

Representative Evan J. Vickers proposes the following substitute bill:

PHARMACY AUDIT RIGHTS

2012 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

Senate Sponsor: Stephen H. Urquhart

LONG TITLE

General Description:

This bill requires health benefit plans, the Public Employees' Benefits and Insurance Program, and pharmacy benefit managers to implement certain pharmacy audit procedures when auditing pharmacy claims.

Highlighted Provisions:

This bill:

- ▶ requires a health insurer and a pharmacy benefits manager for a health insurer to comply with pharmacy audit rights established in the Pharmacy Practice Act;
- ▶ requires the Public Employees' Benefit and Insurance Program to comply with pharmacy audit rights established in the Pharmacy Practice Act;
- ▶ amends the definition of pharmacy benefits manager in the Pharmacy Practice Act to be consistent with the definition of pharmacy benefits manager in the Pharmacy Benefits Manager Act; and
- ▶ enacts pharmacy audit rights in the Pharmacy Practices Act that include:
 - definitions;
 - requirements for notice of an audit;
 - limits on the types of claims that may be audited; and
 - requirements for an entity conducting an audit.



26 **Money Appropriated in this Bill:**

27 None

28 **Other Special Clauses:**

29 None

30 **Utah Code Sections Affected:**

31 AMENDS:

32 **49-20-503**, as enacted by Laws of Utah 2011, Chapter 83

33 **58-17b-102**, as last amended by Laws of Utah 2010, Chapter 101

34 ENACTS:

35 **31A-22-640**, Utah Code Annotated 1953

36 **58-17b-622**, Utah Code Annotated 1953



38 *Be it enacted by the Legislature of the state of Utah:*

39 Section 1. Section **31A-22-640** is enacted to read:

40 **31A-22-640. Pharmacy benefit management services -- Audit restrictions.**

41 (1) For purposes of this section "pharmacy benefits manager or coordinator" means a
42 person or entity that provides pharmacy benefit management services as defined in Section
43 49-20-502 on behalf of an insurer as defined in Subsection 31A-22-636(1).

44 (2) An insurer and an insurer's pharmacy benefits manager or coordinator is subject to
45 the pharmacy audit provisions of Section 58-17b-622.

46 Section 2. Section **49-20-503** is amended to read:

47 **49-20-503. Request for proposals for pharmacy benefits manager for Public**
48 **Employees' Benefit and Insurance Program.**

49 (1) When the board issues a request for proposals for a pharmacy benefits manager to
50 provide pharmacy benefits management services for the program, the request for proposals
51 shall:

52 (a) require each responder to comply with the pharmacy audit provisions of Section
53 58-17b-622; and

54 (b) provide each responder with the option to include, among the billing options
55 proposed, a billing option that complies with the requirements described in this section.

56 (2) The billing option described in Subsection (1) shall require the pharmacy benefits

57 manager to, on at least a monthly basis, submit to the board an invoice for all pharmacy
58 services paid by the pharmacy benefits manager on behalf of the program since the last request
59 for payment or reimbursement.

60 (3) The invoice described in Subsection (2) shall state, as a separate item from any
61 other amount:

62 (a) the total amount due to the pharmacy benefits manager for all pharmacy services
63 billed in the invoice; and

64 (b) the total amount paid by the pharmacy benefits manager for the same pharmacy
65 services for which payment is sought in that invoice.

66 Section 3. Section **58-17b-102** is amended to read:

67 **58-17b-102. Definitions.**

68 In addition to the definitions in Section 58-1-102, as used in this chapter:

69 (1) "Administering" means:

70 (a) the direct application of a prescription drug or device, whether by injection,
71 inhalation, ingestion, or by any other means, to the body of a human patient or research subject
72 by another person; or

73 (b) the placement by a veterinarian with the owner or caretaker of an animal or group
74 of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other
75 means directed to the body of the animal by the owner or caretaker in accordance with written
76 or verbal directions of the veterinarian.

77 (2) "Adulterated drug or device" means a drug or device considered adulterated under
78 21 U.S.C.S. Sec. 351 (2003).

79 (3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for
80 the purpose of analysis.

81 (b) "Analytical laboratory" does not include a laboratory possessing prescription drugs
82 used as standards and controls in performing drug monitoring or drug screening analysis if the
83 prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid
84 components, organic solvents, or inorganic buffers at a concentration not exceeding one
85 milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic
86 use.

87 (4) "Animal euthanasia agency" means an agency performing euthanasia on animals by

88 the use of prescription drugs.

