



KING COUNTY
Signature Report

1200 King County Courthouse
516 Third Avenue
Seattle, WA 98104

June 5, 2013

R&R

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

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

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

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

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

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

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

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

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

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

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

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

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

351 3. Establish a toll-free telephone number and web site where collection options
352 and current locations of drop-off sites will be publicized and prepare educational and
353 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

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

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

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

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

- 412 1. Collection and transportation supplies for each drop-off site;
- 413 2. Purchase of all secure drop boxes for drop-off sites in any independent
414 stewardship plan;
- 415 3. Purchase of additional secure drop boxes needed for drop-off sites in the
416 standard stewardship plan beyond the four hundred provided under subsection B. of this
417 section;
- 418 4. Ongoing maintenance or replacement of secure drop boxes, as requested by
419 collectors;
- 420 5. Prepaid, preaddressed mailers provided to differentially-abled and home
421 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

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

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

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

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

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

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

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

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

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

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

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

547 C. If the director determines that a stewardship plan is not in compliance with
548 this chapter or its plan approved under section 14 of this rule, the director may send the
549 producer or group of producers participating in the plan a written warning stating the plan
550 is in noncompliance, providing notice of the compliance requirements and warning of
551 penalties for noncompliance. The producer or group of producers has thirty days after
552 receipt of the notice to achieve compliance. If the stewardship plan is not in compliance
553 after thirty days, the director may assess a penalty under subsections D. and E. of this
554 section. This subsection does not preclude the director from suspending an approved
555 plan if a violation of this chapter or an approved plan creates a condition that, in the
556 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

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

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

606 **Powers of the committee.**

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

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

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

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

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

623 C. The committee shall develop an annual plan and budget for implementation of
624 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

KING COUNTY BOARD OF HEALTH
KING COUNTY, WASHINGTON

Joe McDermott, Chair

ATTEST:

Anne Noris, Clerk of the Board

Attachments: None