

RULE ANALYSIS

Introduction: THESE NEW RULES ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS PROPOSED RULES

Short Title: Centralized Prescription Processing Pharmacy

Rule Numbers: §291.153

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy;
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act; and
- (3) Section 560.053 gives the Board the authority to adopt rules establishing additional pharmacy classifications.

Purpose: The amendments, if adopted, establish a new class of pharmacy for pharmacies performing centralized prescription drug or medication order processing.

Background: A pilot project was conducted by H.E.B. Pharmacy at a pharmacy performing central prescription processing with a increased ratio of pharmacy technicians. The proposed rules would create a new class of pharmacy and allow for an increased ratio of pharmacists to pharmacy technicians/trainees of 1:5.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER H OTHER CLASSES OF PHARMACIES

5
6 §291.153 Central Prescription Drug or Medication Order Processing Pharmacy
7

8 **(a) Purpose.**

9
10 **(1) The purpose of this section is to provide standards for a centralized prescription**
11 **drug or medication order processing pharmacy.**

12
13 **(2) Any facility established for the purpose of processing prescription drug or**
14 **medication drug orders shall be licensed as a Class G pharmacy under the Act.**
15 **However, nothing in this subsection shall prohibit an individual pharmacist employee**
16 **who is licensed in Texas from remotely accessing the pharmacy's electronic data**
17 **base from outside the pharmacy in order to process prescription or medication drug**
18 **orders, provided the pharmacy establishes controls to protect the privacy and**
19 **security of confidential records.**

20
21 **(b) Definitions. The following words and terms, when used in this section, shall have**
22 **the following meanings, unless the context clearly indicates otherwise. Any term not**
23 **defined in this section shall have the definition set out in the Act. Centralized**
24 **prescription drug or medication order processing--the processing of a prescription**
25 **drug or medication orders by a Class G pharmacy on behalf of another pharmacy, a**
26 **health care provider, or a payor. Centralized prescription drug or medication order**
27 **processing does not include the dispensing of a prescription drug order but includes**
28 **any of the following:**

29
30 **(1) receiving, interpreting, or clarifying prescription drug or medication drug orders;**

31
32 **(2) data entering and transferring of prescription drug or medication order**
33 **information;**

34
35 **(3) performing drug regimen review;**

36
37 **(4) obtaining refill and substitution authorizations;**

38
39 **(5) verifying accurate prescription data entry;**

40
41 **(6) interpreting clinical data for prior authorization for dispensing;**

42
43 **(7) performing therapeutic interventions; and**

44
45 **(8) providing drug information concerning a patient's prescription.**

46
47 **(c) Personnel.**

48
49 **(1) Pharmacist-in-charge.**

50
51 **(A) General.**

52
53 (i) Each Class G pharmacy shall have one pharmacist-in-charge who is employed
54 on a full-time basis, who may be the pharmacist-in-charge for only one such
55 pharmacy; provided, however, such pharmacist-in-charge may be the pharmacist-in-
56 charge of:

57
58 (I) more than one Class G pharmacy, if the additional Class G pharmacies are not
59 open to provide pharmacy services simultaneously; or

60
61 (II) up to two Class G pharmacies open simultaneously if the pharmacist-in-charge
62 works at least 10 hours per week in each pharmacy.

63
64 (ii) The pharmacist-in-charge shall comply with the provisions of §291.17 of this
65 title (relating to Inventory Requirements).

66
67 (B) Responsibilities. The pharmacist-in-charge shall have responsibility for the
68 practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-
69 charge. The pharmacist-in-charge may advise the owner on administrative or
70 operational concerns. The pharmacist-in-charge shall have responsibility for, at a
71 minimum, the following:

72
73 (i) education and training of pharmacy technicians and pharmacy technician
74 trainees;

75
76 (ii) maintaining records of all transactions of the Class G pharmacy required by
77 applicable state and federal laws and sections;

78
79 (iii) adherence to policies and procedures regarding the maintenance of records in
80 a data processing system such that the data processing system is in compliance with
81 Class G pharmacy requirements; and

82
83 (iv) legal operation of the pharmacy, including meeting all inspection and other
84 requirements of all state and federal laws or sections governing the practice of
85 pharmacy.

86
87 (2) Owner. The owner of a Class G pharmacy shall have responsibility for all
88 administrative and operational functions of the pharmacy. The pharmacist-in-charge
89 may advise the owner on administrative and operational concerns. The owner shall
90 have responsibility for, at a minimum, the following, and if the owner is not a Texas
91 licensed pharmacist, the owner shall consult with the pharmacist-in-charge or
92 another Texas licensed pharmacist:

93
94 (A) providing the pharmacy with the necessary equipment and resources
95 commensurate with its level and type of practice; and

96
97 (B) establishment of policies and procedures regarding maintenance, storage, and
98 retrieval of records in a data processing system such that the system is in
99 compliance with state and federal requirements.

100
101 (3) Pharmacists.
102

103 (A) General.

104
105 (i) The pharmacist-in-charge shall be assisted by sufficient number of additional
106 licensed pharmacists as may be required to operate the Class G pharmacy
107 competently, safely, and adequately to meet the needs of the patients of the
108 pharmacy.

