

1 §291.121.Remote Pharmacy Services.

2 (a) Remote pharmacy services using automated pharmacy systems.

3 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
4 services by a Class A or Class C pharmacy in a facility that is not at the same location as the
5 Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of
6 the Texas Pharmacy Act.

7 (2) Definitions. The following words and terms, when used in this section, shall have the
8 following meanings, unless the context clearly indicates otherwise. All other words and terms
9 shall have the meanings defined in the Act.

10 (A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and
11 maintains related transaction information.

12 (B) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at
13 which remote pharmacy services are provided using an automated pharmacy dispensing system.

14 (C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
15 manufacturer's original commercial container, or quantities of unit dosed drugs, into another
16 cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

17 (D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy
18 (Class C) providing remote pharmacy services.

19 (E) Remote pharmacy service--The provision of pharmacy services, including the storage and
20 dispensing of prescription drugs, in remote sites.

21 (F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a
22 particular patient, by the prescribed route at the prescribed time, and properly labeled with name,
23 strength, and expiration date of the drug.

24 (3) General requirements.

25 (A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy
26 system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local
27 government or a healthcare facility regulated under Chapter 142, 242, 247, or 252, Health and
28 Safety Code, provided drugs are administered by a licensed healthcare professional working in
29 the jail, prison, or healthcare facility.

30 (B) A provider pharmacy may only provide remote pharmacy services using an automated
31 pharmacy system to inpatients of the remote site.

32 (C) A provider pharmacy may provide remote pharmacy services at more than one remote site.

- 33 (D) Before providing remote pharmacy services, the automated pharmacy system at the remote
34 site must be tested by the provider pharmacy and found to dispense accurately. The provider
35 pharmacy shall make the results of such testing available to the board upon request.
- 36 (E) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to
37 comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel,
38 Operational Standards, and Records for Class A (Community) Pharmacies) and this section.
- 39 (F) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
40 operations involving the automated pharmacy system located at the remote site including
41 supervision of the automated pharmacy system and compliance with this section.
- 42 (G) A pharmacist from the provider pharmacy shall be accessible at all times to respond to
43 patient's or other health professionals' questions and needs pertaining to drugs dispensed through
44 the use of the automated pharmacy system. Such access may be through a 24 hour pager service
45 or telephone which is answered 24 hours a day.
- 46 (4) Operational standards.
- 47 (A) Application for permission to provide pharmacy services using an automated pharmacy
48 system.
- 49 (i) A Class A or Class C Pharmacy shall file a completed application containing all information
50 required by [make application to] the board to provide remote pharmacy services using an
51 automated pharmacy system. [~~The application shall contain an affidavit with the notarized~~
52 ~~signatures of the pharmacist in charge, and the medical director or the person responsible for the~~
53 ~~on-site operation of the facility (e.g., administrator, chief operating officer, owner, chief~~
54 ~~executive officer), and include the following:]~~
- 55 ~~[(I) the name, address, and license number of the provider pharmacy;]~~
- 56 ~~[(II) name and address of the facility where the remote pharmacy services will be provided;~~
- 57 ~~[(III) a statement indicating that the provider pharmacy and the facility have entered into a~~
58 ~~written contract or agreement which outlines the services to be provided and the responsibilities~~
59 ~~and accountabilities of each party in fulfilling the terms of the contract or agreement in~~
60 ~~compliance with federal and state laws and regulations; and]~~
- 61 ~~[(IV) documentation that the automated pharmacy system is located where medications are~~
62 ~~administered by license healthcare professionals and is:]~~
- 63 ~~[(a) a facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code; or]~~
- 64 ~~[(b) a jail or prison, operated by the State of Texas or local government.]~~

65 (ii) Such application shall be resubmitted every two years in conjunction with the application for
66 renewal of the provider pharmacy's license. [~~The renewal petition shall contain the~~
67 ~~documentation required in clause (i) of this subparagraph except the notarized signature of the~~
68 ~~medical director or the person responsible for the on-site operation of the facility (e.g.,~~
69 ~~administrator, chief operating officer, owner, chief executive officer) is not required.~~]

70 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
71 must be displayed at the remote site.

72 (B) Notification requirements.

73 (i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of~~
74 ~~location,~~] discontinuance of service, or closure of:

75 (I) a remote site where an automated pharmacy system is operated by the pharmacy; or

76 (II) a remote pharmacy service at a remote site.

77 (ii) A provider pharmacy shall comply with appropriate federal and state controlled substance
78 registrations for each remote site if controlled substances are maintained within an automated
79 pharmacy system at the facility.

80 (iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified
81 in §291.3 (relating to Notifications) of this title.

82 (C) Environment/Security.

83 (i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy
84 system which is locked by key, combination or other mechanical or electronic means so as to
85 prohibit access by unauthorized personnel.

86 (ii) An automated pharmacy system shall be under the continuous supervision of a provider
87 pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be
88 physically present at the site of the automated pharmacy system if the system is supervised
89 electronically by a pharmacist.

90 (iii) Automated pharmacy systems shall have adequate security and procedures to:

91 (I) comply with federal and state laws and regulations; and

92 (II) maintain patient confidentiality.

93 (iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

94 (I) are designated in writing by the pharmacist-in-charge; and

95 (II) have completed documented training concerning their duties associated with the automated
96 pharmacy system.

97 (v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to
98 Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and
99 handling of outdated drugs.

100 (D) Prescription dispensing and delivery.

101 (i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after
102 receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a
103 manner authorized by §291.34(b) of this title.

