

1 *These proposed rules repeal OAR 855-043-0110 thru 0130 AND OAR 855-043-0300 thru 0310 and adopt*
2 *a new section of rules to combine the County Health and Family Planning drug outlet registrations into a*
3 *single "Community Health Clinic Drug Outlet" with rules beginning at 855-043-0700.*
4

5 **County Health Clinics**

6 **855-043-0110**

7 **Purpose and Scope**

8 ~~(1) A Registered Nurse who is licensed with the Oregon State Board of Nursing, and who is an~~
9 ~~employee of a local health department established under the authority of a county or district~~
10 ~~board of health may dispense a drug or device to a client of the health department for purposes of~~
11 ~~earies prevention, birth control, or prevention or treatment of a communicable disease.~~

12 ~~(2) Such dispensing shall be pursuant to the order of a person authorized to prescribe a drug or~~
13 ~~device, and shall be subject to rules jointly adopted by the Board and DHS.~~

14 ~~Stat. Auth.: ORS 689.205~~

15 ~~Stats. Implemented: ORS 689.155~~
16

17 **855-043-0130**

18 **Drug Delivery and Control**

19 ~~(1) The health officer is responsible for the establishment of policies and procedures that include:~~

20 ~~(a) Procedures for drug dispensing, storage, security, and accountability;~~

21 ~~(b) Maintenance of all drug records required by federal and state law;~~

22 ~~(c) Procedures for procurement of drugs.~~

23 ~~(2) Dispensing:~~

24 ~~(a) A drug may only be dispensed by a practitioner who has been given dispensing privileges by~~
25 ~~their licensing board or by a Registered Nurse;~~

26 ~~(b) A drug must be dispensed in a container complying with the federal Poison Prevention~~
27 ~~Packaging Act unless the patient requests a non-complying container;~~

28 ~~(c) A Registered Nurses may only dispense a drug listed in, or for a condition listed in, the~~
29 ~~formulary;~~

30 ~~(d) Each drug that is dispensed must be labeled with the following information:~~

- 31 ~~(A) Name of patient;~~
- 32 ~~(B) Name of prescriber;~~
- 33 ~~(C) Name, address, and phone number of the clinic;~~
- 34 ~~(D) Date of dispensing;~~
- 35 ~~(E) Name and strength of the drug. If the drug does not have a brand name, then the generic~~
36 ~~name of the drug and the drug manufacturer must be stated;~~
- 37 ~~(F) Directions for use;~~
- 38 ~~(G) Initials of the person dispensing;~~
- 39 ~~(H) Cautionary statements, if any, as required by law;~~
- 40 ~~(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should~~
41 ~~not use the drug.~~
- 42 ~~(e) A drug information fact sheet must accompany each drug dispensed from a county health~~
43 ~~clinic.~~
- 44 ~~(3) Repackaged Drugs. A drug repackaged for dispensing must be in a container meeting USP~~
45 ~~standards and labeled to identify at a minimum:~~
- 46 ~~(a) Brand name, or generic name and manufacturer;~~
- 47 ~~(b) Strength;~~
- 48 ~~(c) Lot number;~~
- 49 ~~(d) Manufacturer's expiration date or an earlier date if preferable. An internal control number~~
50 ~~which references manufacturer and lot number may be used.~~
- 51 ~~(4) Drug Security, Storage, and Disposal:~~
- 52 ~~(a) In the absence of a dispensing practitioner or a Registered Nurse, drugs must be kept in a~~
53 ~~locked drug cabinet or drug room which is sufficiently secure to deny access to unauthorized~~
54 ~~persons. Only dispensing practitioners and Registered Nurses may have a key to the drug cabinet~~
55 ~~or drug room. In their absence, the drug cabinet or drug room must remain locked.~~
- 56 ~~(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light,~~
57 ~~ventilation and moisture control as recommended by the manufacturer.~~

58 ~~(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be~~
59 ~~quarantined and physically separated from other drugs until they are destroyed or returned to~~
60 ~~their supplier.~~

