title 11.

64        NEW SECTION. SECTION 3. Short title. This chapter may be cited and  
65 referred to, and shall be known as, the King County Board of Health Secure Medicine  
66 Return Regulations.

67        NEW SECTION. SECTION 4. Purpose and scope of chapter.

68        A. This chapter is enacted as an exercise of the Board of Health powers of King  
69 County to protect and preserve the public health, safety and welfare. Its provisions shall  
70 be liberally construed for the accomplishment of these purposes. This chapter governs  
71 the protection of human health and safety against the improper handling and disposal of  
72 leftover or expired medicines.

73        B. It is the intent of this chapter to place the obligation of complying with its  
74 requirements upon drug producers and other persons designated by this chapter within its  
75 scope, and any provision of or term used in this chapter is not intended to impose any  
76 duty whatsoever upon King County or any of its officers or employees, for whom the  
77 implementation or enforcement of this chapter shall be discretionary and not mandatory.

78        NEW SECTION. SECTION 5. Definitions. The definitions in this section apply  
79 throughout this chapter unless the context clearly requires otherwise.

80        A. "Collector" means a person that gathers unwanted covered drugs from covered  
81 entities for the purpose of collection, transportation and disposal.

82        B.1. "Covered drug" means a drug sold in any form and used by covered entities,  
83 including prescription, nonprescription, brand name and generic drugs.

84        2. "Covered drug" does not include:

85            a. vitamins or supplements;

86            b. herbal-based remedies and homeopathic drugs, products or remedies;

87 c. cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants or  
88 other personal care products that are regulated as both cosmetics and nonprescription  
89 drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9);

90 d. Drugs for which producers provide a pharmaceutical product stewardship or  
91 take-back program as part of a federal food and drug administration managed risk  
92 evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1);

93 e. Drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it  
94 exists on the effective date of this rule if the producer already provides a pharmaceutical  
95 product stewardship or take-back program;

96 f. Medical devices, their component parts or accessories, or a covered drug  
97 contained in or on medical devices or their component parts or accessories; and

98 g. Pet pesticide products contained in pet collars, powders, shampoos, topical  
99 applications, or other forms.

100 C. "Covered entities" means residents of King County, including individuals  
101 living in single and multiple family residences and other residential settings, and  
102 including other nonbusiness sources of prescription and nonprescription drugs that are  
103 unused, unwanted, disposed of or abandoned by residents as identified by the director.  
104 "Covered entities" does not include business generators of pharmaceutical waste, such as  
105 hospitals, clinics, doctor's offices, veterinarian clinics, pharmacies, or airport security and  
106 law enforcement drug seizures.

107 D. "Director" means the director of the Seattle-King County Department of  
108 Public Health or the director's duly authorized representative.

109 E. "Drug wholesaler" means a corporation, individual or other entity that buys  
110 drugs or devices for resale and distribution to corporations, individuals or entities other  
111 than consumers.

112 F. "Drugs" means:

113 1. Articles recognized in the official United States pharmacopoeia, the official  
114 national formulary, the official homeopathic pharmacopoeia of the United States or any  
115 supplement of the formulary or those pharmacopoeias as published by the U.S.

116 Pharmacopeial Convention and the Homeopathic Pharmacopoeia Convention of the  
117 United States;

118 2. Substances intended for use in the diagnosis, cure, mitigation, treatment or  
119 prevention of disease in humans or other animals;

120 3. Substances, other than food, intended to affect the structure or any function of  
121 the body of humans or other animals; or

122 4. Substances intended for use as a component of any substances specified in 1.,  
123 2. or 3. of this subsection, but not including medical devices, their component parts or  
124 accessories, or a covered drug contained in or on medical devices or their component  
125 parts or accessories.

126 G. "Independent stewardship plan" means a plan other than the standard  
127 stewardship plan for the collection, transportation and disposal of unwanted covered  
128 drugs that:

129 1. May be proposed by a producer or group of producers; and

130           2. If approved, is financed, developed and implemented by the participating  
131 producer or group of producers, and operated by the participating producer or group of  
132 producers or a stewardship organization.

133           H. "Local hazardous waste management program" means the King County local  
134 hazardous waste management program identified in BOH 2.08.080.

