

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

**Short Title:** Non-sterile Compounding

**Rule Numbers:** §291.131

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-569, 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; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

**Purpose:** The amendments, if adopted, specify that a pharmacist must review the original prescription record when dispensing a non-sterile compounded preparation.

1 TITLE 22 EXAMINING BOARDS  
2 PART 15 TEXAS STATE BOARD OF PHARMACY  
3 CHAPTER 291 PHARMACIES  
4 SUBCHAPTER G SERVICES PROVIDED BY PHARMACIES  
5 §291.131 Pharmacies Compounding Non-Sterile Preparations  
6  
7

8 (a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical  
9 products and distributing those products shall comply with all requirements for their specific  
10 license classification and this section. The purpose of this section is to provide standards for  
11 the:

12  
13 (1) compounding of non-sterile preparations pursuant to a prescription or medication order for  
14 a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-  
15 resident) pharmacies;

16  
17 (2) compounding, dispensing, and delivery of a reasonable quantity of a compounded non-  
18 sterile preparation in a Class A [~~Community~~], Class C [~~Institutional~~], and Class E [~~Non-~~  
19 ~~resident~~] pharmacies to a practitioner's office for office use by the practitioner;

20  
21 (3) compounding and distribution of compounded non-sterile preparations by a Class A  
22 (Community) pharmacy for a Class C [~~Institutional~~] pharmacy; and

23  
24 (4) compounding of non-sterile preparations by a Class C [~~Institutional~~] pharmacy and the  
25 distribution of the compounded preparations to other Class C [~~Institutional~~] pharmacies under  
26 common ownership.

27  
28 (b) Definitions. In addition to the definitions for specific license classifications, the following  
29 words and terms, when used in this section, shall have the following meanings, unless the  
30 context clearly indicates otherwise.

31  
32 (1) Beyond-use date--The date or time after which the compounded non-sterile preparation  
33 shall not be stored or transported or begin to be administered to a patient. The beyond-use date  
34 is determined from the date or time when the preparation was compounded.

35  
36 (2) Component--Any ingredient intended for use in the compounding of a drug preparation,  
37 including those that may not appear in such preparation.

38  
39 (3) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or  
40 device:

41  
42 (A) as the result of a practitioner's prescription drug or medication order, based on the  
43 practitioner-patient-pharmacist relationship in the course of professional practice;

44  
45 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative  
46 based on the practitioner-patient-pharmacist relationship in the course of professional practice;

47  
48 (C) in anticipation of prescription drug or medication orders based on routine, regularly  
49 observed prescribing patterns; or  
50

51 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or  
52 dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.

53  
54 (4) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of  
55 105 degrees F (41 degrees C).

56  
57 (5) Reasonable quantity--An amount of a compounded drug that:

58  
59 (A) does not exceed the amount a practitioner anticipates may be used in the practitioner's  
60 office or facility before the beyond use date of the drug;

61  
62 (B) is reasonable considering the intended use of the compounded drug and the nature of the  
63 practitioner's practice; and

64  
65 (C) for any practitioner and all practitioners as a whole, is not greater than an amount the  
66 pharmacy is capable of compounding in compliance with pharmaceutical standards for identity,  
67 strength, quality, and purity of the compounded drug that are consistent with United States  
68 Pharmacopoeia guidelines and accreditation practices.

69  
70 (6) SOPs--Standard operating procedures.

71  
72 (7) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.

73  
74 (c) Personnel.

75  
76 (1) Pharmacist-in-charge. In addition to the responsibilities for the specific class of pharmacy,  
77 the pharmacist-in-charge shall have the responsibility for, at a minimum, the following  
78 concerning non-sterile compounding:

79  
80 (A) determining that all personnel involved in non-sterile compounding possess the  
81 education, training, and proficiency necessary to properly and safely perform compounding  
82 duties undertaken or supervised;

83  
84 (B) determining that all personnel involved in non-sterile compounding obtain continuing  
85 education appropriate for the type of compounding done by the personnel;

86  
87 (C) assuring that the equipment used in compounding is properly maintained;

88  
89 (D) maintaining an appropriate environment in areas where non-sterile compounding occurs;  
90 and

91  
92 (E) assuring that effective quality control procedures are developed and followed.