109
110 (ii) All pharmacists shall assist the pharmacist-in-charge in meeting his or her
111 responsibilities.

112
113 (iii) Pharmacists are solely responsible for the direct supervision of pharmacy
114 technicians and pharmacy technician trainees and for designating and delegating
115 duties, other than those listed in subparagraph (B) of this paragraph, to pharmacy
116 technicians and pharmacy technician trainees. Each pharmacist:

117
118 (I) shall verify the accuracy of all acts, tasks, and functions performed by
119 pharmacy technicians and pharmacy technician trainees; and

120
121 (II) shall be responsible for any delegated act performed by pharmacy technicians
122 and pharmacy technician trainees under his or her supervision.

123
124 (iv) Pharmacists shall directly supervise pharmacy technicians and pharmacy
125 technician trainees who are entering prescription data into the pharmacy's data
126 processing system by one of the following methods.

127
128 (I) Physically present supervision. A pharmacist shall be physically present to
129 directly supervise a pharmacy technician or pharmacy technician trainee who is
130 entering prescription data into the data processing system. Each prescription entered
131 into the data processing system shall be verified at the time of data entry. If the
132 pharmacist is not physically present due to a temporary absence as specified in
133 §291.33(b)(4) of this title (relating to Operational Standards), on return the pharmacist
134 must:

135
136 (-a-) conduct a drug regimen review for the prescriptions data entered during this
137 time period as specified in §291.33(c)(2) of this title; and

138
139 (-b-) verify that prescription data entered during this time period was entered
140 accurately.

141
142 (II) Electronic supervision. A pharmacist may electronically supervise a pharmacy
143 technician or pharmacy technician trainee who is entering prescription data into the
144 data processing system provided the pharmacist:

145
146 (-a-) is on-site, in the pharmacy where the technician/trainee is located;

147
148 (-b-) has immediate access to any original document containing prescription
149 information or other information related to the dispensing of the prescription. Such
150 access may be through imaging technology provided the pharmacist has the ability to
151 review the original, hardcopy documents if needed for clarification; and

152

153 (-c-) verifies the accuracy of the data entered information prior to the release of
154 the information to the system for storage and/or generation of the prescription label.

155
156 (v) All pharmacists while on duty, shall be responsible for complying with all state
157 and federal laws or rules governing the practice of pharmacy.

158
159 (vi) A dispensing pharmacist shall be responsible for and ensure that the drug is
160 dispensed and delivered safely, and accurately as prescribed, unless the pharmacy's
161 data processing system can record the identity of each pharmacist involved in a
162 specific portion of the dispensing processing. If the system can track the identity of
163 each pharmacist involved in the dispensing process, each pharmacist involved in the
164 dispensing process shall be responsible for and ensure that the portion of the
165 process the pharmacist is performing results in the safe and accurate dispensing and
166 delivery of the drug as prescribed. The dispensing process shall include, but not be
167 limited to, drug regimen review and verification of accurate prescription data entry,
168 including data entry of prescriptions placed on hold, packaging, preparation,
169 compounding and labeling, and performance of the final check of the dispensed
170 prescription.

171
172 (B) Duties. Duties which may only be performed by a pharmacist are as follows:

173
174 (i) receiving oral prescription drug orders and reducing these orders to writing,
175 either manually or electronically;

176
177 (ii) interpreting prescription drug orders;

178
179 (iii) selection of drug products;

180
181 (iv) performing the final check of the dispensed prescription before delivery to the
182 patient to ensure that the prescription has been dispensed accurately as prescribed;

183
184 (v) communicating to the patient or patient's agent information about the
185 prescription drug or device which in the exercise of the pharmacist's professional
186 judgment, the pharmacist deems significant, as specified in §291.33(c) of this title;

187
188 (vi) communicating to the patient or the patient's agent on his or her request
189 information concerning any prescription drugs dispensed to the patient by the
190 pharmacy;

191
192 (vii) assuring that a reasonable effort is made to obtain, record, and maintain
193 patient medication records;

194
195 (viii) interpreting patient medication records and performing drug regimen reviews;
196 and

197
198 (ix) performing a specific act of drug therapy management for a patient delegated
199 to a pharmacist by a written protocol from a physician licensed in this state in
200 compliance with the Medical Practice Act.

201
202 (4) Pharmacy Technicians and Pharmacy Technician Trainees.

203

204 (A) General. All pharmacy technicians and pharmacy technician trainees shall meet
205 the training requirements specified in §297.6 of this title (relating to Pharmacy
206 Technician and Pharmacy Technician Trainee Training).

207
208 (B) Duties.

209
210 (i) Pharmacy technicians and pharmacy technician trainees may not perform any of
211 the duties listed in paragraph (3)(B) of this subsection.