135           I. "Manufacture" means "manufacture" as defined in RCW 18.64.011 that is the  
136 production, preparation, propagation, compounding or processing of a drug or other  
137 substance or device or the packaging or repackaging of the substance or device, or the  
138 labeling or relabeling of the commercial container of such substance or device, but does  
139 not include the activities of a practitioner who, as an incident to his or her administration  
140 or dispensing such substance or device in the course of his or her professional practice,  
141 prepares, compounds, packages, or labels such substance or device.

142           J. "Manufacturer" means a person, corporation or other entity engaged in the  
143 manufacture of drugs or devices, as defined in RCW 18.64.011.

144           K. "Mail-back services" means a collection method for the return of unwanted  
145 covered drugs from covered entities utilizing prepaid and preaddressed mailing  
146 envelopes.

147           L. "Nonprescription drug" means a drug that may be lawfully sold without a  
148 prescription.

149           M. "Person" means a firm, sole proprietorship, corporation, limited liability  
150 company, general partnership, limited partnership, limited liability partnership,  
151 association, cooperative or other entity of any kind or nature.

152 N. "Pharmacy" means a place licensed by the state of Washington board of  
153 pharmacy where the practice of pharmacy, as defined in RCW 18.64.011, is conducted.

154 O. "Prescription drug" means any drugs, including controlled substances, that are  
155 required by an applicable federal or state law or regulation to be dispensed by  
156 prescription only or are restricted to use by practitioners only.

157 P. "Producer" means a manufacturer that is engaged in the manufacture of a  
158 covered drug sold in or into King County, including a brand-name or generic drug.

159 "Producer" does not include:

160 1. A retailer whose store label appears on a covered drug or the drug's  
161 packaging if the manufacturer from whom the retailer obtains the drug is identified under  
162 section 6.C. of this rule;

163 2. A pharmacist who compounds a prescribed individual drug product for a  
164 consumer; or

165 3. A wholesaler who is not also a manufacturer.

166 Q. "Retail pharmacy" means a pharmacy licensed by the state of Washington  
167 board of pharmacy for retail sale and dispensing of drugs.

168 R. "Standard stewardship plan" means the plan for the collection, transportation  
169 and disposal of unwanted covered drugs that is:

170 1. Financed, developed, implemented and participated in by producers;  
171 2. Operated by the participating producers or a stewardship organization; and  
172 3. Approved as the standard stewardship plan.

173           S. "Stewardship organization" means an organization designated by a producer or  
174 group of producers to act as an agent on behalf of each producer to develop and  
175 implement and operate the standard stewardship plan or an independent stewardship plan.

176           T. "Unincorporated community service area" means any of the areas established  
177 under King County Ordinances 17139 and 17415.

178           U. "Unwanted covered drug" means any covered drug no longer wanted by its  
179 owner, that:

- 180               1. Has been abandoned or discarded; or
- 181               2. Is intended to be discarded by its owner.

182           NEW SECTION. SECTION 6. Stewardship plans - participation.

183           A. Each producer shall participate in the standard stewardship plan approved by  
184 the director, except that a producer may individually, or with a group of producers, form  
185 and participate in an independent stewardship plan if approved by the director.

186           B. The standard stewardship plan and any independent stewardship plan shall be  
187 approved by the director before collecting unwanted covered drugs. Once approved,  
188 stewardship plans must have prior written approval of the director for proposed changes  
189 as described under section 15 of this rule.

190           C. By six months after the date of adoption of this rule, or by six months after a  
191 producer initiates sale of a covered drug in or into King County, a producer shall notify  
192 the director in writing of the producer's intent to participate in the standard stewardship  
193 plan or to form and participate in an independent stewardship plan. A retailer whose  
194 store label appears on a covered drug or the drug's packaging must notify the director of

195 intent to participate or provide written notification that the manufacturer from whom the  
196 retailer obtains the drug has provided its notice of intent to participate.

