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HOUSE BILL NO. 945

Offered January 11, 2006

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A BILL to amend and reenact §§ 38.2-3407.4:2, 38.2-3407.5, 38.2-3407.5:1, 38.2-3407.6:1, 38.2-3407.7, 38.2-3407.9:01, 38.2-3407.9:02, 38.2-3407.15, 38.2-4209.1, 38.2-4214, 38.2-4312.1, 38.2-4319, and 38.2-4509 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 13 of Title 38.2 an article numbered 10, consisting of sections numbered 38.2-1365 through 38.2-1384, relating to the registration and regulation of pharmacy benefits managers.

Patrons—Morgan and O'Bannon

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3407.4:2, 38.2-3407.5, 38.2-3407.5:1, 38.2-3407.6:1, 38.2-3407.7, 38.2-3407.9:01, 38.2-3407.9:02, 38.2-3407.15, 38.2-4209.1, 38.2-4214, 38.2-4312.1, 38.2-4319, and 38.2-4509 of the Code of Virginia are amended and reenacted, and that the Code of Virginia is amended by adding in Chapter 13 of Title 38.2 an article numbered 10, consisting of sections numbered 38.2-1365 through 38.2-1384, as follows:

*Article 10.**Registration and Regulation of Pharmacy Benefits Managers.**§ 13.1-1365. Definitions.**As used in this article:*

"Beneficiary" means an individual on whose behalf a purchaser enters into an agreement with a pharmacy benefits manager.

"Extrapolation audit" means an audit of a sample of prescription benefit claims submitted by a pharmacy to a pharmacy benefits manager or its designated contractor or agent that is used to estimate audit results for a larger batch or group of claims.

"Labeler" means a person that:

1. Receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale; and

2. Has a labeler code from the federal Food and Drug Administration under 21 CFR Part 207.20.

"Pharmacy benefits management services" means the administration or management of prescription drug benefits, and includes:

1. Procuring of prescription drugs at a negotiated rate for dispensation within the Commonwealth;

2. Processing of prescription drug claims;

3. Administering payments related to prescription drug claims; and

4. Negotiating or entering into contractual arrangements with pharmacy providers.

"Pharmacy benefits manager" means a person who performs pharmacy benefits management services.

"Pharmacy provider" means a pharmacy or pharmacist.

"Prospective purchaser" means a person to which a pharmacy benefits manager offers to provide pharmacy benefits management services.

"Purchaser" means a person that enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services. As used herein, the term "purchaser" shall include the Commonwealth and any political subdivision of the Commonwealth.

"Trade secret" has the meaning stated in § 59.1-336 of the Uniform Trade Secrets Act.

"Utilization review" has the meaning stated in § 32.1-137.7, and shall include:

1. Drug utilization management;

2. Drug utilization review services; and

3. Step protocol therapy management.

§ 38.2-1366. Registration of pharmacy benefits managers.

A. No person shall act as or represent himself as a pharmacy benefits manager in this Commonwealth unless such person has registered with the Commission pursuant to this article.

B. An applicant for registration shall, pursuant to regulations to be adopted by the Commission:

1. File with the Commission an application in the form determined by the Commission; and

2. Pay to the Commission a registration fee in the form and amount determined by the Commission.

C. The Commission shall register each applicant that meets the requirements established by the Commission by regulation.

§ 38.2-1367. Expiration and renewal of registration.

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59 A. A registration shall expire at the end of every other June 30, unless it is renewed as provided in
60 this section.

61 B. Before a registration expires, the registrant may renew for an additional two-year term, if the
62 registrant:

63 1. Otherwise is entitled to be registered;

64 2. Files with the Commission a renewal application in the form and by the date established by the
65 Commission; and

66 3. Pays to the Commission a renewal fee as set by the Commission.

67 § 38.2-1368. Prohibited acts.

68 A pharmacy benefits manager shall not:

69 1. Violate any provision of this article;

70 2. Violate any regulation adopted pursuant to this article;

71 3. Knowingly fail to comply with an order of the Commission;

72 4. Fail to meet the requirements for registration established by the Commission pursuant to this
73 article;

74 5. Obtain or attempt to obtain a registration based on inaccurate information;

75 6. Fraudulently or deceptively obtain or use a registration;

76 7. Fail to protect the confidentiality of medical records in accordance with applicable state and
77 federal laws; or

78 8. Act as a pharmacy benefits manager prior to registering with the Commission.

79 § 38.2-1369. Penalties and liabilities; grounds for placing on probation; refusal to issue or renew
80 registration; revocation or suspension of registration.

81 A. The Commission may, in addition to or in lieu of a penalty imposed under § 38.2-218, place on
82 probation, suspend, revoke, or refuse to issue or renew any registration for any one or more of the
83 following causes:

84 1. Providing materially incorrect, misleading, incomplete, or untrue information in the registration
85 application or any other document filed with the Commission;

86 2. Violating any insurance laws or violating any regulation, subpoena, or order of the Commission
87 or of another state's regulatory authority with jurisdiction over the registrant;

88 3. Obtaining or attempting to obtain a registration through misrepresentation or fraud;

89 4. Improperly withholding, misappropriating, or converting any moneys or properties received in the
90 course of doing business;

91 5. Having been convicted of a felony;

92 6. Using fraudulent, coercive, or dishonest practices, or demonstrating incompetence or
93 untrustworthiness in the conduct of business in this Commonwealth or elsewhere, or demonstrating
94 financial irresponsibility in the handling of funds;

95 7. Having its license or registration as a pharmacy benefits manager denied, suspended, or revoked
96 in another state, province, territory, or by the federal government; or

97 8. Failing to pay state income tax or comply with any administrative or court order directing
98 payment of state income tax.