104 (ii) A pharmacist at the provider pharmacy shall control all operations of the automated
105 pharmacy system and approve the release of the initial dose of a prescription drug order.
106 Subsequent doses from an approved prescription drug order may be removed from the automated
107 medication system after this initial approval. Any change made in the prescription drug order
108 shall require a new approval by a pharmacist to release the drug.

109 (iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in
110 §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy
111 system.

112 (iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall
113 comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

114 (v) An automated pharmacy system used to meet the emergency medication needs for residents
115 of a remote site must comply with the requirements for emergency medication kits in subsection
116 (b) of this section.

117 (E) Drugs.

118 (i) Drugs for use in an automated pharmacy system shall be packaged in the original
119 manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance
120 with the board's prepackaging requirements for the class of pharmacy.

121 (ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for
122 reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

123 (F) Stocking an automated pharmacy system.

124 (i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist,
125 pharmacy technician, or pharmacy technician trainee under the direct supervision of a
126 pharmacist, except as provided in clause (ii) of this subparagraph.

127 (ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the
128 prepackaging of the cartridges or containers shall occur at the provider pharmacy unless
129 provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent
130 to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-
131 charge provided:

132 (I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

133 (II) the individual cartridges or containers are transported to the remote site in a secure, tamper-
134 evident container; and

135 (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure
136 that the containers are accurately loaded in the automated pharmacy system.

137 (iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote
138 site by the provider pharmacy.

139 (G) Quality assurance program. A pharmacy that provides pharmacy services through an
140 automated pharmacy system at a remote site shall operate according to a written program for
141 quality assurance of the automated pharmacy system which:

142 (i) requires continuous supervision of the automated pharmacy system; and

143 (ii) establishes mechanisms and procedures to routinely test the accuracy of the automated
144 pharmacy system at a minimum of every six months and whenever any upgrade or change is
145 made to the system and documents each such activity.

146 (H) Policies and procedures of operation.

147 (i) A pharmacy that provides pharmacy services through an automated pharmacy system at a
148 remote site shall operate according to written policies and procedures. The policy and procedure
149 manual shall include, but not be limited to, the following:

150 (I) a current list of the name and address of the pharmacist-in-charge and personnel designated
151 by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy
152 system;

153 (II) duties which may only be performed by a pharmacist;

154 (III) a copy of the portion of the written contract or agreement between the pharmacy and the
155 facility which outlines the services to be provided and the responsibilities and accountabilities of
156 each party relating to the operation of the automated pharmacy system in fulfilling the terms of
157 the contract in compliance with federal and state laws and regulations;

158 (IV) date of last review/revision of the policy and procedure manual; and

- 159 (V) policies and procedures for:
- 160 (-a-) security;
- 161 (-b-) operation of the automated pharmacy system;
- 162 (-c-) preventative maintenance of the automated pharmacy system;
- 163 (-d-) sanitation;
- 164 (-e-) storage of drugs;
- 165 (-f-) dispensing;
- 166 (-g-) supervision;
- 167 (-h-) drug procurement;
- 168 (-i-) receiving of drugs;
- 169 (-j-) delivery of drugs; and
- 170 (-k-) recordkeeping.
- 171 (ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a
172 remote site shall, at least annually, review its written policies and procedures, revise them if
173 necessary, and document the review.
- 174 (iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall
175 maintain a written plan for recovery from an event which interrupts the ability of the automated
176 pharmacy system to dispense prescription drugs. The written plan for recovery shall include:
- 177 (I) planning and preparation for maintaining pharmacy services when an automated pharmacy
178 system is experiencing downtime;
- 179 (II) procedures for response when an automated pharmacy system is experiencing downtime; and
- 180 (III) procedures for the maintenance and testing of the written plan for recovery.
- 181 (5) Records.
- 182 (A) Maintenance of records.
- 183 (i) Every record required under this section must be:

184 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
185 copying by the board or its representative and to other authorized local, state, or federal law
186 enforcement agencies; and

187 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of
188 the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
189 format, the requested records must be provided in an electronic format if specifically requested
190 by the board or its representative. Failure to provide the records set out in this section, either on
191 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
192 in violation of the Act.

193 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed
194 from an automated pharmacy system in compliance with §291.34(b) of this title.

195 (iii) if prescription drug records are maintained in a data processing system, the system shall
196 have a workable (electronic) data retention system which can produce a separate audit trail of
197 drug usage by the provider pharmacy and each remote site for the preceding two years as
198 specified in §291.34(e) of this title.

199 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

200 (C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained
201 by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

202 (D) Transaction information.

203 (i) The automated pharmacy system shall electronically record all transactions involving drugs
204 stored in, removed, or dispensed from the system.

205 (ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained
206 by the providing pharmacy and include the:

207 (I) identity of the system accessed;

208 (II) identification of the individual accessing the system;

209 (III) date of transaction;

210 (IV) name, strength, dosage form, and quantity of drug accessed; and

211 (V) name of the patient for whom the drug was accessed.