61 ~~(5) Drug Records;~~

62 ~~(a) A dispensing record must be maintained separately from the patient chart and kept for a~~
63 ~~minimum of three years. The record must show, at a minimum, the following:~~

64 ~~(A) Name of patient;~~

65 ~~(B) Brand name of drug, or generic name and name of manufacturer or distributor;~~

66 ~~(C) Date;~~

67 ~~(D) Initials of person dispensing the prescription.~~

68 ~~(b) All records of receipt and disposal of drugs must be kept for a minimum of three years;~~

69 ~~(c) All records required by these rules or by federal and state law must be readily retrievable and~~
70 ~~available for inspection by the Board.~~

71 ~~(6) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice~~
72 ~~of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from~~
73 ~~the label, the patient's name may be omitted from the records and a drug may be dispensed to the~~
74 ~~patient to be given to the patient's partner even if the partner has not been examined by a~~
75 ~~licensed health care provider acting within their scope of practice.~~

76 ~~(7) Upon written request, the Board may waive any of the requirements of this rule if a waiver~~
77 ~~will further public health and safety. A waiver granted under this section shall only be effective~~
78 ~~when it is issued in writing.~~

79 ~~Stat. Auth.: ORS 689.205 & 689.605~~

80 ~~Stats. Implemented: ORS 689.155, 689.505 & 676.350~~

81

82 **Family Planning Clinics**

83 **855-043-0300**

84 **Purpose and Scope**

85 ~~(1) A practitioner who has been given dispensing privileges by their licensing board, or a~~
86 ~~Registered Nurse, who is an employee of a clinic that is registered with the Board and is~~
87 ~~supported by DHS for purposes of providing public health family planning services, may~~

88 dispense drugs or devices to clients for the purpose of birth control, the treatment of amenorrhea,
89 hormone deficiencies, urinary tract infections or sexually transmitted diseases.

90 (2) Such dispensing must be pursuant to the prescription of a person authorized to prescribe a
91 drug or device, and is subject to rules jointly adopted by the Board and DHS.

92 Stat. Auth.: ORS 689.205

93 Stats. Implemented: ORS 689.305

94 Hist.: BP 4 2002, f. 6 27 02, cert. ef. 7 1 02; BP 1 2010, f. & cert. ef. 2 8 10

95 **855-043-0310**

96 **Drug Delivery and Control**

97 (1) Policies and Procedures. The licensed facility is responsible for the following:

98 (a) Maintaining written policies and procedures for drug dispensing, storage, security, and
99 accountability;

100 (b) Maintenance of all drug records required by federal and state law; and

101 (c) Establishing procedures for procurement of drugs.

102 (2) Dispensing:

103 (a) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy
104 and completeness of the prescription is verified by a practitioner who has been given dispensing
105 privileges by their licensing board, or by a Registered Nurse, prior to being delivered or
106 transferred to the patient.

107 (b) A drug must be dispensed in a containers complying with the federal Poison Prevention
108 Packaging Act unless the patient requests a non-complying container.

109 (c) A prescription must be labeled with the following information:

110 (A) Name of patient;

111 (B) Name of prescriber;

112 (C) Name, address, and phone number of the clinic;

113 (D) Date of dispensing;

114 (E) Name and strength of the drug. If the drug does not have a brand name, then the generic
115 name of the drug and the drug manufacturer must be stated;

116 (F) Directions for use;