99 B. If the Commission believes that any applicant for a pharmacy benefits manager registration is not
100 of good character or does not have a good reputation for honesty, it may refuse to issue the
101 registration, subject to the right of the applicant to demand a hearing on the application. The
102 Commission shall not revoke or suspend an existing registration until the registrant is given an
103 opportunity to be heard before the Commission. If the Commission refuses to issue a new registration or
104 proposes to place on probation, suspend, revoke or refuse to renew any registration, it shall give the
105 applicant or registrant at least 10 calendar days' notice in writing of the time and place of the hearing,
106 if a hearing is requested. The notice shall contain a statement of the objections to the issuance of the
107 registration, or the reason for its proposed placement on probation, suspension, revocation, or refusal to
108 renew, as the case may be. The notice shall be given to the applicant or registrant by registered or
109 certified mail, sent to the last known address of record pursuant to § 38.2-1371, or the last known
110 business address if the address of record is incorrect, or in any other lawful manner the Commission
111 prescribes. The Commission may summon witnesses to testify with respect to the applicant or registrant,
112 and the applicant or registrant may introduce evidence in its behalf. No applicant to whom a
113 registration is refused after a hearing, nor any registrant whose registration is revoked, shall again
114 apply for registration until after the expiration of a period of five years from the date of the
115 Commission's order, or such other period of time as the Commission prescribes in its order.

116 C. If the registration of a pharmacy benefits manager is suspended or revoked, the Commission, to
117 protect the interests of beneficiaries and pharmacy providers, may permit the continued operation of the
118 pharmacy benefits manager for a limited period, not to exceed 60 days, under conditions and
119 restrictions determined by the Commission.

120 D. The Commission may, in addition to or in lieu of a penalty imposed under § 38.2-218, impose a

civil penalty not exceeding \$10,000 upon any person who violates this article.

§ 38.2-1370. Requirement to report to the Commission.

A. Each registrant shall report within 30 calendar days to the Commission any change in business address or name.

B. In addition to the requirements of §§ 59.1-69 and 59.1-70, any registrant operating in this Commonwealth under an assumed or fictitious name shall notify the Commission, at the earlier of the time the application for registration as a pharmacy benefits manager is filed or within 30 calendar days from the date the assumed or fictitious name is adopted, setting forth the name under which the pharmacy benefits manager intends to operate in Virginia. The Commission shall also be notified within 30 calendar days from the date of cessation of the use of such assumed or fictitious name.

C. Each registrant convicted of a felony shall report within 30 calendar days to the Commission the facts and circumstances regarding the criminal conviction.

§ 38.2-1371. Registration as a private review agent.

A pharmacy benefits manager that conducts utilization reviews as defined in § 32.1-137.7 shall register with the Commissioner of Health as a private review agent pursuant to Article 1.1 (§ 32.1-137.1 et seq.) of Chapter 5 of Title 32.1.

§ 38.2-1372. Contracts with unregistered pharmacy benefits managers prohibited.

No (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense incurred basis; (ii) corporation providing individual or group accident and sickness subscription contracts; or (iii) health maintenance organization providing a health care plan for health care services shall enter into an agreement with a pharmacy benefits manager that has not obtained a registration from the Commission.

§ 38.2-1373. Examination by the Commission.

A. Whenever the Commission considers it advisable, the Commission shall examine the affairs, transactions, accounts, records, and assets of each registered pharmacy benefits manager.

B. The examination shall be conducted in accordance with Article 4 (§ 38.2-1317 et seq.) of this chapter.

§ 38.2-1374. Books and records.

A pharmacy benefits manager shall maintain adequate books and records about each purchaser for which the pharmacy benefits manager provides pharmacy benefits management services:

1. In accordance with prudent standards of record keeping;

2. For the duration of the agreement between the pharmacy benefits manager and the purchaser; and

3. For three years after the pharmacy benefits manager ceases to provide pharmacy benefits management services to the purchaser.

§ 38.2-1375. Prerequisites to disclosure.

A. Except for utilization information, and except as provided in subsection D, a pharmacy benefits manager need not make the disclosures required under §§ 38.2-1377 and 38.2-1378 unless and until the prospective purchaser or the purchaser agrees in writing to maintain as confidential any proprietary information disclosed by the pharmacy benefits manager.

B. The agreement under subsection A may:

1. Provide for equitable and legal remedies in the event of a violation of the agreement; and

2. Include persons with whom the prospective purchaser or purchaser contracts to provide consulting services relating to pharmacy benefits management services.

C. Proprietary information includes:

1. Trade secrets; and

2. Information about pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy benefits manager and used for its business purposes.

D. Nothing in this section shall limit the authority of the Commission to obtain information and use the information in any proceeding.

§ 38.2-1376. Disclosure to prospective purchaser.