89 (5) "Automated pharmacy systems" includes mechanical systems which perform
90 operations or activities, other than compounding or administration, relative to the storage,
91 packaging, dispensing, or distribution of medications, and which collect, control, and maintain
92 all transaction information.

93 (6) "Beyond use date" means the date determined by a pharmacist and placed on a
94 prescription label at the time of dispensing that indicates to the patient or caregiver a time
95 beyond which the contents of the prescription are not recommended to be used.

96 [~~(8)~~] (7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy
97 created in Section 58-17b-201.

98 [~~(7)~~] (8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically
99 underserved area, used for the storage and dispensing of prescription drugs, which is dependent
100 upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and
101 approved by the division as the parent pharmacy.

102 (9) "Centralized prescription processing" means the processing by a pharmacy of a
103 request from another pharmacy to fill or refill a prescription drug order or to perform
104 processing functions such as dispensing, drug utilization review, claims adjudication, refill
105 authorizations, and therapeutic interventions.

106 (10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a
107 retail pharmacy to compound or dispense a drug or dispense a device to the public under a
108 prescription order.

109 (11) "Class B pharmacy":

110 (a) means a pharmacy located in Utah:

111 (i) that is authorized to provide pharmaceutical care for patients in an institutional
112 setting; and

113 (ii) whose primary purpose is to provide a physical environment for patients to obtain
114 health care services; and

115 (b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

116 (ii) pharmaceutical administration and sterile product preparation facilities.

117 (12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to
118 engage in the manufacture, production, wholesale, or distribution of drugs or devices.

119 (13) "Class D pharmacy" means a nonresident pharmacy.

120 (14) "Class E pharmacy" means all other pharmacies.

121 (15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a
122 defined and exclusive group of patients who have access to the services of the pharmacy
123 because they are treated by or have an affiliation with a specific entity, including a health
124 maintenance organization or an infusion company, but not including a hospital pharmacy, a
125 retailer of goods to the general public, or the office of a practitioner.

126 (16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or
127 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or
128 more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical
129 care functions authorized by the practitioner or practitioners under certain specified conditions
130 or limitations.

131 (17) "Collaborative pharmacy practice agreement" means a written and signed
132 agreement between one or more pharmacists and one or more practitioners that provides for
133 collaborative pharmacy practice for the purpose of drug therapy management of patients and
134 prevention of disease of human subjects.

135 (18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or
136 labeling of a limited quantity drug, sterile product, or device:

137 (i) as the result of a practitioner's prescription order or initiative based on the
138 practitioner, patient, or pharmacist relationship in the course of professional practice;

139 (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and
140 not for sale or dispensing; or

141 (iii) in anticipation of prescription drug orders based on routine, regularly observed
142 prescribing patterns.

143 (b) "Compounding" does not include:

144 (i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to
145 another pharmacist or pharmaceutical facility;

146 (ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a
147 dosage form which is regularly and commonly available from a manufacturer in quantities and
148 strengths prescribed by a practitioner; or

149 (iii) the preparation of a prescription drug, sterile product, or device which has been

150 withdrawn from the market for safety reasons.

151 (19) "Confidential information" has the same meaning as "protected health
152 information" under the Standards for Privacy of Individually Identifiable Health Information,
153 45 C.F.R. Parts 160 and 164.

154 (20) "Controlled substance" has the same definition as in Section 58-37-2.

155 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
156 417, Sec. 3a(ff) which is incorporated by reference.

157 (22) "Dispense" means the interpretation, evaluation, and implementation of a
158 prescription drug order or device or nonprescription drug or device under a lawful order of a
159 practitioner in a suitable container appropriately labeled for subsequent administration to or use
160 by a patient, research subject, or an animal.

161 (23) "Distribute" means to deliver a drug or device other than by administering or
162 dispensing.

163 (24) (a) "Drug" means:

164 (i) a substance recognized in the official United States Pharmacopoeia, Official
165 Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any
166 supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or
167 prevention of disease in humans or animals;

168 (ii) a substance that is required by any applicable federal or state law or rule to be
169 dispensed by prescription only or is restricted to administration by practitioners only;

170 (iii) a substance other than food intended to affect the structure or any function of the
171 body of humans or other animals; and

172 (iv) substances intended for use as a component of any substance specified in
173 Subsections (24)(a)(i), (ii), (iii), and (iv).

174 (b) "Drug" does not include dietary supplements.

175 (25) "Drug product equivalent" means a drug product that is designated as the
176 therapeutic equivalent of another drug product in the Approved Drug Products with
177 Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research
178 of the Federal Food and Drug Administration.