212
213 (ii) A pharmacist may delegate to pharmacy technicians and pharmacy technician
214 trainees any nonjudgmental technical duty associated with the preparation and
215 distribution of prescription drugs provided:

216
217 (I) a pharmacist verifies the accuracy of all acts, tasks, and functions performed
218 by pharmacy technicians and pharmacy technician trainees;

219
220 (II) pharmacy technicians and pharmacy technician trainees are under the direct
221 supervision of and responsible to a pharmacist; and

222
223 (iii) Pharmacy technicians and pharmacy technician trainees may perform only
224 nonjudgmental technical duties associated with the preparation of prescription drugs,
225 as follows:

226
227 (i) initiating and receiving refill authorization requests; and

228
229 (ii) entering prescription data into a data processing system.

230
231 (C) Ratio of pharmacist to pharmacy technicians and pharmacy technician trainees.
232 A Class G pharmacy may have a ratio of pharmacists to pharmacy
233 technicians/pharmacy technician trainees of 1:5 provided:

234
235 (i) at least four are pharmacy technicians and not pharmacy technician trainees;
236 and

237
238 (ii) the pharmacy has written policies and procedures regarding the supervision of
239 pharmacy technicians and pharmacy technician trainees, including requirements that
240 the pharmacy technicians and pharmacy technician trainees included in a 1:5 ratio
241 may be involved only in one process at a time. For example, a technician/trainee who
242 is involved in the data entry of prescription drug orders may not also call physicians
243 for authorization of refills.

244
245 (5) Identification of pharmacy personnel. All pharmacy personnel shall be identified
246 as follows.

247
248 (A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag
249 or badge that bears the person's name and identifies him or her as a pharmacy
250 technician, or a certified pharmacy technician, if the technician maintains current
251 certification with the Pharmacy Technician Certification Board or any other entity
252 providing an examination approved by the board.

253

254 (B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an
255 identification tag or badge that bears the person's name and identifies him or her as a
256 pharmacy technician trainee.

257
258 (C) Pharmacist interns. All pharmacist interns shall wear an identification tag or
259 badge that bears the person's name and identifies him or her as a pharmacist intern.

260
261 (D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears
262 the person's name and identifies him or her as a pharmacist.

263
264 (d) Operational Standards.

265
266 (1) General requirements. A Class A, Class C, or Class E Pharmacy may outsource
267 prescription drug or medication order processing to a Class G pharmacy provided the
268 pharmacies:

269 (A) have:

270
271
272 (i) the same owner; or

273
274 (ii) entered into a written contract or agreement which outlines the services to be
275 provided and the responsibilities and accountabilities of each pharmacy in
276 compliance with federal and state laws and regulations; and

277
278 (B) share a common electronic file or have appropriate technology to allow access
279 to sufficient information necessary or required to process a non-dispensing function.

280
281 (2) Notifications to patients.

282
283 (A) A pharmacy that outsources prescription drug or medication order processing
284 to another pharmacy shall prior to outsourcing their prescription:

285
286 (i) notify patients that prescription processing may be outsourced to another
287 pharmacy; and

288
289 (ii) give the name of that pharmacy; or if the pharmacy is part of a network of
290 pharmacies under common ownership and any of the network pharmacies may
291 process the prescription, the patient shall be notified of this fact. Such notification
292 may be provided through a one-time written notice to the patient or through use of a
293 sign in the pharmacy.

294
295 (B) The provisions of this paragraph do not apply to patients in facilities where
296 drugs are administered to patients by a person required to do so by the laws of the
297 state (i.e., hospitals or nursing homes).

298
299 (3) Policy and Procedures. A policy and procedure manual as it relates to central
300 processing shall be maintained at all pharmacies involved in central processing and
301 be available for inspection. Each pharmacy is required to maintain only those
302 portions of the policy and procedure manual that relate to that pharmacy's
303 operations. The manual shall:

305 (A) outline the responsibilities of each of the pharmacies;
306
307 (B) include a list of the name, address, telephone numbers, and all
308 license/registration numbers of the pharmacies involved in centralized prescription
309 drug or medication order processing; and
310
311 (C) include policies and procedures for:
312
313 (i) protecting the confidentiality and integrity of patient information;
314
315 (ii) maintenance of appropriate records to identify the name(s), initials, or
316 identification code(s) and specific activity(ies) of each pharmacist or pharmacy
317 technician who performed any processing;
318
319 (iii) complying with federal and state laws and regulations;
320
321 (iv) operating a continuous quality improvement program for pharmacy services
322 designed to objectively and systematically monitor and evaluate the quality and
323 appropriateness of patient care, pursue opportunities to improve patient care, and
324 resolve identified problems; and
325
326 (v) annually reviewing the written policies and procedures and documenting such
327 review.
328
329 (e) Records. All pharmacies shall maintain appropriate records which identify, by
330 prescription drug or medication order, the name(s), initials, or identification code(s)
331 of each pharmacist, pharmacy technician, or pharmacy technician trainee who
332 performs a processing function for a prescription drug or medication order. Such
333 records may be maintained:
334
335 (1) separately by each pharmacy and pharmacist; or
336
337 (2) in a common electronic file as long as the records are maintained in such a
338 manner that the data processing system can produce a printout which lists the
339 functions performed by each pharmacy and pharmacist.
340
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