- 117 ~~(G) Initials of the person dispensing;~~
- 118 ~~(H) Cautionary statements, if any, as required by law; and~~
- 119 ~~(I) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should~~
120 ~~not use the drug.~~
- 121 ~~(d) The prescriber must verbally counsel the patient concerning all new medications and a drug~~
122 ~~information fact sheet must accompany all drugs dispensed from a family planning clinic.~~
- 123 ~~(3) Repackaged drugs. Drugs repackaged for dispensing must be in a container meeting USP~~
124 ~~standards and labeled to identify at a minimum:~~
- 125 ~~(a) Brand name, or generic name and manufacturer;~~
- 126 ~~(b) Strength;~~
- 127 ~~(c) Lot number; and~~
- 128 ~~(d) Manufacturer's expiration date, or an earlier date if preferable. An internal control number~~
129 ~~which references manufacturer and lot number may be utilized.~~
- 130 ~~(4) Drug security, storage, and disposal:~~
- 131 ~~(a) In the absence of a physician, pharmacist, Registered Nurse, Clinical Nurse Specialist, or~~
132 ~~nurse practitioner, all drugs must be kept in a locked drug cabinet or drug room that is~~
133 ~~sufficiently secure to deny access to unauthorized persons. Only physicians, pharmacists,~~
134 ~~Registered Nurses, Clinical Nurse Specialists or nurse practitioners shall have a key to the drug~~
135 ~~cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.~~
- 136 ~~(b) All drugs must be stored in areas which will assure proper sanitation, temperature, light,~~
137 ~~ventilation, and moisture control as recommended by the manufacturer.~~
- 138 ~~(c) Drugs which are outdated, damaged, deteriorated, misbranded, or adulterated must be~~
139 ~~quarantined and physically separated from other drugs until they are destroyed or returned to~~
140 ~~their supplier.~~
- 141 ~~(5) Drug records:~~
- 142 ~~(a) A dispensing record must be maintained separately from the patient chart and kept for a~~
143 ~~minimum of three years. The record must show, at a minimum, the following:~~
- 144 ~~(A) Name of patient;~~
- 145 ~~(B) Brand name of drug, or generic name and name of manufacturer or distributor;~~

- 146 (C) Date of dispensing; and
- 147 (D) Initials of person dispensing the prescription;
- 148 (b) All records of receipt and disposal of drugs must be kept for a minimum of three years.
- 149 (c) All records required by these rules or by federal and state law must be readily retrievable and
150 available for inspection by the Board.
- 151 (6) A consultant pharmacist must conduct and document an annual inspection of the clinic in
152 accordance with the directions of the Board. The completed report form must be filed in the
153 clinic, and be available to the Board for inspection for three years.
- 154 (7) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice
155 of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from
156 the label, the patient's name may be omitted from the records and a drug may be dispensed to the
157 patient to be given to the patient's partner even if the partner has not been examined by a
158 licensed health care provider acting within their scope of practice.

159 Stat. Auth.: ORS 689.205
160 Stats. Implemented: ORS 689.305, 2009 OL Ch 522

161
162 **Community Health Clinic Drug Outlet**

163 **855-043-0700**

164 **Purpose and Scope**

165 **(1) The purpose of 855-043-0700 to 855-043-0750 is to provide minimum requirements of**
166 **operation for a Community Health Clinic (CHC) which utilizes Registered Nurses to**
167 **dispense medications. A Community Health Clinic drug outlet registration replaces a**
168 **Family Planning or County Health Drug Outlet registration. A legend or non-prescription**
169 **drug may be dispensed to a client for the purpose of birth control, carries prevention, the**
170 **treatment of amenorrhea, the treatment of a communicable disease, hormone deficiencies,**
171 **urinary tract infections or sexually transmitted diseases by a practitioner who has been**
172 **given dispensing privileges by their licensing Board, or a Registered Nurse, who is an**
173 **employee of a clinic or local public health authority (LPHA), and is recognized by the**
174 **Oregon Public Health Division for the purposes of providing public health services.**

175 **(2) Such dispensing must be pursuant to the order or prescription of a person authorized**
176 **by their Board to prescribe a drug or established by the Medical Director or clinic**
177 **practitioner with prescriptive and dispensing authority.**

178 **(3) Family Planning or County Health Drug Outlet registrations that currently expire**
179 **March 31, 2017 will be converted to the new category upon renewal in 2017, however these**
180 **new rules will take effect on July 1, 2016.**