93  
94 (2) Pharmacists. Special requirements for non-sterile compounding.

95  
96 (A) All pharmacists engaged in compounding shall:

97  
98 (i) possess the education, training, and proficiency necessary to properly and safely perform  
99 compounding duties undertaken or supervised; and

100

101 (ii) obtain continuing education appropriate for the type of compounding done by the  
102 pharmacist.

103  
104 (B) A pharmacist shall inspect and approve all components, drug product containers,  
105 closures, labeling, and any other materials involved in the compounding process.  
106

107 (C) A pharmacist shall review all compounding records for accuracy and conduct **periodic** in-  
108 process **checks as defined in the pharmacy's policies and procedures.** [~~and final checks to~~  
109 ~~ensure that errors have not occurred in the compounding process.~~]  
110

111 (D) **A pharmacist shall review all compounding records for accuracy, including the**  
112 **original prescription drug order, and conduct a final check.**  
113

114 **(E)** A pharmacist is responsible for the proper maintenance, cleanliness, and use of all  
115 equipment used in the compounding process.  
116

117 (3) Pharmacy technicians and pharmacy technician trainees. All pharmacy technicians and  
118 pharmacy technician trainees engaged in non-sterile compounding shall:  
119

120 (A) possess the education, training, and proficiency necessary to properly and safely perform  
121 compounding duties undertaken;  
122

123 (B) obtain continuing education appropriate for the type of compounding done by the  
124 pharmacy technician or pharmacy technician trainee; and  
125

126 (C) perform compounding duties under the direct supervision of and responsible to a  
127 pharmacist.  
128

129 (4) Training.  
130

131 (A) All training activities shall be documented and covered by appropriate SOPs as outlined in  
132 subsection (d)(8)(A) of this section.  
133

134 (B) All personnel involved in non-sterile compounding shall be well trained and must  
135 participate in continuing relevant training programs.  
136

137 (d) Operational Standards.  
138

139 (1) General requirements.  
140

141 (A) Non-sterile drug preparations may be compounded in licensed pharmacies:  
142

143 (i) upon presentation of a practitioner's prescription drug or medication order based on a  
144 valid pharmacist/patient/prescriber relationship;  
145

146 (ii) in anticipation of future prescription drug or medication orders based on routine, regularly  
147 observed prescribing patterns; or  
148

149 (iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.  
150

151 (B) Non-sterile compounding in anticipation of future prescription drug or medication orders  
152 must be based upon a history of receiving valid prescriptions issued within an established  
153 pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional  
154 judgment the quantity prepared is stable for the anticipated shelf time.

155  
156 (i) The pharmacist's professional judgment shall be based on the criteria used to determine  
157 a beyond-use date outlined in paragraph (5)(C) of this subsection.

158  
159 (ii) Documentation of the criteria used to determine the stability for the anticipated shelf time  
160 must be maintained and be available for inspection.

161  
162 (iii) Any preparation compounded in anticipation of future prescription drug or medication  
163 orders shall be labeled. Such label shall contain:

164  
165 (I) name and strength of the compounded preparation or list of the active ingredients and  
166 strengths;

167  
168 (II) facility's lot number;

169  
170 (III) beyond-use date as determined by the pharmacist using appropriate documented  
171 criteria as outlined in paragraph (5)(C) of this subsection; and

172  
173 (IV) quantity or amount in the container.

174  
175 (C) Commercially available products may be compounded for dispensing to individual  
176 patients provided the following conditions are met:

177  
178 (i) the commercial product is not reasonably available from normal distribution channels in a  
179 timely manner to meet patient's needs;

180  
181 (ii) the pharmacy maintains documentation that the product is not reasonably available due  
182 to a drug shortage or unavailability from the manufacturer; and

183  
184 (iii) the prescribing practitioner has requested that the drug be compounded as described in  
185 subparagraph (D) of this paragraph.