197 D. A producer or group of producers participating in the standard stewardship  
198 plan or an independent stewardship plan shall:

199 1. By nine months after this rule is adopted, identify in writing to the director a  
200 plan operator, including the plan operator's telephone, mailing address and email contact  
201 information, who is authorized to be the official point of contact for the stewardship plan;

202 2.a. By nine months after this rule is adopted, notify all retail pharmacies and  
203 law enforcement agencies in the county of the opportunity to participate as a drop-off site  
204 in accordance with section 8.A. and E. of this rule, and provide a process for forming an  
205 agreement between the plan and interested collectors; and

206 b. annually thereafter, make the same notification to any nonparticipating or  
207 new retail pharmacies or law enforcement agencies in the county;

208 3. By one year after this rule is adopted, submit a proposed stewardship plan as  
209 described in section 7 of this rule to the director for review;

210 4. Within three months after the director's approval of the stewardship plan,  
211 operate or participate in a stewardship plan in accordance with this chapter;

212 5. At least every four years after each plan initiates operations, submit an  
213 updated plan to the director explaining any substantive changes to components of the  
214 stewardship plan required in section 7 of this rule, and accompanied by the review fee in  
215 accordance with section 18 of this rule. The director shall review updated stewardship  
216 plans using the process described in section 14 of this rule; and

217           6. Pay all administrative and operational costs and fees associated with their  
218       stewardship plan as required under sections 11 and 18 of this rule.

219           E. A producer or group of producers participating in the standard stewardship  
220       plan or an independent stewardship plan may:

221           1. Enter into contracts and agreements with stewardship organizations, other  
222       service providers, or other entities as necessary, useful or convenient to provide all or  
223       portions of their stewardship plan;

224           2. Notify the director of any producer selling covered drugs in or into the county  
225       that is failing to participate in a stewardship plan; and

226           3. Perform any other functions as may be necessary or proper to provide the  
227       stewardship plan and to fulfill any or all of the purposes for which the plan is organized.

228           F. After the first full year of operation of the approved standard stewardship plan,  
229       a producer or group of producers participating in the standard stewardship plan may  
230       notify the director in writing of intent to form an independent stewardship plan, and  
231       identify a plan operator, including the plan operator's telephone, mailing address and  
232       email contact information, who is authorized to be the official point of contact for the  
233       proposed independent stewardship plan. Within three months of such notification, the  
234       producer or group of producers may submit a proposed independent stewardship plan as  
235       described under section 7 of this rule to the director for review.

236           G. The director may approve in writing extensions to later dates for the  
237       submission dates and deadlines in this section.

238           H. After presenting official credentials and providing notice of an audit or  
239       inspection to determine compliance with this chapter or to investigate a complaint, the

240 director may audit a producer's, group of producers' or stewardship organization's records  
241 related to a stewardship plan or request that the producer, group of producers or  
242 stewardship organization arrange for the director to inspect at reasonable times a  
243 stewardship plan's or a collector's facilities, vehicles and equipment used in carrying out  
244 the stewardship plan.

245 NEW SECTION. SECTION 7. Stewardship plans - components. The standard  
246 stewardship plan or any independent stewardship plan, which must be submitted and  
247 reviewed according to section 14 of this rule, shall include:

248 A. Contact information for all drug producers participating in the stewardship  
249 plan;

250 B. A description of the proposed collection system to provide convenient  
251 ongoing collection service for all unwanted covered drugs from covered entities in  
252 compliance with the provisions and requirements in section 8 of this rule, including a list  
253 of all collection methods and participating collectors, a list of drop-off locations, a  
254 description of how periodic collection events will be scheduled and located if applicable,  
255 a description of how mail-back services will be provided and an example of the prepaid,  
256 preaddressed mailers to be utilized. The description shall include a list of retail  
257 pharmacies and law enforcement agencies contacted by the plan under section 6.D.2. of  
258 this rule, and a list of all collectors who offered to participate;

259 C. A description of the handling and disposal system, including identification of  
260 and contact information for collectors, transporters and waste disposal facilities to be  
261 used by the stewardship plan in accordance with sections 8 and 10 of this rule;

262 D. A description of the policies and procedures to be followed by persons  
263 handling unwanted covered drugs collected under the stewardship plan, including a  
264 description of how all collectors, transporters and waste disposal facilities utilized will  
265 ensure the collected, unwanted covered drugs are safely and securely tracked from  
266 collection through final disposal, and how all entities participating in the stewardship  
267 plan will operate under all applicable federal and state laws, rules and guidelines,  
268 including those of the United States Drug Enforcement Administration, and how any  
269 pharmacy collection site will operate under applicable rules and guidelines of the state of  
270 Washington Board of Pharmacy;

271 E. A description of how patient information on drug packaging will be kept  
272 secure during: collection; transportation; and recycling or disposal;

273 F. A description of the public education effort and promotion strategy required in  
274 section 9 of this rule, including a copy of standardized instructions for residents, signage  
275 developed for collectors and required promotional materials;

276 G. A proposal on the short-term and long-term goals of the stewardship plan for  
277 collection amounts, education and promotion; and

278 H. A description of how the stewardship plan will consider:

- 279 1. Use of existing providers of waste pharmaceutical services;
- 280 2. Separating covered drugs from packaging to the extent possible to reduce  
281 transportation and disposal costs; and
- 282 3. Recycling of drug packaging to the extent feasible.

