

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;
 - requirements for an entity conducting an audit; and



26 • procedures to appeal an audit.

27 **Money Appropriated in this Bill:**

28 None

29 **Other Special Clauses:**

30 None

31 **Utah Code Sections Affected:**

32 AMENDS:

33 **49-20-503**, as enacted by Laws of Utah 2011, Chapter 83

34 **58-17b-102**, as last amended by Laws of Utah 2010, Chapter 101

35 ENACTS:

36 **31A-22-640**, Utah Code Annotated 1953

37 **58-17b-622**, Utah Code Annotated 1953



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

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

41 **31A-22-640. Pharmacy benefit management services -- Audit restrictions.**

42 (1) For purposes of this section "pharmacy benefits manager or coordinator" means a
43 person or entity that provides pharmacy benefit management services as defined in Section
44 49-20-502 on behalf of an insurer as defined in Subsection 31A-22-636(1).

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

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

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

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

53 (a) require each responder to comply with the pharmacy audit provisions of Section
54 58-17b-622; and

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

57 (2) The billing option described in Subsection (1) shall require the pharmacy benefits
58 manager to, on at least a monthly basis, submit to the board an invoice for all pharmacy
59 services paid by the pharmacy benefits manager on behalf of the program since the last request
60 for payment or reimbursement.

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

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

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

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

68 **58-17b-102. Definitions.**

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

70 (1) "Administering" means:

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

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

78 (2) "Adulterated drug or device" means a drug or device considered adulterated under
79 21 U.S.C.S. Sec. 351 (2003).

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

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

88 (4) "Animal euthanasia agency" means an agency performing euthanasia on animals by
89 the use of prescription drugs.

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

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

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

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

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

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

110 (11) "Class B pharmacy":

111 (a) means a pharmacy located in Utah:

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

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

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

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

118 (12) "Class C pharmacy" means a pharmacy located in Utah that is authorized to

119 engage in the manufacture, production, wholesale, or distribution of drugs or devices.

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

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

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

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

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

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

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

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

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

144 (b) "Compounding" does not include:

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

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

150 (iii) the preparation of a prescription drug, sterile product, or device which has been
151 withdrawn from the market for safety reasons.

152 (19) "Confidential information" has the same meaning as "protected health
153 information" under the Standards for Privacy of Individually Identifiable Health Information,
154 45 C.F.R. Parts 160 and 164.

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

156 (21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter
157 417, Sec. 3a(ff) which is incorporated by reference.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

236 (38) "Misbranded drug or device" means a drug or device considered misbranded under
237 21 U.S.C.S. Sec. 352 (2003).

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

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

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

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

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

243 person in Utah.

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

245 (42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located
246 outside the state that is licensed and in good standing in another state, that:

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

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

251 or

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

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

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

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

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

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

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

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

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

273 (iii) arresting or slowing a disease process.

274 (b) "Pharmaceutical care" does not include prescribing of drugs without consent of a
275 prescribing practitioner.

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

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

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

285 (i) intracompany sales;

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

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

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

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

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

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

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

304 (a) drugs are dispensed;

305 (b) pharmaceutical care is provided;

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

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

308 (52) "Pharmacy benefits manager or coordinator" means a person or entity that
309 ~~[administers the prescription drug or device portion of a health insurance plan]~~ provides
310 pharmacy benefit management services as defined in Section 49-20-502 on behalf of a
311 self-insured employer, insurance company, health maintenance organization, or other plan
312 sponsor, as defined by rule.

313 (53) "Pharmacy intern" means an individual licensed by this state to engage in practice
314 as a pharmacy intern.

315 (54) "Pharmacy technician training program" means an approved technician training
316 program providing education for pharmacy technicians.

317 (55) (a) "Practice as a licensed pharmacy technician" means engaging in practice as a
318 pharmacy technician under the general supervision of a licensed pharmacist and in accordance
319 with a scope of practice defined by division rule made in collaboration with the board.