186  
187 (D) A pharmacy may not compound preparations that are essentially copies of commercially  
188 available products (e.g., the preparation is dispensed in a strength that is only slightly different  
189 from a commercially available product) unless the prescribing practitioner specifically orders the  
190 strength or dosage form and specifies why the patient needs the particular strength or dosage  
191 form of the preparation. The prescribing practitioner shall provide documentation of a patient  
192 specific medical need and the preparation produces a clinically significant therapeutic response  
193 (e.g. the physician requests an alternate product due to hypersensitivity to excipients or  
194 preservative in the FDA-approved product, or the physician requests an effective alternate  
195 dosage form) or if the drug product is not commercially available. The unavailability of such drug  
196 product must be documented prior to compounding. The methodology for documenting  
197 unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered,  
198 discontinued, or out-of-stock items. This documentation must be available in hard-copy or  
199 electronic format for inspection by the board.

200

201 (E) A pharmacy may enter into an agreement to compound and dispense  
202 prescription/medication orders for another pharmacy provided the pharmacy complies with the  
203 provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

204  
205 (F) Compounding pharmacies/pharmacists may advertise and promote the fact that they  
206 provide non-sterile prescription compounding services, which may include specific drug  
207 products and classes of drugs.

208  
209 (G) A pharmacy may not compound veterinary preparations for use in food producing animals  
210 except in accordance with federal guidelines.

211  
212 (H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's  
213 agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-  
214 date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise  
215 documented. Documentation of beyond-use-dates longer than fourteen days shall be  
216 maintained by the pharmacy electronically or manually and made available to agents of the  
217 board on request. A pharmacist may not add flavoring to an over-the-counter product at the  
218 request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-  
219 the-counter product from the patient's practitioner.

220  
221 (2) Library. In addition to the library requirements of the pharmacy's specific license  
222 classification, a pharmacy shall maintain a current copy, in hard-copy or electronic format, of  
223 Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations.

224  
225 (3) Environment.

226  
227 (A) Pharmacies regularly engaging in compounding shall have a designated and adequate  
228 area for the safe and orderly compounding of non-sterile preparations, including the placement  
229 of equipment and materials. Pharmacies involved in occasional compounding shall prepare an  
230 area prior to each compounding activity which is adequate for safe and orderly compounding.

231  
232 (B) Only personnel authorized by the responsible pharmacist shall be in the immediate  
233 vicinity of a drug compounding operation.

234  
235 (C) A sink with hot and cold running water, exclusive of rest room facilities, shall be  
236 accessible to the compounding areas and be maintained in a sanitary condition. Supplies  
237 necessary for adequate washing shall be accessible in the immediate area of the sink and  
238 include:

239  
240 (i) soap or detergent; and

241  
242 (ii) air-driers or single-use towels.

243  
244 (D) If drug products which require special precautions to prevent contamination, such as  
245 penicillin, are involved in a compounding operation, appropriate measures, including dedication  
246 of equipment for such operations or the meticulous cleaning of contaminated equipment prior to  
247 its use for the preparation of other drug products, must be used in order to prevent cross-  
248 contamination.

249  
250 (4) Equipment and Supplies. The pharmacy shall:

251

252 (A) have a Class A prescription balance, or analytical balance and weights which shall be  
253 properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;  
254 and

255  
256 (B) have equipment and utensils necessary for the proper compounding of prescription drug  
257 or medication orders. Such equipment and utensils used in the compounding process shall be:

258  
259 (i) of appropriate design and capacity, and be operated within designed operational limits;

260  
261 (ii) of suitable composition so that surfaces that contact components, in-process material, or  
262 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,  
263 strength, quality, or purity of the drug product beyond the desired result;

264  
265 (iii) cleaned and sanitized immediately prior and after to each use; and

266  
267 (iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

268  
269 (5) Labeling. In addition to the labeling requirements of the pharmacy's specific license  
270 classification, the label dispensed or distributed pursuant to a prescription drug or medication  
271 order shall contain the following.

272  
273 (A) The generic name(s) or the official name(s) of the principal active ingredient(s) of the  
274 compounded preparation.

275  
276 (B) A statement that the preparation has been compounded by the pharmacy. (An auxiliary  
277 label may be used on the container to meet this requirement).