A. A pharmacy benefits manager shall disclose to a prospective purchaser in writing:

1. The amount of all rebates, administrative fees, detailing payments, educational payments, and other retrospective discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if the prospective purchaser were to contract with the pharmacy benefits manager;

2. The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if the prospective purchaser were to contract with the pharmacy benefits manager;

182 3. Any administrative or other fees that would be charged by the pharmacy benefits manager to the
183 prospective purchaser;

184 4. Any arrangements with prescribing providers, medical groups, individual practice associations,
185 pharmacy providers, or other persons that are associated with activities of the pharmacy benefits
186 manager to encourage formulary compliance or otherwise manage prescription drug benefits; and

187 5. A list of any drugs that the pharmacy benefits manager, directly or indirectly, repackaged and
188 assigned new or different national drug code numbers including, for each drug on the list:

189 a. The drug name and strength;

190 b. The original national drug code number and the new national drug code number; and

191 c. The original price and the new price.

192 B. The disclosure required under subdivision A 1 shall be provided:

193 1. In the aggregate;

194 2. For each therapeutic class of drugs on a list of specified therapeutic classes; and

195 3. For five individual prescribed drugs in each therapeutic class of drugs as requested by the
196 prospective purchaser.

197 C. A therapeutic class shall include at least two drugs.

198 § 38.2-1377. Disclosure to purchaser.

199 A. At least quarterly, a pharmacy benefits manager shall disclose to a purchaser in writing:

200 1. The amount of all rebates, administrative fees, detailing payments, educational programs, and
201 other retrospective discounts that the pharmacy benefits manager receives, directly or indirectly, from
202 pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the
203 purchaser;

204 2. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives,
205 directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription
206 drug benefits related to the purchaser;

207 3. Any prescription drug utilization information related to utilization by the purchaser's beneficiaries
208 or aggregate utilization data that is not specific to an individual beneficiary, prescriber, or purchaser;

209 4. Any administrative or other fees charged by the pharmacy benefits manager to the purchaser;

210 5. Any arrangements with prescribing providers, medical groups, individual practice associations,
211 pharmacy providers, or other persons that are associated with activities of the pharmacy benefits
212 manager to encourage formulary compliance or otherwise manage prescription drug benefits;

213 6. A list of any drugs that the pharmacy benefits manager, directly or indirectly, repackaged and
214 assigned new or different national drug code numbers including, for each drug on the list:

215 a. The drug name and strength;

216 b. The original national drug code number and the new national drug code number; and

217 c. The original price and the new price; and

218 7. A list of prescriptions for which there was a difference between the price paid to a retail
219 pharmacy and the amount that was billed to the purchaser including, for each prescription:

220 a. The prescription number;

221 b. The date the prescription was processed by the pharmacy benefits manager;

222 c. The national drug code number;

223 d. The beneficiary's name; and

224 e. The price paid to the retail pharmacy and the amount billed to the purchaser.

225 B. The disclosure required under subdivision A 1 shall be provided:

226 a. In the aggregate;

227 b. For each therapeutic class of drugs on a list of specified therapeutic classes; and

228 c. For five individual prescribed drugs in each therapeutic class of drugs as requested by the
229 purchaser.

230 C. A therapeutic class shall include at least two drugs.

231 § 38.2-1378. Contracts; agreements must be approved; prohibited provisions.

232 A. No person shall act on behalf of or as an agent of a pharmacy benefits manager without a
233 written agreement between such person and the pharmacy benefits manager.

234 B. No pharmacy benefits manager shall require a pharmacist or pharmacy to participate in one
235 contract in order to participate in another contract. The pharmacy benefits manager shall not exclude
236 an otherwise qualified pharmacist or pharmacy from participation in a particular network solely
237 because the pharmacist or pharmacy declined to participate in another plan or network managed by the
238 pharmacy benefits manager.

239 C. The pharmacy benefits manager shall file for approval by the Commission all contracts or
240 agreements with pharmacies. Such filings shall be received by the Commission not less than 30 days
241 before the execution of the contract or agreement. The contract shall be deemed approved unless the
242 Commission disapproves it within 30 days after it has been received by the Commission.

243 D. The written agreement between the purchaser and the pharmacy benefits manager shall not

provide that the pharmacist or pharmacy is responsible for the actions of the purchaser or the pharmacy benefits manager.

E. All agreements shall provide that when the pharmacy benefits manager receives payment for the services of the pharmacist or pharmacy, the pharmacy benefits manager shall act as a fiduciary of the pharmacist or pharmacy that provided the services. The pharmacy benefits manager shall distribute said funds in accordance with the time frames provided in this article.

§ 38.2-1379. Contracts; required provisions.