179 (26) "Drug regimen review" includes the following activities:

180 (a) evaluation of the prescription drug order and patient record for:

181 (i) known allergies;
182 (ii) rational therapy-contraindications;
183 (iii) reasonable dose and route of administration; and
184 (iv) reasonable directions for use;
185 (b) evaluation of the prescription drug order and patient record for duplication of
186 therapy;

187 (c) evaluation of the prescription drug order and patient record for the following
188 interactions:

189 (i) drug-drug;
190 (ii) drug-food;
191 (iii) drug-disease; and
192 (iv) adverse drug reactions; and
193 (d) evaluation of the prescription drug order and patient record for proper utilization,
194 including over- or under-utilization, and optimum therapeutic outcomes.

195 (27) "Drug sample" means a prescription drug packaged in small quantities consistent
196 with limited dosage therapy of the particular drug, which is marked "sample", is not intended to
197 be sold, and is intended to be provided to practitioners for the immediate needs of patients for
198 trial purposes or to provide the drug to the patient until a prescription can be filled by the
199 patient.

200 (28) "Electronic signature" means a trusted, verifiable, and secure electronic sound,
201 symbol, or process attached to or logically associated with a record and executed or adopted by
202 a person with the intent to sign the record.

203 (29) "Electronic transmission" means transmission of information in electronic form or
204 the transmission of the exact visual image of a document by way of electronic equipment.

205 (30) "Extern" means a college of pharmacy student enrolled in a college coordinated
206 practical experience program in a health care setting under the supervision of a preceptor, as
207 defined in this act, and approved by a college of pharmacy.

208 (31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to
209 inpatients of a general acute hospital or specialty hospital licensed by the Department of Health
210 under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

211 (32) "Legend drug" has the same meaning as prescription drug.

212 (33) "Licensed pharmacy technician" means an individual licensed with the division,
213 that may, under the supervision of a pharmacist, perform the activities involved in the
214 technician practice of pharmacy.

215 (34) "Manufacturer" means a person or business physically located in Utah licensed to
216 be engaged in the manufacturing of drugs or devices.

217 (35) (a) "Manufacturing" means:

218 (i) the production, preparation, propagation, conversion, or processing of a drug or
219 device, either directly or indirectly, by extraction from substances of natural origin or
220 independently by means of chemical or biological synthesis, or by a combination of extraction
221 and chemical synthesis, and includes any packaging or repackaging of the substance or labeling
222 or relabeling of its container; and

223 (ii) the promotion and marketing of such drugs or devices.

224 (b) "Manufacturing" includes the preparation and promotion of commercially available
225 products from bulk compounds for resale by pharmacies, practitioners, or other persons.

226 (c) "Manufacturing" does not include the preparation or compounding of a drug by a
227 pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation,
228 compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical
229 analysis.

230 (36) "Medical order" means a lawful order of a practitioner which may include a
231 prescription drug order.

232 (37) "Medication profile" or "profile" means a record system maintained as to drugs or
233 devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze
234 the profile to provide pharmaceutical care.

235 (38) "Misbranded drug or device" means a drug or device considered misbranded under
236 21 U.S.C.S. Sec. 352 (2003).

237 (39) (a) "Nonprescription drug" means a drug which:

238 (i) may be sold without a prescription; and

239 (ii) is labeled for use by the consumer in accordance with federal law.

240 (b) "Nonprescription drug" includes homeopathic remedies.

241 (40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a
242 person in Utah.

243 (41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

244 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located

245 outside the state that is licensed and in good standing in another state, that:

246 (a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in
247 this state pursuant to a lawfully issued prescription;

248 (b) provides information to a patient in this state on drugs or devices which may
249 include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses;
250 or

251 (c) counsels pharmacy patients residing in this state concerning adverse and therapeutic
252 effects of drugs.

253 (43) "Patient counseling" means the written and oral communication by the pharmacist
254 or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of
255 drugs, devices, and dietary supplements.

256 (44) "Pharmaceutical administration facility" means a facility, agency, or institution in
257 which:

258 (a) prescription drugs or devices are held, stored, or are otherwise under the control of
259 the facility or agency for administration to patients of that facility or agency;

260 (b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist
261 or pharmacy intern with whom the facility has established a prescription drug supervising
262 relationship under which the pharmacist or pharmacy intern provides counseling to the facility
263 or agency staff as required, and oversees drug control, accounting, and destruction; and

264 (c) prescription drugs are professionally administered in accordance with the order of a
265 practitioner by an employee or agent of the facility or agency.