283 NEW SECTION. SECTION 8. Stewardship plans - collection of covered  
284 drugs.

285           A. This chapter does not require any person to serve as a collector in a  
286       stewardship plan. A person may offer to serve as a collector voluntarily, or may agree to  
287       serve as a collector in exchange for incentives or payment offered by a producer, group of  
288       producers or stewardship organization. Collectors may include law enforcement,  
289       pharmacies, mail-back services or other entities, operating in accordance with state and  
290       federal laws and regulations for the handling of covered drugs, including those of the  
291       United States Drug Enforcement Administration, and in compliance with this chapter. A  
292       pharmacy collection site shall operate under applicable rules and guidelines of the state of  
293       Washington Board of Pharmacy.

294           B. The collection system shall be convenient on an ongoing, year-round basis to  
295       adequately serve the needs of covered entities and shall be designed in consideration of  
296       equitable opportunities for all King County residents for the safe and convenient return of  
297       unwanted covered drugs, in accordance with this section.

298           C. The collection system for all unwanted covered drugs shall be safe and secure,  
299       including protection of patient information on drug packaging.

300           D.1. The service convenience goal for the standard stewardship plan and any  
301       independent stewardship plan is a system of drop-off sites distributed to provide  
302       reasonably convenient and equitable access for all residents in incorporated and  
303       unincorporated areas of the county.

304           2. In establishing and operating a stewardship plan, a producer, group of  
305       producers or stewardship organization shall give preference to having retail pharmacies  
306       and law enforcement agencies serve as drop-off sites. A stewardship plan shall include,  
307       as collectors, any retail pharmacy or any law enforcement agency willing voluntarily to

308 serve as a drop-off site for unwanted covered drugs and able to meet the requirements of  
309 this chapter within three months of their offer to participate, unless the collector requests  
310 a longer time frame. A producer or group of producers establishing and operating a  
311 stewardship plan may also accept other collectors willing to serve as a drop-off site for  
312 unwanted covered drugs and able to meet the requirements of this chapter.

313           3. The system of drop-off sites shall provide in every city, town, or  
314 unincorporated community service area with a pharmacy or law enforcement facility, one  
315 drop-off site and a minimum of at least one additional drop-off site for every thirty  
316 thousand residents, geographically distributed to provide reasonably convenient and  
317 equitable access.

318           4. If the service convenience goal in 3. of this subsection cannot be achieved by  
319 the standard stewardship plan or any independent stewardship plan due to a lack of drop-  
320 off sites at pharmacies, law enforcement agencies or other qualified collectors in specific  
321 areas of the county, then those areas shall be served through periodic collection events or  
322 mail-back services, or a combination of these collection methods.

323           E. Drop-off sites shall accept covered drugs from covered entities during all  
324 hours that the retail pharmacy, law enforcement agency, or other collector is normally  
325 open for business with the public. Drop-off sites shall utilize secure drop boxes in  
326 compliance with all applicable requirements of the United States Drug Enforcement  
327 Administration and the state of Washington Board of Pharmacy.

328           F. Mail-back services shall be free of charge, and shall be made available to  
329 differentially-abled and home bound residents upon request through the stewardship  
330 plan's toll-free telephone number and web site, and through distribution of prepaid,

preaddressed mailers to persons providing services to such residents, and may also be utilized as a collection method according to subsection D.4. of this section.

G. Periodic collection events, if utilized as a collection method according to subsection D.4. of this section, must be arranged with law enforcement personnel through voluntary agreements, and shall be conducted in compliance with United States Drug Enforcement Administration protocols, any additional requirements of participating law enforcement agencies, and in compliance with this chapter.