A contract executed by a pharmacy benefits manager for the provision of pharmacy benefits management services shall include:

1. The amount of the total revenues, rebates, and discounts identified in §§ 38.2-1377 and 38.2-1378 that will be passed on to the purchaser;

2. The maximum allowable cost and average wholesale price resources used to determine the price paid to a pharmacy and billed to the purchaser;

3. The conditions under which beneficiary utilization data may be disclosed or sold by the pharmacy benefits manager to any person other than the purchaser;

4. Any administrative or other fees:

a. Charged by the pharmacy benefits manager to the purchaser; or

b. Collected by the pharmacy benefits manager on behalf of the purchaser;

5. The conditions under which an audit will be conducted of the contract for pharmacy benefit management services, including:

a. Who will conduct the audit; and

b. Who will pay for the audit;

6. Any revenues, rebates, or discounts received, directly or indirectly, by the pharmacy benefits manager from persons other than pharmaceutical manufacturers and labelers that are related to the pharmacy benefits management services to be provided to the purchaser;

7. The process for the development of formularies, notification of changes to formularies, and approval of changes by the purchaser; and

8. An agreement to provide to the purchaser a list of prescriptions for which there was a difference between the price paid to a retail pharmacy and the amount that will be or was billed to the purchaser including, for each prescription:

a. The prescription number;

b. The date the prescription drug was processed by the pharmacy benefits manager;

c. The national drug code number;

d. The beneficiary's name; and

e. The price paid to the retail pharmacy and the amount billed to the purchaser.

§ 38.2-1380. Substitution prohibited; exceptions.

A. A pharmacy benefits manager shall not substitute another drug for the drug originally prescribed unless:

1. The substitution is made for medical reasons that benefit the beneficiary; or

2. The substitution results in financial savings and benefits to the purchaser.

B. If a prescription drug substitution is made under this section, the pharmacy benefits manager shall disclose to the purchaser any benefit or payment received in any form by the pharmacy benefits manager from a pharmaceutical manufacturer or other person related to the substitution.

§ 38.2-1381. Substitution; authorization and disclosure.

A. Except as provided in subsection C, a pharmacy benefits manager shall:

1. Obtain authorization from a prescriber to substitute a prescription drug; and

2. Disclose to the prescriber:

a. The cost savings for the purchaser, if any, that result from the drug substitution;

b. The difference, if any, in copayments or other out-of-pocket costs paid by the beneficiary to obtain the substitute drug;

c. The existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser;

d. The circumstances, if any, under which the currently prescribed drug will be covered;

e. The circumstances, if any, and extent to which health care costs related to the drug substitution will be compensated; and

f. Any known differences in potential effects on a beneficiary's health and safety, including side effects.

B. If authorization is given orally, a pharmacy benefits manager shall record the name and title of the prescriber authorizing the prescription drug substitution.

C. A pharmacy benefits manager may make a prescription drug substitution without obtaining authorization from a prescriber or making the disclosures required under subsection A if:

305 1. The substitution is from a brand name drug to a generic drug, and the substitution is made in
306 accordance with § 54.1-3408.03;

307 2. The currently prescribed drug is no longer available in the market; or

308 3. The substitution is required for coverage reasons because the prescribed drug is not covered by
309 the beneficiary's formulary or plan.

310 D. A pharmacy benefits manager shall not substitute a prescription drug for a currently prescribed
311 prescription drug unless the pharmacy benefits manager provides the beneficiary or the beneficiary's
312 representative the following:

313 1. Unless the substitution was exempted under subsection C, a notification that:

314 a. The pharmacy benefits manager requested a drug substitution by contacting the beneficiary's
315 prescriber; and

316 b. The prescriber approved the drug substitution;

317 2. The names of the proposed drug substitution and the currently prescribed drug;

318 3. The difference, if any, in copayments or other out-of-pocket costs paid by the beneficiary to obtain
319 the substitute drug;

320 4. Any known differences in potential effects on a beneficiary's health and safety, including side
321 effects;

322 5. The circumstances, if any, under which the currently prescribed drug will be covered;

323 6. The circumstances, if any, and the extent to which health care costs related to the drug
324 substitution will be compensated;

325 7. A notification that the beneficiary may decline the drug substitution if the currently prescribed
326 drug remains on the beneficiary's formulary, and the beneficiary is willing to pay any difference in the
327 copayment amount; and

328 8. A toll-free telephone number to communicate with the pharmacy benefits manager.

329 E. The following shall apply to cancellations of drug substitutions:

330 1. A pharmacy benefits manager shall cancel and reverse the prescription drug substitution on
331 written or oral instructions from a prescriber, the beneficiary, or the beneficiary's representative.

332 2. If a prescriber, the beneficiary, or the beneficiary's representative cancels and reverses a drug
333 substitution, the pharmacy benefits manager shall:

334 a. Obtain a prescription for and dispense the currently prescribed drug;

335 b. Charge the beneficiary only one copayment; and

336 c. If a beneficiary will exhaust the supply of the currently prescribed drug before a replacement
337 shipment will be delivered to the beneficiary, arrange for dispensing of an appropriate quantity of
338 replacement drugs at a retail or institutional pharmacy at no additional cost to the beneficiary.

339 3. A pharmacy benefits manager shall not be required to cancel and reverse a drug substitution if
340 the prescribed drug is no longer on the purchaser's formulary or the beneficiary is unwilling to pay a
341 higher copayment or other cost associated with the prescribed drug.

342 F. A pharmacy benefits manager shall maintain a toll-free telephone number 24 hours per day, seven
343 days per week, for prescribers, pharmacy providers, and beneficiaries.

344 § 38.2-1382. Contracts between pharmacy benefits managers and pharmacy providers.