212 (iii) Records of stocking or removal from an automated pharmacy system shall be maintained by
213 the pharmacy and include the:

214 (I) date;

- 215 (II) name, strength, dosage form, and quantity of drug stocked or removed;
- 216 (III) name, initials, or identification code of the person stocking or removing drugs from the
217 system;
- 218 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
219 system has been accurately filled;
- 220 (E) Patient medication records. Patient medication records shall be created and maintained by the
221 provider pharmacy in the manner required by §291.34(c) of this title.
- 222 (F) Inventory.
- 223 (i) A provider pharmacy shall:
- 224 (I) keep a record of all drugs sent to and returned from a remote site separate from the records of
225 the provider pharmacy and from any other remote site's records; and
- 226 (II) keep a perpetual inventory of controlled substances and other drugs required to be
227 inventoried under §291.17 of this title (relating to Inventory Requirements for All Classes of
228 Pharmacies) that are received and dispensed or distributed from each remote site.
- 229 (ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each
230 remote site. The following is applicable to this inventory.
- 231 (I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.
- 232 (II) The inventory of each remote site shall be included with, but listed separately from, the drugs
233 of other remote sites and separately from the drugs of the provider pharmacy.
- 234 (b) Remote pharmacy services using emergency medication kits.
- 235 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
236 services by a Class A or Class C pharmacy in a facility that is not at the same location as the
237 Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of
238 the Texas Pharmacy Act.
- 239 (2) Definitions. The following words and terms, when used in this subsection, shall have the
240 following meanings, unless the context clearly indicates otherwise. All other words and terms
241 shall have the meanings defined in the Act or §291.31 of this title.
- 242 (A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and
243 maintains related transaction information.
- 244 (B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a
245 provider pharmacy to meet the emergency medication needs of a resident:

- 246 (i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or
- 247 (ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans
248 home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United
249 States Department of Veterans Affairs pharmacy or another federally operated pharmacy.
- 250 (C) Remote site--A facility not located at the same location as a Class A, Class C, Class E
251 pharmacy or a United States Department of Affairs pharmacy or another federally operated
252 pharmacy, at which remote pharmacy services are provided using an emergency medication kit.
- 253 (D) Prepackaging--The act of repackaging and relabeling quantities of drug products from a
254 manufacturer's original commercial container, or quantities of unit dosed drugs, into another
255 cartridge or container for dispensing by a pharmacist using an emergency medication kit.
- 256 (E) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class
257 C), the non-resident (Class E) pharmacy located not more than 20 miles from an institution
258 licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of
259 Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy
260 services.
- 261 (F) Remote pharmacy service--The provision of pharmacy services, including the storage and
262 dispensing of prescription drugs, in remote sites.
- 263 (3) General requirements.
- 264 (A) A provider pharmacy may provide remote pharmacy services using an emergency
265 medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.
- 266 (B) A provider pharmacy may provide remote pharmacy services at more than one remote site.
- 267 (C) A provider pharmacy shall not place an emergency medication kit in a remote site which
268 already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of
269 this subsection.
- 270 (D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class
271 E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this
272 section.
- 273 (E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy
274 operations involving the emergency medication kit located at the remote site including
275 supervision of the emergency medication kit and compliance with this section.
- 276 (4) Operational standards.
- 277 (A) Application for permission to provide pharmacy services using an emergency medication kit.

278 (i) A Class A, Class C, or Class E Pharmacy shall file a completed application containing all
279 information required by [make application to] the board to provide remote pharmacy services
280 using an emergency medication kit. [~~The application shall contain an affidavit with the notarized~~
281 ~~signatures of the pharmacist in charge, and the medical director or the person responsible for the~~
282 ~~on-site operation of the facility (e.g., administrator, owner, chief executive officer, chief~~
283 ~~operating officer), and include the following:]~~

284 [~~(I) the name, address, and license number of the provider pharmacy;]~~

285 [~~(II) name and address of the healthcare facility where the remote pharmacy services will be~~
286 ~~provided;]~~

287 [~~(III) a statement indicating that the provider pharmacy and the healthcare facility have entered~~
288 ~~into a written contract or agreement which outlines the services to be provided and the~~
289 ~~responsibilities and accountabilities of each party in fulfilling the terms of the contract or~~
290 ~~agreement in compliance with federal and state laws and regulations;]~~

291 [~~(IV) documentation that the emergency medication kit is located in a facility regulated under~~
292 ~~Chapter 242, or 252, Health and Safety Code; and]~~

293 [~~(V) if applicable, documentation that the emergency kit is located in a facility that is not more~~
294 ~~than 20 miles from the Class E pharmacy providing the emergency kit.]~~

295 (ii) Such application shall be resubmitted every two years in conjunction with the application for
296 renewal of the provider pharmacy's license. [~~The renewal petition shall contain the~~
297 ~~documentation required in clause (i) of this subparagraph except the notarized signature of the~~
298 ~~medical director or the person responsible for the on-site operation of the facility (e.g.,~~
299 ~~administrator, owner, chief executive officer, chief operating officer) is not required.]~~

300 (iii) Upon approval of the application, the provider pharmacy will be sent a certificate which
301 must be displayed at the remote site.

302 (B) Notification requirements.

303 (i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of~~
304 ~~location,~~] discontinuance of service, or closure of:

305 (I) a remote site where an emergency medication kit is operated by the pharmacy; or

306 (II) a remote pharmacy service at a remote site.

307 (ii) A provider pharmacy shall comply with appropriate federal and state controlled substance
308 registrations for each remote site if controlled substances are maintained within an emergency
309 medication kit at the facility.

310 (iii) If more than one provider pharmacy provides an emergency kit to a remote site, the provider
311 pharmacies must enter into a written agreement as to the emergency medications supplied by
312 each pharmacy. The provider pharmacies shall not duplicate drugs stored in the emergency
313 medication kits. The written agreement shall include reasons why an additional pharmacy is
314 required to meet the emergency medication needs of the residents of the institution.

315 (iv) A provider pharmacy shall file a change of location and/or name of a remote site as specified
316 in §291.3 of this title.