**NEW SECTION. SECTION 9. Stewardship plans - promotion.**

A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall:

1. Promote the use of their stewardship plan so that collection options for covered drugs are widely understood by residents, pharmacists, retailers of covered drugs and health care practitioners including doctors and other prescribers, and promote the safe storage of covered drugs by residents before secure disposal through their stewardship plan;

2. Work with collectors participating in their stewardship plan to develop clear, standardized instructions for residents on the use of drop boxes and a readily recognizable, consistent design of drop boxes. The local hazardous waste management program may provide guidance to producers and collectors on the development of the instructions and design;

3. Establish a toll-free telephone number and web site where collection options and current locations of drop-off sites will be publicized and prepare educational and outreach materials promoting safe storage of medicines and describing where and how to

354 return unwanted covered drugs to the stewardship plan. These materials must be  
355 provided to pharmacies, health care facilities and other interested parties for  
356 dissemination to residents. Plain language and explanatory images should be utilized to  
357 make use of medicine collection services readily understandable by all residents,  
358 including individuals with limited English proficiency. A producer or group of producers  
359 participating in the standard stewardship plan or any independent stewardship plan shall  
360 coordinate these promotional activities to ensure that residents can easily identify,  
361 understand and access the collection services provided by any stewardship plan;

362 4. Annually evaluate the effectiveness of its outreach and stewardship plan  
363 activities; and

364 5. Conduct a survey of residents of King County and a survey of pharmacists  
365 and health professionals in the county who interact with patients on use of medicines  
366 after the first full year of operation of the plan, and again after five and nine years of  
367 operation. Survey questions shall measure percent awareness of the stewardship plan,  
368 assess to what extent drop-off sites and other collection methods are convenient and easy  
369 to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses  
370 from prescription and nonprescription medicines used in the home. Draft survey  
371 questions shall be submitted to the director for review and comment at least thirty days  
372 prior to initiation of the survey. Results of the survey shall be reported to the director and  
373 made available to the public on the stewardship plan's website.

374 B. The local hazardous waste management program shall:

375 1. Promote the use of stewardship plans and the plans' toll-free telephone  
376 numbers and web sites through their standard educational methods;

377           2. Provide sample educational materials for use by pharmacies, law enforcement  
378 agencies, health care providers and local government agencies in the county;

379           3. Conduct educational outreach to targeted populations and groups as informed  
380 by survey results and other research indicators; and

381           4. Assume the costs of developing and providing promotional and educational  
382 materials under this subsection.

383           NEW SECTION. SECTION 10. Stewardship plans - disposal of covered  
384 **drugs.**

385           A. Covered drugs collected under a stewardship plan must be disposed of at a  
386 permitted hazardous waste disposal facility as defined by the United States  
387 Environmental Protection Agency under 40 CFR parts 264 and 265.

388           B. The director may grant approval for a producer or group of producers  
389 participating in the standard stewardship plan or an independent stewardship plan to  
390 dispose of some or all collected covered drugs at a permitted large municipal waste  
391 combustor, as defined by the United States environmental protection agency under 40  
392 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility described under  
393 subsection A. of this section is deemed not feasible for the stewardship plan based on  
394 cost, logistics or other considerations.

395           C. A producer or group of producers participating in the standard stewardship  
396 plan or an independent stewardship plan may petition the director for approval to use  
397 final disposal technologies that provide superior environmental and human health  
398 protection than provided by the disposal technologies in subsections A. and B. of this

section, or equivalent protection at lesser cost. The proposed technology must provide equivalent or superior protection in each of the following areas:

1. Monitoring of any emissions or waste;
2. Worker health and safety;
3. Air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and
4. Overall impact to the environment and human health.

**NEW SECTION. SECTION 11. Stewardship plans - administrative and operational costs and fees.**

A. A producer or group of producers participating in the standard stewardship plan or an independent stewardship plan shall pay all administrative and operational costs related to their stewardship plan, except as provided under this section. Administrative and operational costs related to the stewardship plan include:

1. Collection and transportation supplies for each drop-off site;
2. Purchase of all secure drop boxes for drop-off sites in any independent stewardship plan;
3. Purchase of additional secure drop boxes needed for drop-off sites in the standard stewardship plan beyond the four hundred provided under subsection B. of this section;
4. Ongoing maintenance or replacement of secure drop boxes, as requested by collectors;
5. Prepaid, preaddressed mailers provided to differentially-abled and home bound residents, and to specific areas of the county if utilized;

422 6. Operating periodic collection events if utilized, including costs of law  
423 enforcement staff time if necessary;

424 7. Transportation of all collected pharmaceuticals to final disposal, including  
425 costs of law enforcement escort if necessary;

426 8. Environmentally sound disposal of all collected pharmaceuticals under  
427 section 10 of this rule; and

428 9. Program promotion under section 9 of this rule.