345 A. If the pharmacy benefits management services performed by a pharmacy benefits manager for a
346 purchaser include negotiating or entering into contractual arrangements with pharmacy providers, then
347 before the pharmacy benefits manager may provide pharmacy benefits management services for the
348 purchaser, the pharmacy benefits manager shall enter into any necessary written contracts with
349 pharmacy providers.

350 B. A written contract shall require the pharmacy benefits manager to:

351 1. Disclose to pharmacy providers:

352 a. The terms, conditions, fees, benefit designs, process, and procedures for accessing the pharmacy
353 benefits management services provided by the pharmacy benefits manager; and

354 b. The pharmacy benefits manager's procedures for handling disputes;

355 2. Provide at least 30 days' written notice to pharmacy providers of benefit changes, including
356 additions or deletions to covered prescription drugs, with the exception of new drugs approved by the
357 U.S. Food and Drug Administration; and

358 3. Stipulate that pharmacy providers will not be required to agree to extrapolation audits as a
359 condition of entering into the contract or participating in the pharmacy benefits manager's network.

360 § 38.2-1383. Termination of agreements between pharmacy benefit manager and pharmacy provider.

361 A. A pharmacy provider shall not be terminated or penalized by a pharmacy benefits manager solely
362 because of filing a complaint, grievance, or appeal pursuant to this article.

363 B. A pharmacy provider shall not be terminated or penalized because it expresses a disagreement
364 with the pharmacy benefit manager's decision to deny or limit benefits to a beneficiary or because the
365 pharmacy provider assists such beneficiary to seek reconsideration of the pharmacy benefit manager's
366 decision or because the pharmacy provider discusses alternative medications with the beneficiary.

C. Prior to terminating a pharmacy provider from the network, the pharmacy benefits manager shall give the pharmacy provider a written explanation of the reason for the termination at least 30 days prior to the termination date, unless the termination is based on (i) loss of the pharmacy provider's license to practice pharmacy or cancellation of professional liability insurance or (ii) conviction of fraud.

D. Termination of a contract between a pharmacy benefits manager and a pharmacy provider, or termination of a pharmacy provider from a pharmacy benefits manager's network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy provider for pharmacist services rendered.

§ 38.2-1384. Non-discrimination.

A pharmacy benefits manager:

A. Shall allow a beneficiary to obtain covered pharmacy services from the pharmacy provider of the beneficiary's choice within the pharmacy benefits manager's network;

B. Shall allow a retail or institutional pharmacy that can meet the same terms and conditions as a mail order pharmacy to provide the same services provided by a mail order pharmacy; and

C. Shall not:

1. Require a beneficiary to obtain pharmacy services from a mail order pharmacy, if a retail or institutional pharmacy can meet the same terms and conditions as a mail order pharmacy;

2. Use any financial or other disincentives, penalties, or other means to influence, coerce, or steer beneficiaries away from a retail or institutional pharmacy that can meet the same terms and conditions as a mail order pharmacy; or

3. Limit the quantity of drugs that a beneficiary may obtain at any one time from any type of pharmacy provider, unless the limit is applied uniformly to all pharmacy providers that are within the pharmacy benefits manager's network, under contract, or otherwise authorized to provide pharmacy services to beneficiaries.

§ 38.2-3407.4:2. Requirements for prescription benefit cards.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, and (iv) pharmacy benefits manager who provides services, including services provided as an agent or contractor under a policy, subscription contract, or health care plan, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis, shall provide its insureds, subscribers or enrollees a prescription benefit card, health insurance benefit card or other technology that complies with the National Council for Prescription Drug Programs Pharmacy ID Card Implementation Guide in effect at the time of card issuance or includes, at a minimum, the following data elements:

1. The name or identifying trademark of the insurer, corporation, or health maintenance organization or, if a pharmacy benefits manager or another entity administers the prescription benefit, the name or identifying trademark of the pharmacy benefits manager or benefit administrator;

2. The insured's, subscriber's, or enrollee's name and identification number;

3. The telephone number that providers may call for pharmacy benefit assistance; and

4. The electronic transaction routing information and other numbers required by the insurer, corporation, health maintenance organization, pharmacy benefits manager, or benefit administrator to electronically process a prescription claim.

B. The prescription benefit card, health insurance benefit card, or other technology shall be issued to each insured, subscriber or enrollee, and shall upon any changes in the required data elements set forth in subsection A, either reissue the card or provide the insured, subscriber or enrollee such corrective information as may be required to electronically process a prescription claim. Notwithstanding the requirements of § 38.2-4300 and subdivision A 2 of § 38.2-4306, a prescription benefit card, health benefit card or other technology issued pursuant to this section shall not be considered part of the evidence of coverage and shall not be required to be filed with or approved by the Commission.

C. An insurer, corporation, or health maintenance organization, or pharmacy benefits manager may comply with this section by issuing to each insured, subscriber or enrollee a health insurance benefit card that contains data elements related to both prescription and non-prescription health insurance benefits.

D. Compliance with any federal law or regulation that requires the prescription benefit data elements on a prescription benefit card or health insurance benefit card pursuant to subsection A shall be deemed to be compliance with this section.

E. The provisions of this section shall not apply to (i) short-term travel, or accident-only, policies, (ii) short-term nonrenewable policies of not more than six months' duration, (iii) such an insurer,

428 corporation, or health maintenance organization that does not include coverage for prescription drugs; or
429 (iv) any health maintenance organization that operates or maintains its own pharmacies and dispenses,
430 on an annual basis, over ninety-five percent of prescription drugs or devices to its enrollees at its own
431 pharmacies.