278  
279 (C) A beyond-use date after which the compounded preparation should not be used. The  
280 beyond-use date shall be determined as outlined in Chapter 795 of the USP/NF concerning  
281 Pharmacy Compounding Non-Sterile Preparations including the following:

282  
283 (i) The pharmacist shall consider:

284  
285 (I) physical and chemical properties of active ingredients;

286  
287 (II) use of preservatives and/or stabilizing agents;

288  
289 (III) dosage form;

290  
291 (IV) storage containers and conditions; and

292  
293 (V) scientific, laboratory, or reference data from a peer reviewed source and retained in the  
294 pharmacy. The reference data should follow the same preparation instructions for combining  
295 raw materials and packaged in a container with similar properties.

296  
297 (ii) In the absence of stability information applicable for a specific drug or preparation, the  
298 following maximum beyond-use dates are to be used when the compounded preparation is  
299 packaged in tight, light-resistant containers and stored at controlled room temperatures.

300

301 (I) Nonaqueous liquids and solid formulations (Where the manufactured drug product is the  
302 source of active ingredient): 25% of the time remaining until the product's expiration date or 6  
303 months, whichever is earlier.

304  
305 (II) Water-containing formulations (Prepared from ingredients in solid form): Not later than  
306 14 days when refrigerated between 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit).

307  
308 (III) All other formulations: Intended duration of therapy or 30 days, whichever is earlier.

309  
310 (iii) Beyond-use date limits may be exceeded when supported by valid scientific stability  
311 information for the specific compounded preparation.

312  
313 (6) Written drug information. Written information about the compounded preparation or its  
314 major active ingredient(s) shall be given to the patient at the time of dispensing. A statement  
315 which indicates that the preparation was compounded by the pharmacy must be included in this  
316 written information. If there is no written information available, the patient should be advised that  
317 the drug has been compounded and how to contact a pharmacist, and if appropriate the  
318 prescriber, concerning the drug.

319  
320 (7) Drugs, components, and materials used in non-sterile compounding.

321  
322 (A) Drugs used in non-sterile compounding shall be a USP/NF grade substances  
323 manufactured in an FDA-registered facility.

324  
325 (B) If USP/NF grade substances are not available, or when food, cosmetics, or other  
326 substances are, or must be used, the substance shall be of a chemical grade in one of the  
327 following categories:

328  
329 (i) Chemically Pure (CP);

330  
331 (ii) Analytical Reagent (AR); or

332  
333 (iii) American Chemical Society (ACS); or

334  
335 (iv) Food Chemical Codex; or

336  
337 (C) If a drug, component or material is not purchased from a FDA-registered facility, the  
338 pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the  
339 supplier and the pharmacist shall compare the monograph of drugs in a similar class to the  
340 Certificate of Analysis.

341  
342 (D) A manufactured drug product may be a source of active ingredient. Only manufactured  
343 drugs from containers labeled with a batch control number and a future expiration date are  
344 acceptable as a potential source of active ingredients. When compounding with manufactured  
345 drug products, the pharmacist must consider all ingredients present in the drug product relative  
346 to the intended use of the compounded preparation.

347  
348 (E) All components shall be stored in properly labeled containers in a clean, dry area, under  
349 proper temperatures.

350

351 (F) Drug product containers and closures shall not be reactive, additive, or absorptive so as  
352 to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond  
353 the desired result.

354  
355 (G) Components, drug product containers, and closures shall be rotated so that the oldest  
356 stock is used first.

357  
358 (H) Container closure systems shall provide adequate protection against foreseeable external  
359 factors in storage and use that can cause deterioration or contamination of the compounded  
360 drug product.

361  
362 (I) A pharmacy may not compound a preparation that contains ingredients appearing on a  
363 federal Food and Drug Administration list of drug products withdrawn or removed from the  
364 market for safety reasons.

365  
366 (8) Compounding process.

367  
368 (A) All significant procedures performed in the compounding area shall be covered by written  
369 SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the  
370 compounding process. At a minimum, SOPs shall be developed for:

- 371 (i) the facility;  
372  
373 (ii) equipment;  
374  
375 (iii) personnel;  
376  
377 (iv) preparation evaluation;  
378  
379 (v) quality assurance;  
380  
381 (vi) preparation recall;  
382  
383 (vii) packaging; and  
384  
385 (viii) storage of compounded preparations.