317 (C) Environment/Security.

318 (i) Emergency medication kits shall have adequate security and procedures to:

319 (I) prohibit unauthorized access;

320 (II) comply with federal and state laws and regulations; and

321 (III) maintain patient confidentiality.

322 (ii) Access to the emergency medication kit shall be limited to pharmacists and licensed
323 healthcare personnel employed by the facility.

324 (iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this
325 title including the requirements for temperature and handling outdated drugs.

326 (D) Prescription dispensing and delivery.

327 (i) Drugs in the emergency medication kit shall be accessed for administration to meet the
328 emergency medication needs of a resident of the remote site pursuant to an order from a
329 practitioner. The prescription drug order for the drugs used from the emergency medication kit
330 shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

331 (ii) The remote site shall notify the provider pharmacy of each entry into an emergency
332 medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this
333 subsection.

334 (E) Drugs.

335 (i) The contents of an emergency medication kit:

336 (I) may consist of dangerous drugs and controlled substances; and

337 (II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider
338 pharmacy, medical director, and the director of nurses and limited to those drugs necessary to
339 meet the resident's emergency medication needs. For the purpose of this subsection, this shall

340 mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time
341 period.

342 (ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant
343 pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of
344 nurses must determine, select, and record a prudent number of drugs for potential emergency
345 incidents based on:

346 (I) clinical criteria applicable to each facility's demographics;

347 (II) the facility's census; and

348 (III) the facility's healthcare environment.

349 (iii) A current list of the drugs stored in each remote site's emergency medication kit shall be
350 maintained by the provider pharmacy and a copy kept with the emergency medication kit.

351 (iv) An automated pharmacy system may be used as an emergency medication kit provided the
352 system limits emergency access to only those drugs approved for the emergency medication kit.

353 (v) Drugs for use in an emergency medication kit shall be packaged in the original
354 manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance
355 with the board's prepackaging requirements for the class of pharmacy.

356 (F) Stocking emergency medication kits.

357 (i) Stocking of drugs in an emergency medication kit shall be completed at the provider
358 pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee
359 under the direct supervision of a pharmacist, except as provided in clause (ii) of this
360 subparagraph.

361 (ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding,
362 microchip, or other technologies to ensure that the containers or unit dose drugs are accurately
363 loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider
364 pharmacy unless provided by a FDA approved repackager. The prepackaged containers or unit
365 dose drugs may be sent to the remote site to be loaded into the machine by personnel designated
366 by the pharmacist-in-charge provided:

367 (I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

368 (II) the individual containers or unit dose drugs are transported to the remote site in a secure,
369 tamper-evident container; and

370 (III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure
371 that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

372 (iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site
373 by the provider pharmacy.

374 (G) Policies and procedures of operation.

375 (i) A provider pharmacy that provides pharmacy services through an emergency medication kit
376 at a remote site shall operate according to written policies and procedures. The policy and
377 procedure manual shall include, but not be limited to, the following:

378 (I) duties which may only be performed by a pharmacist;

379 (II) a copy of the written contract or agreement between the pharmacy and the facility which
380 outlines the services to be provided and the responsibilities and accountabilities of each party in
381 fulfilling the terms of the contract in compliance with federal and state laws and regulations;

382 (III) date of last review/revision of the policy and procedure manual; and

383 (IV) policies and procedures for:

384 (-a-) security;

385 (-b-) operation of the emergency medication kit;

386 (-c-) preventative maintenance of the automated pharmacy system if the emergency medication
387 kit is an automated pharmacy system;

388 (-d-) sanitation;

389 (-e-) storage of drugs;

390 (-f-) dispensing;

391 (-g-) supervision;

392 (-h-) drug procurement;

393 (-i-) receiving of drugs;

394 (-j-) delivery of drugs; and

395 (-k-) recordkeeping.

396 (ii) A pharmacy that provides pharmacy services through an emergency medication kit at a
397 remote site shall, at least annually, review its written policies and procedures, revise them if
398 necessary, and document the review.

399 (iii) A pharmacy providing remote pharmacy services using an emergency medication kit which
400 is an automated pharmacy system shall maintain a written plan for recovery from an event which
401 interrupts the ability of the automated pharmacy system to provide emergency medications. The
402 written plan for recovery shall include:

403 (I) planning and preparation for maintaining pharmacy services when an automated pharmacy
404 system is experiencing downtime;

405 (II) procedures for response when an automated pharmacy system is experiencing downtime; and

406 (III) procedures for the maintenance and testing of the written plan for recovery.

407 (5) Records.

408 (A) Maintenance of records.

409 (i) Every record required under this section must be:

410 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
411 copying by the board or its representative and to other authorized local, state, or federal law
412 enforcement agencies; and

413 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of
414 the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
415 format, the requested records must be provided in an electronic format if specifically requested
416 by the board or its representative. Failure to provide the records set out in this section, either on
417 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
418 in violation of the Act.

419 (ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed
420 from an emergency medication kit in compliance with §291.34(b) of this title.

421 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

422 (C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained
423 by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

424 (D) Transaction information.

425 (i) A prescription drug order shall be maintained by the provider pharmacy as the record of
426 removal of a drug from an emergency medication kit for administration to a patient.

427 (ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry
428 into an emergency medication kit. Such notification may be included on the prescription drug
429 order or a separate document and shall include the name, strength, and quantity of the drug
430 removed, the time of removal, and the name of the person removing the drug.