432 F. The provisions of this section shall apply to contracts, policies or plans delivered, issued for
433 delivery or renewed in this Commonwealth on and after July 1, 2002.

434 § 38.2-3407.5. Denial of benefits for certain prescription drugs prohibited.

435 A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies
436 providing hospital, medical and surgical or major medical coverage on an expense incurred basis, (ii)
437 corporation providing individual or group accident and sickness subscription contracts, ~~and~~ (iii) health
438 maintenance organization providing a health care plan for health care services, *and (iv) pharmacy*
439 *benefits manager who provides services, including services provided as an agent or contractor under a*
440 *policy, subscription contract, or health care plan*, whose policy, contract or plan, including any
441 certificate or evidence of coverage issued in connection with such policy, contract or plan, includes
442 coverage for prescription drugs, whether on an inpatient basis, outpatient basis, or both, shall provide in
443 each such policy, contract, plan, certificate, and evidence of coverage that such benefits will not be
444 denied for any drug approved by the United States Food and Drug Administration for use in the
445 treatment of cancer on the basis that the drug has not been approved by the United States Food and
446 Drug Administration for the treatment of the specific type of cancer for which the drug has been
447 prescribed, provided the drug has been recognized as safe and effective for treatment of that specific
448 type of cancer in any of the standard reference compendia.

449 B. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies
450 providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii)
451 corporation providing individual or group accident and sickness subscription contracts, ~~and~~ (iii) health
452 maintenance organization providing a health care plan for health care services, *and (iv) pharmacy*
453 *benefits manager who provides services, including services provided as an agent or contractor under a*
454 *policy, subscription contract, or health care plan*, whose policy, contract or plan, including any
455 certificate or evidence of coverage issued in connection with such policy, contract or plan, includes
456 coverage for prescription drugs, whether on an inpatient basis, outpatient basis, or both, shall provide in
457 each such policy, contract, plan, certificate, and evidence of coverage that such benefits will not be
458 denied for any drug prescribed to treat a covered indication so long as the drug has been approved by
459 the United States Food and Drug Administration for at least one indication and the drug is recognized
460 for treatment of the covered indication in one of the standard reference compendia or in substantially
461 accepted peer-reviewed medical literature.

462 C. For the purposes of subsections A and B:

463 "Peer-reviewed medical literature" means a scientific study published only after having been critically
464 reviewed for scientific accuracy, validity, and reliability by unbiased independent experts in a journal
465 that has been determined by the International Committee of Medical Journal Editors to have met the
466 Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical
467 literature does not include publications or supplements to publications that are sponsored to a significant
468 extent by a pharmaceutical manufacturing company or health carrier.

469 "Standard reference compendia" means the American Medical Association Drug Evaluations, the
470 American Hospital Formulary Service Drug Information, or the United States Pharmacopoeia Dispensing
471 Information.

472 D. Coverage, as described in subsections A and B, includes medically necessary services associated
473 with the administration of the drug.

474 E. Subsections A and B shall not be construed to do any of the following:

475 1. Require coverage for any drug if the United States Food and Drug Administration has determined
476 its use to be contraindicated for the treatment of the specific type of cancer or indication for which the
477 drug has been prescribed;

478 2. Require coverage for experimental drugs not otherwise approved for any indication by the United
479 States Food and Drug Administration;

480 3. Alter any law with regard to provisions limiting the coverage of drugs that have not been
481 approved by the United States Food and Drug Administration;

482 4. Create, impair, alter, limit, modify, enlarge, abrogate, or prohibit reimbursement for drugs used in
483 the treatment of any other disease or condition; or

484 5. Require coverage for prescription drugs in any contract, policy or plan that does not otherwise
485 provide such coverage.

486 F. The provisions of this section shall not apply to short-term travel, or accident-only policies, or to
487 short-term nonrenewable policies of not more than six months' duration.

488 G. The provisions of subsection A are applicable to contracts, policies or plans delivered, issued for
489 delivery or renewed in this Commonwealth on and after July 1, 1994, and the provisions of subsection

B are applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1997.

§ 38.2-3407.5:1. Coverage for prescription contraceptives.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense incurred basis; (ii) corporation providing individual or group accident and sickness subscription contracts; ~~and~~ (iii) health maintenance organization providing a health care plan for health care services, *and (iv) pharmacy benefits manager who provides services, including services provided as an agent or contractor under a policy, subscription contract, or health care plan,* whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis, shall offer and make available coverage thereunder for any prescribed drug or device approved by the United States Food and Drug Administration for use as a contraceptive.

B. No insurer, corporation ~~or~~, health maintenance organization, *or pharmacy benefits manager that provides services, including services provided as an agent or contractor under a policy, subscription contract, or health care plan* shall impose upon any person receiving prescription contraceptive benefits pursuant to this section any (i) copayment, coinsurance payment or fee that is not equally imposed upon all individuals in the same benefit category, class, coinsurance level or copayment level receiving benefits for prescription drugs, or (ii) reduction in allowable reimbursement for prescription drug benefits.