386  
387  
388 (B) Any compounded preparation with an official monograph in the USP/NF shall be  
389 compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.

390  
391 (C) Any person with an apparent illness or open lesion that may adversely affect the safety or  
392 quality of a drug product being compounded shall be excluded from direct contact with  
393 components, drug product containers, closures, any materials involved in the compounding  
394 process, and drug products until the condition is corrected.

395  
396 (D) Personnel engaged in the compounding of drug preparations shall wear clean clothing  
397 appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons,  
398 hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect  
399 personnel from chemical exposure and drug preparations from contamination.

400

401 (E) At each step of the compounding process, the pharmacist shall ensure that components  
402 used in compounding are accurately weighed, measured, or subdivided as appropriate to  
403 conform to the formula being prepared.

404  
405 (9) Quality Assurance.

406  
407 (A) Initial formula validation. Prior to routine compounding of a non-sterile preparation, a  
408 pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding  
409 a product that contains the stated amount of active ingredient(s).

410  
411 (B) Finished preparation checks. The prescription drug and medication orders, written  
412 compounding procedure, preparation records, and expended materials used to make  
413 compounded non-sterile preparations shall be inspected for accuracy of correct identities and  
414 amounts of ingredients, packaging, labeling, and expected physical appearance before the non-  
415 sterile preparations are dispensed.

416  
417 (10) Quality Control.

418  
419 (A) The pharmacy shall follow established quality control procedures to monitor the quality of  
420 compounded drug preparations for uniformity and consistency such as capsule weight  
421 variations, adequacy of mixing, clarity, or pH of solutions. When developing these procedures,  
422 pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy  
423 Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding  
424 Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription  
425 Compounding contained in the current USP/NF. Such procedures shall be documented and be  
426 available for inspection.

427  
428 (B) Compounding procedures that are routinely performed, including batch compounding,  
429 shall be completed and verified according to written procedures. The act of verification of a  
430 compounding procedure involves checking to ensure that calculations, weighing and measuring,  
431 order of mixing, and compounding techniques were appropriate and accurately performed.

432  
433 (C) Unless otherwise indicated or appropriate, compounded preparations are to be prepared  
434 to ensure that each preparation shall contain not less than 90.0 percent and not more than  
435 110.0 percent of the theoretically calculated and labeled quantity of active ingredient per unit  
436 weight or volume and not less than 90.0 percent and not more than 110.0 percent of the  
437 theoretically calculated weight or volume per unit of the preparation.

438  
439 (e) Records.

440  
441 (1) Maintenance of records. Every record required by this section shall be:

442  
443 (A) kept by the pharmacy and be available, for at least two years for inspecting and copying  
444 by the board or its representative and to other authorized local, state, or federal law  
445 enforcement agencies; and

446  
447 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the  
448 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,  
449 the requested records must be provided in an electronic format. Failure to provide the records  
450 set out in this section, either on site or within 72 hours, constitutes prima facie evidence of  
451 failure to keep and maintain records in violation of the Act.

452  
453 (2) Compounding records.

454  
455 (A) Compounding pursuant to patient specific prescription drug or medication orders.  
456 Compounding records for all compounded preparations shall be maintained by the pharmacy  
457 electronically or manually as part of the prescription drug or medication order, formula record,  
458 formula book, or compounding log and shall include:

459  
460 (i) the date of preparation;

461  
462 (ii) a complete formula, including methodology and necessary equipment which includes the  
463 brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of  
464 the manufacturer(s) of the raw materials and the quantities of each;

465  
466 (iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician  
467 trainee performing the compounding;

468  
469 (iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians  
470 or pharmacy technician trainees and conducting in-process and final checks of compounded  
471 preparations if pharmacy technicians or pharmacy technician trainees perform the compounding  
472 function;

473  
474 (v) the quantity in units of finished preparations or amount of raw materials;

475  
476 (vi) the container used and the number of units prepared;

477  
478 (vii) a reference to the location of the following documentation which may be maintained with  
479 other records, such as quality control records:

480  
481 (I) the criteria used to determine the beyond-use date; and

482  
483 (II) documentation of performance of quality control procedures. Documentation of the  
484 performance of quality control procedures is not required if the compounding process is done  
485 pursuant to a patient specific order and involves the mixing of two or more commercially  
486 available oral liquids or commercially available preparations when the final product is intended  
487 for external use.