431 (iii) A separate record of stocking, removal, or dispensing for administration from an emergency
432 medication kit shall be maintained by the pharmacy and include the:

433 (I) date;

434 (II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for
435 administration;

436 (III) name, initials, or identification code of the person stocking, removing, or dispensing for
437 administration, drugs from the system;

438 (IV) name, initials, or identification code of the pharmacist who checks and verifies that the
439 system has been accurately filled; and

440 (V) unique prescription number assigned to the prescription drug order when the drug is
441 administered to the patient.

442 (E) Inventory.

443 (i) A provider pharmacy shall:

444 (I) keep a record of all drugs sent to and returned from a remote site separate from the records of
445 the provider pharmacy and from any other remote site's records; and

446 (II) keep a perpetual inventory of controlled substances and other drugs required to be
447 inventoried under §291.17 of this title, that are received and dispensed or distributed from each
448 remote site.

449 (ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each
450 remote site. The following is applicable to this inventory.

451 (I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

452 (II) The inventory of each remote site shall be included with, but listed separately from, the drugs
453 of other remote sites and separately from the drugs of the provider pharmacy.

454 (c) Remote pharmacy services using telepharmacy systems.

455 (1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy
456 services by a Class A or Class C pharmacy in a healthcare facility that is not at the same location
457 as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the
458 Texas Pharmacy Act.

459 (2) Definitions. The following words and terms, when used in this section, shall have the
460 following meanings, unless the context clearly indicates otherwise. All other words and terms
461 shall have the meanings defined in the Act or §291.31 of this title.

462 (A) [~~Prepackaging~~—The act of repackaging and relabeling quantities of drug products from a
463 manufacturer's original commercial container into a prescription container for dispensing by a
464 pharmacist to the ultimate consumer.]

465 [~~(B)~~] Provider pharmacy--

466 (i) a Class A pharmacy that provides pharmacy services through a telepharmacy system at a
467 remote dispensing site or at a healthcare facility that is regulated by this state or the United
468 States; or

469 (ii) a Class C pharmacy that provides pharmacy services though a telepharmacy system at a
470 healthcare facility that is regulated by this state or the United States. [~~The community pharmacy~~
471 ~~(Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.~~]

472 (B) Remote dispensing site-- a location licensed as a telepharmacy that is authorized by a
473 provider pharmacy through a telepharmacy system to store and dispense prescription drugs and
474 devices, including dangerous drugs and controlled substances.

475 (C) Remote healthcare site--a healthcare facility regulated by this state or the United States that is
476 a:

477 (i) rural health clinic regulated under 42 U.S.C. Section 1395x(aa);

478 (ii) health center as defined by 42 U.S.C. Section 254b;

479 (iii) healthcare facility located in a medically underserved area as determined by the United
480 States Department of Health and Human Services; or

481 (iv) healthcare facility located in a health professional shortage area as determined by the United
482 States Department of Health and Human Services.

483 [~~(C) Remote site--a facility not located at the same location as a Class A or Class C pharmacy, at~~
484 ~~which remote pharmacy services are provided using a telepharmacy dispensing system.]~~

485 (D) Remote site--a remote healthcare site or a remote dispensing site.

486 (E) [~~(D)~~] Remote pharmacy service--The provision of pharmacy services, including the storage
487 and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote
488 site.

489 (F) [~~(E)~~] Still image capture--A specific image captured electronically from a video or other
490 image capture device.

491 (G) [~~(F)~~] Store and forward--A video or still image record which is saved electronically for
492 future review.

493 (H) ~~[(G)]~~ Telepharmacy system--A system that monitors the dispensing of prescription drugs and
494 provides for related drug use review and patient counseling services by an electronic method
495 which shall include the use of the following types of technology:

496 (i) audio and video;

497 (ii) still image capture; and

498 (iii) store and forward.

499 ~~[(H) Unit of use—A sufficient quantity of a drug for one normal course of therapy as determined~~
500 ~~by the pharmacist in charge and the prescribing practitioner(s) at the healthcare facility.]~~

501 (3) General requirements.

502 (A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system at
503 a [tø]:

504 (i) remote healthcare site; or [a rural health clinic regulated under 42 U.S.C. Section 1395x(aa),
505 as amended];

506 (ii) remote dispensing site. [a health center as defined by 42 U.S.C. Section 254b, as amended;
507 øf]

508 ~~[(iii) healthcare facility located in a medically underserved area as defined by state or federal~~
509 ~~law.]~~

510 (B) A provider pharmacy may not provide remote pharmacy services at a remote healthcare
511 site if a Class A ~~[(Community)]~~ or Class C ~~[(Institutional)]~~ pharmacy that dispenses prescription
512 drug orders to out-patients is located in the same community. For the purposes of this subsection
513 a community is defined as:

514 (i) the census tract in which the remote site is located, if the remote site is located in a
515 Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most
516 recent U.S. Census; or

517 (ii) within 10 miles of the remote site, if the remote site is not located in a MSA.

518 (C) A provider pharmacy may not provide remote pharmacy services at a remote dispensing site
519 if a Class A pharmacy is located:

520 (i) within 25 miles by road of the remote dispensing site; or

521 (ii) if located in a county with a population of at least 13,000 but not more than 14,000, within 22
522 miles by road of the dispensing site. [The provider pharmacy shall have sufficient pharmacists on
523 duty such that each pharmacist may supervise no more three remote sites that are simultaneously

524 ~~open to provide services. An exception to the supervision limit may be granted by the board in~~
525 ~~situations where the provider has documented a need for a pharmacist to supervise additional~~
526 ~~remote sites and has demonstrated that appropriate safeguards are in place to assure proper~~
527 ~~supervision of each remote site.]~~

528 (D) If a Class A or Class pharmacy is established in a community in which a remote healthcare
529 site has been located, the remote healthcare site may continue to operate.