266 (45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a
267 prescribing practitioner, and in accordance with division rule:

268 (i) designing, implementing, and monitoring a therapeutic drug plan intended to
269 achieve favorable outcomes related to a specific patient for the purpose of curing or preventing
270 the patient's disease;

271 (ii) eliminating or reducing a patient's symptoms; or

272 (iii) arresting or slowing a disease process.

273 (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a

274 prescribing practitioner.

275 (46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering,
276 distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this
277 state.

278 (47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility
279 engaged in the business of wholesale vending or selling of any prescription drug or device to
280 other than the consumer or user of the prescription drug or device, which the pharmaceutical
281 facility has not produced, manufactured, compounded, or dispensed.

282 (b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical
283 facility carrying out the following business activities:

284 (i) intracompany sales;

285 (ii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
286 purchase or trade a prescription drug or device between hospitals or other health care facilities
287 that are under common ownership or control of the management and operation of the facilities;

288 (iii) the sale, purchase, or trade of a prescription drug or device, or offer to sell,
289 purchase, or trade a prescription drug or device for emergency medical reasons, or to supply
290 another pharmaceutical facility to alleviate a temporary shortage; or

291 (iv) the distribution of a prescription drug or device as a sample by representatives of a
292 manufacturer.

293 (48) "Pharmacist" means an individual licensed by this state to engage in the practice
294 of pharmacy.

295 (49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing
296 who accepts responsibility for the operation of a pharmacy in conformance with all laws and
297 rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally
298 in full and actual charge of the pharmacy and all personnel.

299 (50) "Pharmacist preceptor" means a licensed pharmacist in good standing with two or
300 more years of licensed experience. The preceptor serves as a teacher, example of professional
301 conduct, and supervisor of interns in the professional practice of pharmacy.

302 (51) "Pharmacy" means any place where:

303 (a) drugs are dispensed;

304 (b) pharmaceutical care is provided;

305 (c) drugs are processed or handled for eventual use by a patient; or

306 (d) drugs are used for the purpose of analysis or research.

307 (52) "Pharmacy benefits manager or coordinator" means a person or entity that

308 [~~administers the prescription drug or device portion of a health insurance plan~~] provides

309 pharmacy benefit management services as defined in Section 49-20-502 on behalf of a

310 self-insured employer, insurance company, health maintenance organization, or other plan

311 sponsor, as defined by rule.

312 (53) "Pharmacy intern" means an individual licensed by this state to engage in practice

313 as a pharmacy intern.

314 (54) "Pharmacy technician training program" means an approved technician training

315 program providing education for pharmacy technicians.

316 (55) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a

317 pharmacy technician under the general supervision of a licensed pharmacist and in accordance

318 with a scope of practice defined by division rule made in collaboration with the board.

319 (b) "Practice as a licensed pharmacy technician" does not include:

320 (i) performing a drug utilization review, prescription drug order clarification from a

321 prescriber, final review of the prescription and prescribed drug prepared for dispensing,

322 dispensing of the drug, or counseling a patient with respect to a prescription drug;

323 (ii) counseling regarding nonprescription drugs and dietary supplements unless

324 delegated by the supervising pharmacist; or

325 (iii) receiving new prescription drug orders when communicating telephonically or

326 electronically unless the original information is recorded so the pharmacist may review the

327 prescription drug order as transmitted.

328 (56) "Practice of pharmacy" includes the following:

329 (a) providing pharmaceutical care;

330 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy

331 practice agreement;

332 (c) compounding, packaging, labeling, dispensing, administering, and the coincident

333 distribution of prescription drugs or devices, provided that the administration of a prescription

334 drug or device is:

335 (i) pursuant to a lawful order of a practitioner when one is required by law; and