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

321 (i) performing a drug utilization review, prescription drug order clarification from a
322 prescriber, final review of the prescription and prescribed drug prepared for dispensing,
323 dispensing of the drug, or counseling a patient with respect to a prescription drug;

324 (ii) counseling regarding nonprescription drugs and dietary supplements unless
325 delegated by the supervising pharmacist; or

326 (iii) receiving new prescription drug orders when communicating telephonically or
327 electronically unless the original information is recorded so the pharmacist may review the
328 prescription drug order as transmitted.

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

330 (a) providing pharmaceutical care;

331 (b) collaborative pharmacy practice in accordance with a collaborative pharmacy
332 practice agreement;

333 (c) compounding, packaging, labeling, dispensing, administering, and the coincident
334 distribution of prescription drugs or devices, provided that the administration of a prescription
335 drug or device is:

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

367 (b) by telephone, facsimile transmission, computer, or other electronic means of
368 communication as defined by division rule.

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

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

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

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

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

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

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

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

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

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

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

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

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

398 (70) "Veterinary pharmaceutical facility" means a pharmaceutical facility that
399 dispenses drugs intended for use by animals or for sale to veterinarians for the administration
400 for animals.

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

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

404 (1) For purposes of this section:

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

407 (b) "Entity" includes:

408 (i) a pharmacy benefits manager or coordinator;

409 (ii) a health benefit plan;

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

411 (iv) a state agency; or

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

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

416 (d) "Health benefit plan" means:

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

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

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

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

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

425 (b) This section does not apply to an audit of pharmacy records for the purpose of
426 detecting fraud in the:

427 (i) state Medicaid program if the audit is conducted:

428 (A) under the provisions of Title 63J, Chapter 4a, Office of Inspector General of

429 Medicaid Services; and
430 (B) by the Office of the Inspector General, or its designee; or
431 (ii) the federal Medicare program, when the audit is authorized under federal
432 regulations or requirements.
433 (3) (a) An audit that involves clinical or professional judgment shall be conducted by
434 or in consultation with a licensed pharmacist who is employed by or working with the auditing
435 entity.
436 (b) If an audit is conducted on site at a pharmacy, the entity conducting the audit:
437 (i) shall give the pharmacy 10 days advanced written notice of:
438 (A) the audit; and
439 (B) the range of prescription numbers included in the audit; and
440 (ii) may not audit a pharmacy during the first five business days of the month, unless
441 the pharmacy agrees to the timing of the audit.
442 (c) An entity may not audit claims:
443 (i) submitted more than 12 months prior to the audit, unless:
444 (A) required by federal law; or
445 (B) the originating prescription is dated in the preceding 12 months; or
446 (ii) that exceed 125 selected prescription claims.
447 (4) (a) An entity may not:
448 (i) include dispensing fees in the calculations of overpayments;
449 (ii) recoup funds for prescription clerical or record keeping errors, including
450 typographical errors, scrivener's errors, and computer errors on a required document or record
451 in the absence of any other evidence deemed fraudulent; or
452 (iii) collect any funds, charge-backs, or penalties until the audit and all appeals are
453 final, unless the entity has evidence the actions by the pharmacy constituted fraud.
454 (b) Auditors shall only have access to previous audit reports on a particular pharmacy
455 if the previous audit was conducted by the same entity.
456 (5) A pharmacy subject to an audit may use the following records to validate a claim
457 for a prescription, refill, or change in a prescription:
458 (a) electronic or physical copies of records of a health care facility, or a health care
459 provider with prescribing authority; and

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

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

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

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

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

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

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

481 (b) The appeals process under Subsection (9)(a) shall offer the pharmacy the option to
482 submit an appeal of the final audit report to binding arbitration or mediation pursuant to
483 contract or provider agreement with the entity or to civil action if binding arbitration or
484 mediation are not otherwise specified in the contract or provider agreement.

485 (10) This section does not apply to any investigative pharmacy audit that involves
486 fraud.