530 (E) If a Class A pharmacy is established within 22 miles by road of a remote dispensing site that
531 is currently operating, the remote dispensing site may continue to operate at that location.

532 (F) [(D)] Before providing remote pharmacy services [service], the telepharmacy system at
533 the remote site [off-site facility] must be tested by the provider pharmacy and found to operate
534 properly. The provider pharmacy shall make the results of such testing available to the board
535 upon request.

536 (G) [(E)] A provider pharmacy which is licensed as a Class C [an institutional (Class C)]
537 pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this
538 section.

539 (H) A provider pharmacy can only provide pharmacy services at no more than two remote
540 dispensing sites.

541 ~~[(F) The pharmacist in charge of the provider pharmacy is responsible for all operations at the~~
542 ~~remote site including supervision of the telepharmacy system and compliance with this section.]~~

543 (4) Personnel.

544 (A) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the
545 remote site including supervision of the telepharmacy system and compliance with this section.

546 (B) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist
547 may supervise no more two remote sites that are simultaneously open to provide services.

548 (C) The following duties shall be performed only by a pharmacist at the provider pharmacy:

549 (i) receiving an oral prescription drug order;

550 (ii) interpreting the prescription drug order;

551 (iii) verifying the accuracy of prescription data entry;

552 (iv) selecting the drug product to be stored and dispensed at the remote site;

553 (v) interpreting the patient's medication record and conducting a drug regimen review;

554 (vi) authorizing the telepharmacy system to print a prescription label at the remote site;

555 (vii) performing the final check of the dispensed prescription to ensure that the prescription drug
556 order has been dispensed accurately as prescribed; and

557 (viii) counseling the patient.

558 (5) [(4)] Operational standards.

559 (A) Application to provide remote pharmacy services using a telepharmacy system.

560 (i) A Class A or class C Pharmacy shall file a completed application containing all information
561 required by [make application to] the board to provide remote pharmacy services using a
562 telepharmacy system. [The application shall contain an affidavit with the notarized signatures of
563 pharmacist in charge, and the medical director or the person responsible for the on-site operation
564 of the facility (e.g., administrator, owner, chief executive officer, chief operating officer), and
565 include the following:]

566 ~~[(I) the name, address, and license number of the provider pharmacy;]~~

567 ~~[(II) name and address of the healthcare facility where the remote pharmacy services will be~~
568 ~~provided;]~~

569 ~~[(III) a statement indicating that the provider pharmacy and the healthcare facility have entered~~
570 ~~into a written contract or agreement which outlines the services to be provided and the~~
571 ~~responsibilities and accountabilities of each party in fulfilling the terms of the contract or~~
572 ~~agreement in compliance with federal and state laws and regulations;]~~

573 ~~[(IV) documentation that the healthcare facility is:]~~

574 ~~[(a) a rural health clinic regulated under 42 U.S.C. Section 1395x(aa), as amended];~~

575 ~~[(b) a health center as defined by 42 U.S.C. Section 254b, as amended; or]~~

576 ~~[(c) located in a medically underserved area as defined by state or federal law; and]~~

577 ~~[(V) documentation that a Class A (Community) or Class C (Institutional) Pharmacy that~~
578 ~~dispenses prescriptions drug orders to out patients is not located within the community, as~~
579 ~~defined in paragraph (3)(B) of this subsection, where the remote site is located.]~~

580 (ii) Such application shall be resubmitted every two years in conjunction with the renewal of the
581 provider pharmacy's license. ~~[The renewal application shall contain the documentation required~~
582 ~~in clause (i) of this subparagraph except the notarized signature of the medical director or the~~
583 ~~person responsible for the on-site operation of the facility (e.g., administrator, owner, chief~~
584 ~~executive officer, chief operating officer) is not required.]~~

585 (iii) On approval of the application, the provider pharmacy will be sent a license for the remote
586 site [~~registration certificate~~], which must be displayed at the remote site.

587 (iv) If the average number of prescriptions dispensed each day at a remote dispensing site is open
588 for business is more than 125 prescriptions, as calculated each calendar year, the remote
589 dispensing site shall apply for a Class A pharmacy license as specified in §291.1 of this title
590 (relating to Pharmacy License Application).

591 (B) Notification requirements.

592 (i) A provider pharmacy shall notify the board in writing within ten days of a [~~change of~~
593 ~~location,~~] discontinuance of service, or closure of[~~;~~]

594 [~~(H)~~] a remote site where a telepharmacy system is operated by the pharmacy[~~;~~~~or~~

595 [~~(H) a remote pharmacy service at a remote site~~].

596 (ii) A provider pharmacy shall comply with appropriate federal and state controlled substance
597 registrations for each remote site, if controlled substances are maintained.

598 (iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified
599 in §291.3 of this title.

600 (C) Environment/Security.

601 (i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at
602 all times the site is open to provide pharmacy services. To qualify as continuous supervision, the
603 pharmacist is not required to be physically present at the remote site and shall supervise
604 electronically through the use of the following types of technology:

605 (I) audio and video;

606 (II) still image capture; and

607 (III) store and forward.

608 (ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this
609 title including the requirements for temperature and handling of outdated drugs.

610 (iii) Drugs for use in the telepharmacy system at a remote healthcare site shall be stored in an
611 area that is:

612 (I) separate from any other drugs used by the healthcare facility; and

613 (II) locked by key, combination or other mechanical or electronic means, so as to prohibit access
614 by unauthorized personnel.