181 **Stat. Auth.: ORS 689.205**
182 **Stats. Implemented: ORS 689.305**

184 **855-043-0705**

185 **Registration**

186 **(1) A Community Health Clinic drug outlet must register with the Board on a form**
187 **prescribed by the Board, and must renew its registration annually on a renewal form**
188 **prescribed by the Board.**

189 **(2) An initial application and renewal application must be accompanied by the fee**
190 **established in Division 110 of this Chapter.**

191 **(3) A certificate of registration will be issued upon Board approval of the application.**

192 **(4) A CHC drug outlet registration expires March 31, annually. If the annual renewal fee is**
193 **not paid by February 28 of the current year, the applicant for renewal must submit the**
194 **delinquent fee established in Division 110 of this Chapter with the renewal application.**

195 **(5) The registration is not transferable and the registration fee cannot be prorated.**

196 **(6) The registrant must notify the Board, within 15 days, of any substantial change to the**
197 **information provided on the registration application. A substantial change shall include**
198 **but not be limited to: a change of ownership; change of business address; change of normal**
199 **business hours; any disciplinary action taken or pending by any state or federal authority**
200 **against the registrant, or any of its principals, owners, directors, officers, or medical**
201 **director.**

202 **(7) A new registration form is required for a change of ownership or location and must be**
203 **submitted to the Board with the fees as specified in Division 110 of this Chapter within 15**
204 **days of the change.**

205 **(8) A CHC drug outlet may be inspected by the Board.**

206 **Stat. Auth.: ORS 689.205**
207 **Stats. Implemented: ORS 689.305**

209 **855-043-0710**

210 **Personnel**

211 **(1) A Community Health Clinic drug outlet must employ a Medical Director who is an**
212 **Oregon practitioner with prescriptive and dispensing authority. The Medical Director shall**
213 **establish and enforce policies and procedures, drug dispensing formulary, and protocols**
214 **for the dispensing of drugs by authorized persons in the CHC.**

215 **(2) A CHC drug outlet must designate a representative employee who will act as the**
216 **Oregon Board of Pharmacy contact person. The designated representative must be on site**
217 **the majority of the CHC's normal operating hours.**

218 **(a) The Medical Director or designated representative must conduct and document an**
219 **annual review of the outlet on a form provided by the Board. The completed report form**
220 **must be filed in the outlet, retained on file for three years and be available to the Board for**
221 **inspection.**

222 **(b) The Medical Director shall develop policies and procedures for the outlet in**
223 **collaboration with the designated representative.**

224 **Stat. Auth.: ORS 689.205**
225 **Stats. Implemented: ORS 689.305**

226 **Policies and Procedures**

227 **855-043-0715**

228 **The Community Health Clinic must:**

229 **(1) Maintain written policies and procedures for drug management, including security,**
230 **acquisition, storage, dispensing and drug delivery, disposal, record keeping; and**

231 **(2) Establish procedures to train a Registered Nurse employed by the CHC to ensure**
232 **continued competence in the dispensing of drugs.**

233 **Stat. Auth.: ORS 689.205**
234 **Stats. Implemented: ORS 689.305**

235

236 **855-043-0720**

237 **Security**

238 **(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is**
239 **sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated**
240 **drug storage area must remain locked and secured when not in use.**

241 **(2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse**
242 **shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or**
243 **drug room must remain locked.**

244 **(3) Upon written request, the Board may waive any of the requirements of this rule if a**
245 **waiver will further public health or safety or the health and safety of a patient. A waiver**
246 **granted under this section shall only be effective when it is issued by the Board in writing.**

247 **Stat. Auth.: ORS 689.205**
248 **Stats. Implemented: ORS 689.305**
249

250 **855-043-0725**

251 **Drug Acquisition**

252 **The CHC must verify that all drugs are acquired from a registrant of the Board.**

253 **Stat. Auth.: ORS 689.205**
254 **Stats. Implemented: ORS 689.305**

255

256 **855-043-0730**

257 **Storage of Drugs**

258 **All drugs, including drug samples, must be stored according to manufacturer's published**
259 **guidelines and be stored in appropriate conditions of temperature, light, humidity,**
260 **sanitation, ventilation, and space.**