C. The provisions of subsection A shall not be construed to:

1. Require coverage for prescription coverage benefits in any contract, policy or plan that does not otherwise provide coverage for prescription drugs;

2. Preclude the use of closed formularies, provided, however, that such formularies shall include oral, implant and injectable contraceptive drugs, intrauterine devices and prescription barrier methods; or

3. Require coverage for experimental contraceptive drugs not approved by the United States Food and Drug Administration.

D. The provisions of this section shall not apply to short-term travel, accident-only, limited or specified disease policies, or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans, or to short-term nonrenewable policies of not more than six months' duration.

E. The provisions of this section shall be applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1997.

§ 38.2-3407.6:1. Denial of benefits for certain prescription drugs prohibited.

A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, ~~and~~ (iii) health maintenance organization providing a health care plan for health care services, *and (iv) pharmacy benefits manager who provides services, including services provided as an agent or contractor under a policy, subscription contract, or health care plan,* whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs, whether on an inpatient basis, an outpatient basis, or both, shall provide in each such policy, contract, plan, certificate, and evidence of coverage that such benefits shall not be denied for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer pain on the basis that the dosage is in excess of the recommended dosage of the pain-relieving agent, if the prescription in excess of the recommended dosage has been prescribed in compliance with §§ 54.1-2971.01, 54.1-3303 and 54.1-3408.1 for a patient with intractable cancer pain.

B. The provisions of this section shall not apply to short-term travel, or accident-only policies, or to short-term nonrenewable policies of not more than six months' duration.

C. The provisions of this section are applicable to contracts, policies or plans delivered, issued for delivery or renewed in this Commonwealth on and after July 1, 1999.

§ 38.2-3407.7. Pharmacies; freedom of choice.

A. Notwithstanding any provision of § 38.2-3407 to the contrary, no insurer proposing to issue preferred provider policies or contracts *nor any pharmacy benefits manager who provides services, including services provided as an agent or contractor under a policy,* shall prohibit any person receiving pharmacy benefits furnished thereunder from selecting, without limitation, the pharmacy of his choice to furnish such benefits. This right of selection extends to and includes pharmacies that are nonpreferred providers and that have previously notified the insurer, by facsimile or otherwise, of their agreement to accept reimbursement for their services at rates applicable to pharmacies that are preferred providers, including any copayment consistently imposed by the insurer, as payment in full. Each insurer *and*

551 *pharmacy benefits manager* shall permit prompt electronic or telephonic transmittal of the reimbursement
552 agreement by the pharmacy and ensure prompt verification to the pharmacy of the terms of
553 reimbursement. In no event shall any person receiving a covered pharmacy benefit from a nonpreferred
554 provider which has submitted a reimbursement agreement be responsible for amounts that may be
555 charged by the nonpreferred provider in excess of the copayment and the insurer's *or pharmacy benefits*
556 *manager's* reimbursement applicable to all of its preferred pharmacy providers.

557 B. No such insurer *or pharmacy benefits manager* shall impose upon any person receiving
558 pharmaceutical benefits furnished under any such policy or contract:

559 1. Any copayment, fee or condition that is not equally imposed upon all individuals in the same
560 benefit category, class or copayment level, whether or not such benefits are furnished by pharmacists
561 who are nonpreferred providers;

562 2. Any monetary penalty that would affect or influence any such person's choice of pharmacy; ~~or~~

563 3. Any reduction in allowable reimbursement for pharmacy services related to utilization of
564 pharmacists who are nonpreferred providers; *or*

565 4. *A different copayment, fee, or condition for persons wishing to have prescriptions filled at a*
566 *participating pharmacy other than a mail order pharmacy, regardless of the number of months for*
567 *which the prescription is written.*

568 C. For purposes of this section, a prohibited condition or penalty shall include, without limitation: (i)
569 denying immediate access to electronic claims filing to a pharmacy which is a nonpreferred provider and
570 which has complied with subsection D below or (ii) requiring a person receiving pharmacy benefits to
571 make payment at point of service, except to the extent such conditions and penalties are similarly
572 imposed on preferred providers.

573 D. Any pharmacy which wishes to be covered by this section shall, if requested to do so in writing
574 by an insurer, within thirty days of the pharmacy's receipt of the request, execute and deliver to the
575 insurer *or pharmacy benefits manager* the direct service agreement or preferred provider agreement
576 which the insurer *or pharmacy benefits manager* requires all of its preferred providers of pharmacy
577 benefits to execute. Any pharmacy which fails to timely execute and deliver such agreement shall not be
578 covered by this section with respect to that insurer *or pharmacy benefits manager* unless and until the
579 pharmacy executes and delivers the agreement.

580 E. The Commission shall have no jurisdiction to adjudicate controversies arising out of this section.

581 § 38.2-3407.9:01. Prescription drug formularies.

582 A. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies
583 providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii)
584 corporation providing individual or group accident and sickness subscription contracts, ~~and~~ (iii) health
585 maintenance organization providing a health care plan for health care services, *and (iv) pharmacy*
586 *benefits manager who provides services, including services provided as an agent or contractor under a*
587 *policy, subscription contract, or health care plan,* whose policy, contract or plan, including any
588 certificate or evidence of coverage issued in connection with such policy, contract or plan, includes
589 coverage for prescription drugs on an outpatient basis may apply a formulary to the prescription drug
590 benefits provided by the insurer, corporation, ~~or~~ health maintenance organization, *or pharmacy benefits*
591 *manager* if the formulary is developed, reviewed at least annually, and updated as necessary in
592 consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose
593 members are actively practicing licensed pharmacists, physicians and other licensed health care
594 providers.