615 (iv) Drugs for use in the telepharmacy system at a remote dispensing site shall be stored in an
616 area that is locked by key, combination, or other mechanical or electronic means, so as to
617 prohibit access by unauthorized personnel.

618 (v) [(iv)] Access to the area where drugs are stored at the remote site and operation of the
619 telepharmacy system shall be limited to [pharmacists employed by the provider pharmacy or
620 personnel who]:

621 (I) pharmacists employed by the provider pharmacy;

622 (II) [(H)] [are] licensed healthcare providers, if the remote site is a remote healthcare site; and

623 (III) pharmacy technicians; [or pharmacy technician trainees;]

624 (vi) Individuals authorized by to access the remote site and operate the telepharmacy system
625 shall:

626 (I) [(H)] be [are] designated in writing by the pharmacist-in-charge; and

627 (II) [(H)] have completed documented training concerning their duties associated with the
628 telepharmacy pharmacy system.

629 (vii) [(v)] Remote sites shall have adequate security and procedures to:

630 (I) comply with federal and state laws and regulations; and

631 (II) maintain patient confidentiality.

632 ~~[(vi) The provider pharmacy shall have procedures that specify that drugs may only be delivered~~
633 ~~to the remote site by the provider pharmacy and shall:]~~

634 ~~[(I) be shipped in a sealed container with a list of drugs delivered;]~~

635 ~~[(II) signed for on receipt by an employee of the healthcare facility;]~~

636 ~~[(III) be quarantined in a locked area, if personnel designated to receive the drugs by the~~
637 ~~pharmacist in charge is not available; and]~~

638 ~~[(IV) be checked by personnel designated by the pharmacist in charge to verify that drugs sent~~
639 ~~by the provider pharmacy were actually received. The designated person who checks the order~~
640 ~~shall document the verification by signing and dating the list of drugs delivered.]~~

641 (D) Prescription dispensing and delivery.

642 ~~{(i) Drugs shall only be dispensed at the remote site through a telepharmacy system after receipt~~
643 ~~of an original prescription drug order by a pharmacist at the provider pharmacy in the manner~~
644 ~~authorized by §291.34(b) of this title.}~~

645 ~~{(ii) Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a~~
646 ~~remote site only in unit of use containers that are:}~~

647 ~~{(I) prepackaged in suitable containers at the provider pharmacy and appropriately labeled as~~
648 ~~specified in §291.33(c)(6) of this title; or}~~

649 ~~{(II) in original manufacturer's containers.}~~

650 ~~{(iii) The following duties shall be performed only by a pharmacist at the provider pharmacy:}~~

651 ~~{(I) receiving an oral prescription drug order;}~~

652 ~~{(II) interpret the prescription drug order;}~~

653 ~~{(III) verify the accuracy of prescription data entry;}~~

654 ~~{(IV) select the drug product;}~~

655 ~~{(V) interpret the patient's medication record and conduct a drug regimen review as specified in~~
656 ~~clause (iv) of this subparagraph;}~~

657 ~~{(VI) authorize the telepharmacy system to print a prescription label at the remote site as~~
658 ~~specified in clause (v) of this subparagraph;}~~

659 ~~{(VII) perform the final check of the dispensed prescription as specified in clause (vi) of this~~
660 ~~subparagraph to ensure that the prescription drug order has been dispensed accurately as~~
661 ~~prescribed;}~~

662 ~~{(VIII) counsel the patient as specified clause (vii) of this subparagraph.}~~

663 (i) ~~[(iv)]~~ A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified
664 in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's
665 agent.

666 (ii) ~~[(v)]~~ The dispensed prescription shall be labeled at the remote site with the information
667 specified in §291.33(c) of this title. ~~[except that:~~

668 ~~{(I) the label shall contain both the name, address, and phone number of the provider pharmacy~~
669 ~~and the name and address of the remote site; and}~~

670 ~~{(II) the unique identification number of the prescription on the label shall in some manner~~
671 ~~identify the remote site which dispensed the prescription using a telepharmacy system}.~~

672 (iii) [~~(vi)~~] A pharmacist at the provider pharmacy shall perform the final check of the dispensed
673 prescription before delivery to the patient to ensure that the prescription has been dispensed
674 accurately as prescribed. This final check shall be accomplished through a visual check using
675 electronic methods.

676 (iv) [~~(vii)~~] A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as
677 specified in §291.33(c) of this title. This counseling may be performed using electronic methods.
678 Non-pharmacist personnel may not ask questions of a patient or patient's agent which are
679 intended to screen and/or limit interaction with the pharmacist.

680 (v) [~~(viii)~~] If the remote site has direct access to the provider pharmacy's data processing system,
681 only a pharmacist or pharmacy technician ~~[, or pharmacy technician trainee]~~ may enter
682 prescription information into the data processing system. ~~[The original prescription shall be sent~~
683 ~~to the provider pharmacy and a pharmacist shall verify the accuracy of the data entry.]~~

684 (vi) [~~(ix)~~] Drugs which require reconstitution through the addition of a specified amount of water
685 may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee,
686 or licensed healthcare provider reconstitutes the product.

687 (vii) A telepharmacy system located at a remote dispensing site may not dispense a schedule II
688 controlled substance.