261 **Stat. Auth.: ORS 689.205**
262 **Stats. Implemented: ORS 689.305**
263

264 **855-043-0735**

265 **Labeling**

266 **(1) A prescription must be labeled with the following information:**

267 **(a) Unique identifier (i.e. prescription number);**

268 **(b) Name of patient;**

- 269 **(c) Name of prescriber;**
- 270 **(d) Name, address, and phone number of the clinic;**
- 271 **(e) Date of dispensing;**
- 272 **(f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label**
273 **must also contain the identifier of the manufacturer or distributor;**
- 274 **(g) Quantity dispensed;**
- 275 **(h) Directions for use;**
- 276 **(i) Initials of the practitioner who has been given dispensing privileges by their licensing**
277 **Board or the Registered Nurse;**
- 278 **(j) Cautionary statements, if any, as required by law; and**
- 279 **(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient**
280 **should not use the drug; and**
- 281 **(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the**
282 **practice of an Expedited Partner Therapy treatment protocol, the name of the patient may**
283 **be omitted from the label, the patient's name may be omitted from the records and a drug**
284 **may be dispensed to the patient to be given to the patient's partner even if the partner has**
285 **not been examined by a licensed health care provider acting within their scope of practice.**

286 **Stat. Auth.: ORS 689.205**
287 **Stats. Implemented: ORS 689.305, 689.505**

289 **855-043-0740**

290 **Dispensing and Drug Delivery**

291 **(1) A drug may only be dispensed by a practitioner who has been given dispensing**
292 **privileges by their licensing Board or by a Registered Nurse.**

293 **(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established**
294 **CHC protocols.**

295 **(3) A Registered Nurse may only dispense drug listed in, or for a condition listed in, the**
296 **formulary.**

297 **(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the**
298 **accuracy and completeness of the prescription is verified by a practitioner who has been**

300 given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to
301 being delivered or transferred to the patient.

302 (5) The CHC will provide appropriate drug information for medications dispensed to a
303 patient, which can be provided by the Registered Nurse or practitioner at the time of
304 dispensing.

305 (6) All drugs must be dispensed in a new container that complies with the current
306 provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S.
307 2162) and rules or regulations and with the current United States Pharmacopoeia/National
308 Formulary monographs for preservation, packaging, storage and labeling.

309 (7) Drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a
310 manufacturer registered with the Board.

311 (8) A CHC may not accept the return of drugs from a previously dispensed prescription
312 and must maintain a list of sites in Oregon where drugs may be disposed.

313 (9) A CHC must have access to the most current issue of at least one pharmaceutical
314 reference with current, properly filed supplements and updates appropriate to and based
315 on the standards of practice for the setting.

316 Stat. Auth.: ORS 689.205
317 Stats. Implemented: ORS 689.305

318 855-043-0745

319 Disposal of Drugs

320 Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or identified as
321 suspect or illegitimate must be documented, quarantined and physically separated from
322 other drugs until they are destroyed or returned to the supplier.

323 Stat. Auth.: ORS 689.205
324 Stats. Implemented: ORS 689.305

325 855-043-0750

326 Record Keeping

327 (1) A dispensing record must be maintained separately from the patient chart and kept for
328 a minimum of three years. The record must show, at a minimum, the following:

329 (a) Name of patient;

- 329 **(b) Unique identifier (i.e. prescription number);**
- 330 **(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic**
331 **name and name of manufacturer or distributor;**
- 332 **(d) Directions for use;**
- 333 **(e) Date of dispensing; and**
- 334 **(f) Initials of person dispensing the prescription.**
- 335 **(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.**
- 336 **(3) All records required by these rules or by other State and federal law must be readily**
337 **retrievable and available for inspection by the Board.**
- 338 **Stat. Auth.: ORS 689.205**
339 **Stats. Implemented: ORS 689.305**