429 B. The local hazardous waste management program shall ensure the provision of  
430 up to four hundred secure drop boxes for retail pharmacies and law enforcement agencies  
431 willing to participate as drop-off sites for the standard stewardship plan. Collectors who  
432 leave the standard stewardship plan for any reason are encouraged to donate the secure  
433 drop box to the standard stewardship plan. Producers participating in the standard  
434 stewardship plan shall retrieve drop boxes from collectors as requested.

435 C. No person or producer may charge a specific point-of-sale fee to consumers to  
436 recoup the costs of their stewardship plan, nor may they charge a specific point-of-  
437 collection fee at the time the covered drugs are collected from covered entities.

438 D. Producers are not required to pay for costs of staff time at drop-off sites  
439 provided by collectors volunteering for a stewardship plan.

440 NEW SECTION. SECTION 12. Stewardship plans - reporting requirements.

441 A. Within six months after the end of the first twelve-month period of operation,  
442 and annually thereafter, the plan operator of the standard stewardship plan and of any  
443 independent stewardship plan shall submit a report to the director on behalf of

444 participating producers describing their plan's activities during the previous reporting  
445 period to comply with this chapter. The report must include:

- 446 1. A list of producers participating in the stewardship plan;
- 447 2. The amount, by weight, of unwanted covered drugs collected, including the  
448 amount by weight from each collection method used;
- 449 3. A list of drop-off locations, the number of mailers provided for differentially-  
450 abled and home bound residents, locations where mailers were provided, if applicable,  
451 dates and locations of collection events held, if applicable, transporters used and the  
452 disposal facility or facilities used;
- 453 4. Whether any safety or security problems occurred during collection,  
454 transportation or disposal of unwanted covered drugs during the reporting period and, if  
455 so, what changes have or will be made to policies, procedures or tracking mechanisms to  
456 alleviate the problem and to improve safety and security in the future;
- 457 5. A description of the public education, outreach and evaluation activities  
458 implemented during the reporting period;
- 459 6. A description of how collected packaging was recycled to the extent feasible,  
460 including the recycling facility or facilities used;
- 461 7. A summary of the stewardship plan's goals, the degree of success in meeting  
462 those goals in the past year and, if any goals have not been met, what effort will be made  
463 to achieve the goals in the next year; and
- 464 8. The total expenditure of the stewardship plan during the reporting period.

465 B. The director shall make reports submitted under this section available to the  
466 public.

467 C. For the purposes of this section, "reporting period" means the period from  
468 January 1 through December 31 of the same calendar year, unless otherwise specified to  
469 the plan operator by the director.

470 NEW SECTION. SECTION 13. **Stewardship plans -lists of producers of**  
471 **covered drugs.** Beginning sixty days after the date of adoption of this rule, each drug  
472 wholesaler that sells any covered drug in or into the county must provide a list of  
473 producers of covered drugs to the local hazardous waste management program in a form  
474 agreed upon with the director. Wholesalers must update the list by January 15 each year.

475 NEW SECTION. SECTION 14. **Stewardship plans - review of proposed**  
476 **plans.**

477 A. By one year after the date of adoption of this rule, a producer, group of  
478 producers or stewardship organization participating in the standard stewardship plan or  
479 any independent stewardship plan shall submit its proposed stewardship plan to the  
480 director for review, accompanied by the plan review fee in accordance with section 18 of  
481 this rule. The director may upon request provide consultation and technical assistance  
482 about the requirements of this chapter to assist a producer, group of producers or  
483 stewardship organization in developing its proposed plan.

484 B. The director shall review the proposed stewardship plan and determine  
485 whether the proposed plan meets the requirements of section 7 of this rule and other  
486 applicable sections of this rule. In reviewing a proposed stewardship plan, the director  
487 shall provide opportunity for written public comment and consider any comments  
488 received.

489 C. After the review under subsection B. of this section and within ninety days  
490 after receipt of the proposed stewardship plan, the director shall either approve or reject  
491 the proposed stewardship plan in writing to a producer, group of producers or  
492 stewardship organization and, if rejected, provide reasons for rejection.