- 336 (ii) in accordance with written guidelines or protocols:
- 337 (A) established by the licensed facility in which the prescription drug or device is to be
- 338 administered on an inpatient basis; or
- 339 (B) approved by the division, in collaboration with the board and the Physicians
- 340 Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be
- 341 administered on an outpatient basis solely by a licensed pharmacist;
- 342 (d) participating in drug utilization review;
- 343 (e) ensuring proper and safe storage of drugs and devices;
- 344 (f) maintaining records of drugs and devices in accordance with state and federal law
- 345 and the standards and ethics of the profession;
- 346 (g) providing information on drugs or devices, which may include advice relating to
- 347 therapeutic values, potential hazards, and uses;
- 348 (h) providing drug product equivalents;
- 349 (i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy
- 350 technicians;
- 351 (j) providing patient counseling, including adverse and therapeutic effects of drugs;
- 352 (k) providing emergency refills as defined by rule;
- 353 (l) telepharmacy; and
- 354 (m) formulary management intervention.
- 355 (57) "Practice of telepharmacy" means the practice of pharmacy through the use of
- 356 telecommunications and information technologies.
- 357 (58) "Practice of telepharmacy across state lines" means the practice of pharmacy
- 358 through the use of telecommunications and information technologies that occurs when the
- 359 patient is physically located within one jurisdiction and the pharmacist is located in another
- 360 jurisdiction.
- 361 (59) "Practitioner" means an individual currently licensed, registered, or otherwise
- 362 authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of
- 363 professional practice.
- 364 (60) "Prescribe" means to issue a prescription:
- 365 (a) orally or in writing; or
- 366 (b) by telephone, facsimile transmission, computer, or other electronic means of

367 communication as defined by division rule.

368 (61) "Prescription" means an order issued:

369 (a) by a licensed practitioner in the course of that practitioner's professional practice or
370 by collaborative pharmacy practice agreement; and

371 (b) for a controlled substance or other prescription drug or device for use by a patient
372 or an animal.

373 (62) "Prescription device" means an instrument, apparatus, implement, machine,
374 contrivance, implant, in vitro reagent, or other similar or related article, and any component
375 part or accessory, which is required under federal or state law to be prescribed by a practitioner
376 and dispensed by or through a person or entity licensed under this chapter or exempt from
377 licensure under this chapter.

378 (63) "Prescription drug" means a drug that is required by federal or state law or rule to
379 be dispensed only by prescription or is restricted to administration only by practitioners.

380 (64) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs
381 and devices to the general public.

382 (65) "Self-audit" means an internal evaluation of a pharmacy to determine compliance
383 with this chapter.

384 (66) "Supervising pharmacist" means a pharmacist who is overseeing the operation of
385 the pharmacy during a given day or shift.

386 (67) "Supportive personnel" means unlicensed individuals who:

387 (a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed
388 pharmacy technician in nonjudgmental duties not included in the definition of the practice of
389 pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as
390 those duties may be further defined by division rule adopted in collaboration with the board;
391 and

392 (b) are supervised by a pharmacist in accordance with rules adopted by the division in
393 collaboration with the board.

394 (68) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

395 (69) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and
396 may be further defined by rule.

397 (70) "Veterinary pharmaceutical facility" means a pharmaceutical facility that

398 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
399 for animals.

400 Section 4. Section **58-17b-622** is enacted to read:

401 **58-17b-622. Pharmacy benefit management services -- Auditing of pharmacy**
402 **records -- Appeals.**

403 (1) For purposes of this section:

404 (a) "Audit" means a review of the records of a pharmacy by or on behalf of an entity
405 that finances or reimburses the cost of health care services or pharmaceutical products.

406 (b) "Entity" includes:

407 (i) a pharmacy benefits manager or coordinator;

408 (ii) a health benefit plan;

409 (iii) a third party administrator as defined in Section 31A-1-301;

410 (iv) a state agency; or

411 (v) a company, group, or agent that represents, or is engaged by, one of the entities
412 described in Subsections (1)(b)(i) through (iv).

413 (c) "Fraud" means an intentional act of deception, misrepresentation, or concealment in
414 order to gain something of value.

415 (d) "Health benefit plan" means:

416 (i) a health benefit plan as defined in Section 31A-1-301; or

417 (ii) a health, dental, medical, Medicare supplement, or conversion program offered
418 under Title 49, Chapter 20, Public Employees' Benefit and Insurance Program Act.

419 (2) (a) Except as provided in Subsection (2)(b), this section applies to:

420 (i) a contract for the audit of a pharmacy entered into, amended, or renewed on or after
421 July 1, 2012; and

422 (ii) an entity that conducts an audit of the pharmacy records of a pharmacy licensed
423 under this chapter.