689 (E) Quality assurance program. A pharmacy that provides remote pharmacy services through a
690 telepharmacy system at a remote site shall operate according to a written program for quality
691 assurance of the telepharmacy system which:

692 (i) requires continuous supervision of the telepharmacy system at all times the site is open to
693 provide remote pharmacy services; and

694 (ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy
695 system at a minimum of every six months and whenever any upgrade or change is made to the
696 system and documents each such activity.

697 (F) Policies and procedures.

698 (i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site
699 shall operate according to written policies and procedures. The policy and procedure manual
700 shall include, but not be limited to, the following:

701 (I) a current list of the name and address of the pharmacist-in-charge and personnel designated
702 by the pharmacist-in-charge to have:

703 (-a-) have access to the area where drugs are stored at the remote site; and

704 (-b-) operate the telepharmacy system;

- 705 (II) duties which may only be performed by a pharmacist;
- 706 (III) if the remote site is located at a remote healthcare site, a copy of the written contact or
707 agreement between the provider pharmacy and the healthcare facility which outlines the services
708 to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of
709 the contract or agreement in compliance with federal and state laws and regulations;
- 710 (IV) date of last review/revision of policy and procedure manual; and
- 711 (V) policies and procedures for:
- 712 (-a-) security;
- 713 (-b-) operation of the telepharmacy system;
- 714 (-c-) sanitation;
- 715 (-d-) storage of drugs;
- 716 (-e-) dispensing;
- 717 (-f-) supervision;
- 718 (-g-) drug and/or device procurement;
- 719 (-h-) receiving of drugs and/or devices;
- 720 (-i-) delivery of drugs and/or devices; and
- 721 (-j-) recordkeeping
- 722 (ii) A pharmacy that provides remote pharmacy services through a telepharmacy system at a
723 remote site shall, at least annually, review its written policies and procedures, revise them if
724 necessary, and document the review.
- 725 (iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall
726 maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to
727 electronically supervise the telepharmacy system and the dispensing of prescription drugs at the
728 remote site. The written plan for recovery shall include:
- 729 (I) a statement that prescription drugs shall not be dispensed at the remote site, if
730 a pharmacist [~~pharmacists~~] is not able to electronically supervise the telepharmacy system and
731 the dispensing of prescription drugs;
- 732 (II) procedures for response when a telepharmacy system is experiencing downtime; and

733 (III) procedures for the maintenance and testing of the written plan for recovery.

734 (6) Additional operational standards for remote dispensing sites.

735 (A) A pharmacist employed by a provider pharmacy shall make at least monthly on-site visits to
736 a remote site. The remote site shall maintain documentation of the visit.

737 (B) A pharmacist employed by a provider pharmacy shall be physically present at a remote
738 dispensing site when the pharmacist is providing services requiring the physical presence of the
739 pharmacist, including immunizations.

740 (C) A remote dispensing site shall be staffed by an on-site pharmacy technician who is under the
741 continuous supervision of a pharmacist employed by the provider pharmacy.

742 (D) All pharmacy technicians at a remote dispensing site shall be counted for the purpose of
743 establishing the pharmacist-pharmacy technician ratio of the provider pharmacy which,
744 notwithstanding Section 568.006 of the Act, may not exceed three pharmacy technicians for each
745 pharmacist providing supervision.

746 (E) A pharmacy technician working at a remote dispensing site must:

747 (i) have worked at least one year at a retail pharmacy during the three years preceding the date
748 the pharmacy technician begins working at the remote dispensing site; and

749 (ii) have completed a training program on the proper use of a telepharmacy system.

750 (F) A pharmacy technician at a remote dispensing site may not perform sterile or nonsterile
751 compounding. However, a pharmacy technician may prepare commercially available
752 medications for dispensing, including the reconstitution of orally administered powder
753 antibiotics.

754 (7) [~~5~~] Records.

755 (A) Maintenance of records.

756 (i) Every record required under this section must be:

757 (I) kept by the provider pharmacy and be available, for at least two years for inspecting and
758 copying by the board or its representative and to other authorized local, state, or federal law
759 enforcement agencies; and

760 (II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of
761 the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic
762 format, the requested records must be provided in an electronic format if specifically requested
763 by the board or its representative. Failure to provide the records set out in this section, either on

764 site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records
765 in violation of the Act.

766 (ii) The provider pharmacy shall maintain original prescription drug orders for medications
767 dispensed from a remote site using a telepharmacy system in the manner required by §291.34(b)
768 of this title.

769 (iii) If prescription drug records are maintained in a data processing system, the system shall
770 have a workable (electronic) data retention system which can produce a separate audit trail of
771 drug usage by the provider pharmacy and by each remote site for the preceding two years as
772 specified in §291.34(e) of this title.

773 (B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

774 (C) Patient medication records. Patient medication records shall be created and maintained at the
775 provider pharmacy in the manner required by §291.34(c) of this title.

776 (D) Inventory.

777 (i) A provider pharmacy shall:

778 (I) keep a record of all drugs ordered and dispensed by [sent to and returned from] a remote site
779 separate from the records of the provider pharmacy and from any other remote site's records;

780 (II) keep a perpetual inventory of all controlled substances [and other drugs required to be
781 inventoried under §291.17 of this title,] that are received and dispensed or distributed from each
782 remote site. The perpetual inventory shall be reconciled, by a pharmacist employed by the
783 provider pharmacy, at least monthly.

784 (ii) As specified in §291.17 of this title. A provider pharmacy shall conduct an inventory at each
785 remote site. The following is applicable to this inventory.

786 (I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

787 (II) The inventory of each remote site shall be included with, but listed separately from, the drugs
788 of other remote sites and separately from the drugs at the provider pharmacy.