493 D. If the proposed stewardship plan is rejected, a producer, group of producers or  
494 stewardship organization must submit a revised stewardship plan to the director within  
495 sixty days after receiving written notice of the rejection. The director shall review and  
496 approve or reject a revised stewardship plan as provided under subsections B. and C. of  
497 this section.

498 E.1. If the director rejects a revised stewardship plan, or any subsequently revised  
499 plan, the director shall deem the producer or group of producers out of compliance with  
500 this chapter and subject to the enforcement provisions in this chapter.

501 2. If the revised standard stewardship plan is rejected, the director may, in the  
502 director's discretion, require the submission of a further revised standard stewardship plan  
503 or develop and impose changes to some or all components of the rejected plan to  
504 constitute an approved standard stewardship plan. If the director imposes some or all of  
505 the approved plan, the director may not deem the producers participating in and  
506 complying with the approved standard stewardship plan in accordance with this chapter  
507 out of compliance with this chapter.

508 3. If a revised independent stewardship plan is rejected, the producer or group of  
509 producers submitting the independent stewardship plan shall participate in the standard  
510 stewardship plan and are not eligible to propose an independent stewardship plan for six  
511 months after the rejection. The director may not deem out of compliance with this

chapter a producer whose revised independent stewardship plan is rejected if the producer participates in and complies with the standard stewardship plan.

F. In approving a proposed stewardship plan, the director may exercise reasonable discretion to waive strict compliance with the requirements of this chapter that apply to producers in order to achieve the objectives of this chapter.

G. The director shall make all stewardship plans submitted under this section available to the public.

**NEW SECTION. SECTION 15. Stewardship plans - prior approval for change.**

A. Proposed changes to an approved stewardship plan that substantively alter plan operations, including, but not limited to, changes to participating manufacturers, collection methods, achievement of the service convenience goal, policies and procedures for handling covered drugs, education and promotion methods or disposal facilities, must have prior written approval of the director.

B. A producer or group of producers participating in the standard stewardship plan or any independent stewardship plan shall submit to the director any proposed change to a stewardship plan as described under subsection A. of this section in writing at least thirty days before the change is scheduled to occur and accompanied by the review fee in accordance with section 18 of this rule.

C. The plan operator of an approved stewardship plan shall notify the director at least fifteen days before implementing any changes to drop-off site locations, methods for scheduling and locating periodic collection events or methods for distributing prepaid, preaddressed mailers, that do not substantively alter achievement of the service

convenience goal under section 8.D. of this rule, or other changes that do not substantively alter plan operations under subsection A. of this section.

**NEW SECTION. SECTION 16. Stewardship plans - enforcement - penalties.**

A. The director shall send a written warning and a copy of this chapter and any rules adopted to implement this chapter to a producer who is not participating in the standard stewardship plan or an independent stewardship plan as required under this chapter. The warning shall state that participation in a plan is required and warn of penalties for noncompliance.

B. A producer not participating in the standard stewardship plan or an independent stewardship plan and whose covered drug continues to be sold in or into the county sixty days after receiving a written warning from the director may be assessed a penalty under subsections D. and E. of this section.

C. If the director determines that a stewardship plan is not in compliance with this chapter or its plan approved under section 14 of this rule, the director may send the producer or group of producers participating in the plan a written warning stating the plan is in noncompliance, providing notice of the compliance requirements and warning of penalties for noncompliance. The producer or group of producers has thirty days after receipt of the notice to achieve compliance. If the stewardship plan is not in compliance after thirty days, the director may assess a penalty under subsections D. and E. of this section. This subsection does not preclude the director from suspending an approved plan if a violation of this chapter or an approved plan creates a condition that, in the director's judgment, constitutes an immediate hazard.

557           D. A violation of this chapter is subject to a civil penalty of up to two thousand  
558 dollars and may be assessed against a producer or group of producers. Each day upon  
559 which a violation occurs or is permitted to continue constitutes a separate violation. In  
560 determining the appropriate penalty, the director shall consider the extent of harm caused  
561 by the violation, the nature and persistence of the violation, the frequency of past  
562 violations, any action taken to mitigate the violation, the financial burden to the violator  
563 and the size of the violator's business.

564           E. The director may utilize BOH chapter 1.08 to assess civil penalties provided in  
565 this section. A producer or group of producers may appeal assessments imposed under  
566 this section as provided in BOH chapter 1.08. In addition to or as an alternative to  
567 utilizing the procedures in BOH chapter 1.08, the director may assess or recover penalties  
568 accruing under this section by legal action filed in King County superior court.