488  
489 (B) Compounding records when batch compounding or compounding in anticipation of future  
490 prescription drug or medication orders.

491  
492 (i) Master work sheet. A master work sheet shall be developed and approved by a  
493 pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work  
494 sheet shall be used as the preparation work sheet from which each batch is prepared and on  
495 which all documentation for that batch occurs. The master work sheet shall contain at a  
496 minimum:

497  
498 (I) the formula;

499  
500 (II) the components;

501  
502 (III) the compounding directions;

503  
504 (IV) a sample label;  
505  
506 (V) evaluation and testing requirements;  
507  
508 (VI) specific equipment used during preparation; and  
509  
510 (VII) storage requirements.  
511  
512 (ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall  
513 document the following:  
514  
515 (I) identity of all solutions and ingredients and their corresponding amounts,  
516 concentrations, or volumes;  
517  
518 (II) lot number or each component;  
519  
520 (III) component manufacturer/distributor or suitable identifying number;  
521  
522 (IV) container specifications;  
523  
524 (V) unique lot or control number assigned to batch;  
525  
526 (VI) beyond use date of batch-prepared preparations;  
527  
528 (VII) date of preparation;  
529  
530 (VIII) name, initials, or electronic signature of the person(s) involved in the preparation;  
531  
532 (IX) name, initials, or electronic signature of the responsible pharmacist;  
533  
534 (X) finished preparation evaluation and testing specifications, if applicable; and  
535  
536 (XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.  
537  
538 (f) Office Use Compounding and Distribution of Compounded Preparations to Class C  
539 Pharmacies or Veterinarians in Accordance With §563.054 of the Act.  
540  
541 (1) General.  
542  
543 (A) A pharmacy may dispense and deliver a reasonable quantity of a compounded  
544 preparation to a practitioner for office use by the practitioner in accordance with this subsection.  
545  
546 (B) A Class A ~~[(Community)]~~ pharmacy is not required to register or be licensed under  
547 Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations to a  
548 Class C ~~[(Institutional)]~~ pharmacy.  
549  
550 (C) A Class C ~~[(Institutional)]~~ pharmacy is not required to register or be licensed under  
551 Chapter 431, Health and Safety Code, to distribute non-sterile compounded preparations that  
552 the Class C pharmacy has compounded for other Class C pharmacies under common  
553 ownership.

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(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:

(i) verify the source of the raw materials to be used in a compounded drug;

(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);

(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;

(iv) comply with all applicable competency and accrediting standards as determined by the board; and

(v) comply with the provisions of this subsection.

(2) Written Agreement. A pharmacy that provides non-sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:

(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded preparations may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;

(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order, or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient; and

(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:

(i) a patient to report an adverse reaction or submit a complaint; and

(ii) the pharmacy to recall batches of compounded preparations.

(3) Recordkeeping.

(A) Maintenance of Records.

(i) Records of orders and distribution of non-sterile compounded preparations to a practitioner for office use or to a Class C (Institutional) pharmacy for administration to a patient shall:

(l) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies;

604 (II) maintained separately from the records of products dispensed pursuant to a  
605 prescription or medication order; and  
606

607 (III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the  
608 Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in  
609 an electronic format, the requested records must be provided in an electronic format. Failure to  
610 provide the records set out in this subsection, either on site or within 72 hours for whatever  
611 reason, constitutes prima facie evidence of failure to keep and maintain records.  
612

613 (ii) Records may be maintained in an alternative data retention system, such as a data  
614 processing system or direct imaging system provided the data processing system is capable of  
615 producing a hard copy of the record upon the request of the board, its representative, or other  
616 authorized local, state, or federal law enforcement or regulatory agencies.  
617

618 (B) Orders. The pharmacy shall maintain a record of all non-sterile compounded preparations  
619 ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient.  
620 The record shall include the following information:

621 (i) date of the order;

622 (ii) name, address, and phone number of the practitioner who ordered the preparation and if  
623 applicable, the name, address and phone number of the Class C pharmacy ordering the  
624 preparation; and  
625  
626

627 (iii) name, strength, and quantity of the preparation ordered.  
628

629 (C) Distributions. The pharmacy shall maintain a record of all non-sterile compounded  
630 preparations distributed pursuant to an order to a practitioner for office use or by a Class C  
631 pharmacy for administration to a patient. The record shall include the following information:  
632

633 (i) date the preparation was compounded;

634 (ii) date the preparation was distributed;

635 (iii) name, strength and quantity in each container of the preparation;

636 (iv) pharmacy's lot number;

637 (v) quantity of containers shipped; and  
638

639 (vi) name, address, and phone number of the practitioner or Class C pharmacy to whom the  
640 preparation is distributed.  
641

642 (D) Audit Trail.  
643

644 (i) The pharmacy shall store the order and distribution records of preparations for all non-  
645 sterile compounded preparations ordered by and or distributed to a practitioner for office use or  
646 by a Class C pharmacy for administration to a patient in such a manner as to be able to provide  
647 a audit trail for all orders and distributions of any of the following during a specified time period.  
648  
649  
650  
651  
652  
653

654 (I) any strength and dosage form of a preparation (by either brand or generic name or  
655 both);

656  
657 (II) any ingredient;

658  
659 (III) any lot number;

660  
661 (IV) any practitioner;

662  
663 (V) any facility; and

664  
665 (VI) any pharmacy, if applicable.

666  
667 (ii) The audit trail shall contain the following information:

668  
669 (I) date of order and date of the distribution;

670  
671 (II) practitioner's name, address, and name of the Class C pharmacy, if applicable;

672  
673 (III) name, strength and quantity of the preparation in each container of the preparation;

674  
675 (IV) name and quantity of each active ingredient;

676  
677 (V) quantity of containers distributed; and

678  
679 (VI) pharmacy's lot number;

680  
681 (4) Labeling. The pharmacy shall affix a label to the preparation containing the following  
682 information:

683  
684 (A) name, address, and phone number of the compounding pharmacy;

685  
686 (B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation  
687 is distributed to a veterinarian the statement: "Compounded Preparation";

688  
689 (C) name and strength of the preparation or list of the active ingredients and strengths;

690  
691 (D) pharmacy's lot number;

692  
693 (E) beyond-use date as determined by the pharmacist using appropriate documented criteria;

694  
695 (F) quantity or amount in the container;

696  
697 (G) appropriate ancillary instructions, such as storage instructions or cautionary statements,  
698 including hazardous drug warning labels where appropriate; and

699  
700 (H) device-specific instructions, where appropriate.

701  
702 (g) Recall Procedures.

703

704 (1) The pharmacy shall have written procedures for the recall of any compounded non-sterile  
705 preparations provided to a patient, to a practitioner for office use, or a pharmacy for  
706 administration. Written procedures shall include, but not be limited to the requirements as  
707 specified in paragraph (3) of this subsection.  
708

709 (2) The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded  
710 by the pharmacy upon identification of a potential or confirmed harm to a patient.  
711

712 (3) In the event of a recall, the pharmacist-in-charge shall ensure that:  
713

714 (A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is  
715 notified, in writing, of the recall;  
716

717 (B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;  
718

719 (C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;  
720

721 (D) if the preparation is distributed for office use, the Texas Department of State Health  
722 Services, Drugs and Medical Devices Group, is notified of the recall, in writing;  
723

724 (E) the preparation is quarantined; and  
725

726 (F) the pharmacy keeps a written record of the recall including all actions taken to notify all  
727 parties and steps taken to ensure corrective measures.  
728

729 (4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if  
730 there is potential for or confirmed harm to a patient.  
731

WRITTEN PRESCRIPTION INFORMATION:

Bethanechol 1mg/ml per GTube  
tid x 30d  
#90ml

PRESCRIPTION LABEL INFORMATION:

BETHANECHOL 5MG/MG

Give 0.8ML BY MOUTH FOUR TIMES DAILY