424 (b) This section does not apply to an audit of pharmacy records $\hat{S}\rightarrow$:

424a (i) $\leftarrow\hat{S}$ for a federally funded

425 prescription drug program, including:

426 $\hat{S}\rightarrow$ [(fi)] (A) $\leftarrow\hat{S}$ the state Medicaid program;

427 $\hat{S}\rightarrow$ [(fii)] (B) $\leftarrow\hat{S}$ the Medicare Part D program;

428 $\hat{S}\rightarrow$ [(fiii)] (C) $\leftarrow\hat{S}$ a Department of Defense prescription drug program; $\hat{S}\rightarrow$ [or] $\leftarrow\hat{S}$

429 ~~§~~→ [(iv)] (D) ~~←~~§ a Veteran's Affairs prescription drug program ~~§~~→ ; or
 429a (ii) when fraud or other intentional and willful misrepresentation is alleged and the
 429b pharmacy audit entity has evidence that the pharmacy's actions reasonably indicate fraud or
 429c intentional and willful misrepresentation ~~←~~§ .

430 (3) (a) An audit that involves clinical or professional judgment shall be conducted by
 431 or in consultation with a licensed pharmacist who is employed by or working with the auditing
 432 entity.

433 (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:

434 (i) shall give the pharmacy 10 days advanced written notice of:

435 (A) the audit; and

436 (B) the range of prescription numbers or a date range included in the audit; and

437 (ii) may not audit a pharmacy during the first five business days of the month, unless
 438 the pharmacy agrees to the timing of the audit.

439 (c) An entity may not audit claims:

440 (i) submitted more than 18 months prior to the audit, unless:

441 (A) required by federal law; or

442 (B) the originating prescription is dated in the preceding 6 months; or

443 (ii) that exceed 200 selected prescription claims.

444 (4) (a) An entity may not:

445 (i) include dispensing fees in the calculations of overpayments unless the prescription
 446 is considered a misfill;

447 (ii) recoup funds for prescription clerical or record keeping errors, including
 448 typographical errors, scrivener's errors, and computer errors on a required document or record

449 ~~§~~→ [~~in the absence of any other evidence deemed fraudulent~~] unless the audit entity is alleging
 449a fraud or other intentional or willful misrepresentation and the audit entity has evidence that
 449b the pharmacy's actions reasonably indicate fraud or intentional and willful
 449c misrepresentation ~~←~~§ ; or

450 (iii) collect any funds, charge-backs, or penalties until the audit and all appeals are

451 final, unless the ~~§~~→ audit ~~←~~§ entity ~~§~~→ is alleging fraud or other intentional or willful

451a misrepresentation and the audit entity ~~←~~§ has evidence ~~§~~→ [~~the actions by the pharmacy~~

451b constituted fraud] that the pharmacy's actions reasonably indicate fraud or intentional and

451c willful misrepresentation ~~←~~§ .

452 (b) Auditors shall only have access to previous audit reports on a particular pharmacy
 453 if the previous audit was conducted by the same entity except as required for compliance with

454 state or federal law.

455 (5) A pharmacy subject to an audit may use the following records to validate a claim
456 for a prescription, refill, or change in a prescription:

457 (a) electronic or physical copies of records of a health care facility, or a health care
458 provider with prescribing authority; and

459 (b) any prescription that complies with state law.

460 (6) (a) An entity that audits a pharmacy shall provide the pharmacy with a preliminary
461 audit report, delivered to the pharmacy or its corporate office of record within 60 days after
462 completion of the audit.

463 (b) A pharmacy has 30 days following receipt of the preliminary audit report to
464 respond to questions, provide additional documentation, and comment on and clarify findings
465 of the audit. Receipt of the report shall be based on the postmark date or the date of a
466 computer transmission if transferred electronically.

467 (7) If an audit results in the dispute or denial of a claim, the entity conducting the audit
468 shall allow the pharmacy to re-submit a claim using any commercially reasonable method,
469 including fax, mail, or electronic claims submission provided that the period of time when a
470 claim may be resubmitted has not expired under the rules of the plan sponsor.

471 (8) (a) Within 120 days after the completion of the appeals process under Subsection
472 (9), a final audit report shall be delivered to the pharmacy or its corporate office of record.

473 (b) The final audit report shall include a disclosure of any money recovered by the
474 entity that conducted the audit.

475 (9) An entity that audits a pharmacy shall establish a written appeals process for
476 appealing a preliminary audit report and a final audit report, and shall provide the pharmacy
477 with notice of the written appeals process. If the pharmacy benefit manager's contract or
478 provider manual contains the information required by this Subsection (9), the requirement for
479 notice is met.

480 ~~**§→ [(10) This section does not apply to any audit, review, or investigation that involves**~~
481 ~~**probable Medicaid fraud, probable Medicaid abuse, probable insurance fraud, or other criminal**~~
482 ~~**fraud or criminal misrepresentation]** ←~~§~~ .~~