569           F. The director may utilize BOH chapter 1.08 to assess civil penalties as provided  
570 in that chapter against a wholesaler who is in violation of section 13 of this rule.

571           NEW SECTION. SECTION 17. Stewardship plans - rules, performance  
572 **standards and report.**

573           A. The director may adopt rules necessary to implement, administer and enforce  
574 this chapter.

575           B. The director may work with the plan operator to define goals for collection  
576 amounts, education, and promotion for a stewardship plan.

577           C. The director shall report annually to the King County Board of Health  
578 concerning the status of the standard and independent stewardship plans and  
579 recommendations for changes to this chapter. The annual report shall include an

580 evaluation of the secure medicine return system, a summary of available data on  
581 indicators and trends of abuse, poisonings and overdoses from prescription and  
582 nonprescription drugs and a review of comprehensive prevention strategies to reduce  
583 risks of drug abuse, overdoses and preventable poisonings.

584 **NEW SECTION. SECTION 18. Plan review and annual operating fees.**

585 A. A producer or group of producers participating in the standard stewardship  
586 plan or an independent stewardship plan shall pay to the director plan review fees to be  
587 established under subsection D. of this section for:

- 588 1. Review of a proposed stewardship plan;
- 589 2. Resubmittal of a proposed stewardship plan;
- 590 3. Review of changes to an approved stewardship plan;
- 591 4. Submittal of an updated stewardship plan at least every four years under  
592 section 6.D.5. of this rule; or
- 593 5. Review of any petition for approval to use alternative final disposal  
594 technologies under section 10.C. of this rule.

595 B. In addition to plan review fees, a producer or group of producers participating  
596 in the standard stewardship plan or an independent stewardship plan shall pay to the  
597 director annual operating fees to be established under subsection D. of this section.

598 C. A plan operator or a stewardship organization may remit the fee on behalf of  
599 participating producers.

600 D. As soon as practicable, the director shall propose to the Board of Health a  
601 schedule of fees to be adopted by rule and charged to a producer or group of producers to

cover costs of administering and enforcing this chapter. Fees shall be calculated to recover actual costs.

SECTION 19. R&R 66, Section 1 (part), as amended, and BOH 2.08.085 are each hereby amended to read as follows:

**Powers of the committee.**

A.1. The committee shall be responsible for accepting and recommending a management plan and budget for:

a. the reduction of moderate risk waste generation, its entry into the solid waste stream, entry into the liquid waste (sewage) stream, into storm drainage or surface waters and evaporation into the air; and

b. the protection and enhancement of the public health and environmental quality in King County by the reduction of the threat posed by the production, use, storage and disposal of hazardous materials.

2. The management coordination committee (~~((will))~~) shall develop an annual plan and budget and reach agreement on it through consensus of the entire committee. Lacking a consensus, a majority and a minority report will be forwarded to the King County Board of Health.

B. The committee shall recommend contracts with the city of Seattle, suburban cities, sewer districts(~~((;))~~) or other governments or entities located entirely or partially within King County, and King County, to implement portions of the management plan, in consideration of sums collected under BOH 2.08.090.

C. The committee shall develop an annual plan and budget for implementation of BOH chapter 11. (the chapter established under section 2 of this rule) and reach

625 agreement on it through consensus of the entire committee. Lacking a consensus, a  
626 majority and a minority report shall be forwarded to the King County Board of Health.  
627 The committee shall recommend contracts or interagency agreements to implement  
628 portions of the plan.

629       SECTION 20. Severability. If any provision of this rule or its application to any

630 person or circumstance is held invalid, the remainder of the rule or the application of the  
631 provision to other persons or circumstances is not affected.  
632

R&R BOH13-03 was introduced on and passed by the Board of Health on 6/20/2013,  
by the following vote:

Yes: 11 - Ms. Frisinger, Mr. Conlin, Ms. Patterson, Ms. Lambert, Mr.  
Licata, Dr. Baker, Dr. Danielson and Mr. McDermott

No: 0

Excused: 2 - Ms. Clark and Dr. Nicola

BOARD OF HEALTH  
KING COUNTY, WASHINGTON



Joe McDermott, Chair

ATTEST:



Anne Noris, Clerk of the Board

**Attachments:** None