595 B. If an insurer, corporation, ~~or~~ health maintenance organization, *or pharmacy benefits manager*
596 maintains one or more closed drug formularies, each insurer, corporation ~~or~~, health maintenance
597 organization, *or pharmacy benefits manager* shall:

598 1. Make available to participating providers and pharmacists and to any nonpreferred or
599 nonparticipating pharmacists as described in §§ 38.2-3407.7 and 38.2-4312.1, the complete, current drug
600 formulary or formularies, or any updates thereto, maintained by the insurer, corporation, ~~or~~ health
601 maintenance organization, *or pharmacy benefits manager*, including a list of the prescription drugs on
602 the formulary by major therapeutic category that specifies whether a particular prescription drug is
603 preferred over other drugs;

604 2. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that
605 provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically
606 necessary nonformulary prescription drug if the formulary drug is determined by the insurer, corporation,
607 ~~or~~ health maintenance organization, *or pharmacy benefits manager*, after reasonable investigation and
608 consultation with the prescribing physician, to be an inappropriate therapy for the medical condition of
609 the enrollee. The insurer, corporation ~~or~~, health maintenance organization, *or pharmacy benefits manager*
610 shall act on such requests within one business day of receipt of the request; and

611 3. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that
612 provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically

necessary nonformulary prescription drug when the enrollee has been receiving the specific nonformulary prescription drug for at least six months previous to the development or revision of the formulary and the prescribing physician has determined that the formulary drug is an inappropriate therapy for the specific patient or that changing drug therapy presents a significant health risk to the specific patient. After reasonable investigation and consultation with the prescribing physician, the insurer, corporation ~~or~~, health maintenance organization, *or pharmacy benefits manager* shall act on such requests within one business day of receipt of the request. For purposes of this subsection, substituting the generic equivalent drug, which has been approved by the U.S. Food and Drug Administration, for a branded version of such drug shall not constitute a change in drug therapy.

§ 38.2-3407.9:02. Requirement for prescription drug coverage.

No (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, ~~or~~ (iii) health maintenance organization providing a health care plan for health care services, *or (iv) pharmacy benefits manager who provides services, including services provided as an agent or contractor under a policy, subscription contract, or health care plan,* whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs shall exclude coverage for any prescription drug solely on the basis of the length of time since the drug obtained FDA approval.

§ 38.2-3407.15. Ethics and fairness in carrier business practices.

A. As used in this section:

"Carrier," "enrollee" and "provider" shall have the meanings set forth in § 38.2-3407.10; however, a "carrier" shall also include any person required to be licensed under this title which offers or operates a managed care health insurance plan subject to Chapter 58 (§ 38.2-5800 et seq.) of this title or which provides or arranges for the provision of health care services, health plans, networks ~~or~~, provider panels ~~which or pharmacy benefits management services that~~ are subject to regulation as the business of insurance under this title.

"Claim" means any bill, claim, or proof of loss made by or on behalf of an enrollee or a provider to a carrier (or its intermediary, administrator or representative) with which the provider has a provider contract for payment for health care services under any health plan; however, a "claim" shall not include a request for payment of a capitation or a withhold.

"Clean claim" means a claim (i) that has no material defect or impropriety (including any lack of any reasonably required substantiation documentation) which substantially prevents timely payment from being made on the claim or (ii) with respect to which a carrier has failed timely to notify the person submitting the claim of any such defect or impropriety in accordance with this section.

"Health care services" means items or services furnished to any individual for the purpose of preventing, alleviating, curing, or healing human illness, injury or physical disability.

"Health plan" means any individual or group health care plan, subscription contract, evidence of coverage, certificate, health services plan, medical or hospital services plan, accident and sickness insurance policy or certificate, managed care health insurance plan, or other similar certificate, policy, contract or arrangement, and any endorsement or rider thereto, to cover all or a portion of the cost of persons receiving covered health care services, which is subject to state regulation and which is required to be offered, arranged or issued in the Commonwealth by a carrier licensed under this title. Health plan does not mean (i) coverages issued pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare), Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. or Title XX of the Social Security Act, 42 U.S.C. § 1397 et seq. (Medicaid), 5 U.S.C. § 8901 et seq. (federal employees), or 10 U.S.C. § 1071 et seq. (CHAMPUS); or (ii) accident only, credit or disability insurance, long-term care insurance, CHAMPUS supplement, Medicare supplement, or workers' compensation coverages.

"Provider contract" means any contract between a provider and a carrier (or a carrier's network, provider panel, intermediary or representative) relating to the provision of health care services.

"Retroactive denial of a previously paid claim" or "retroactive denial of payment" means any attempt by a carrier retroactively to collect payments already made to a provider with respect to a claim by reducing other payments currently owed to the provider, by withholding or setting off against future payments, or in any other manner reducing or affecting the future claim payments to the provider.

B. Subject to subsection H, every provider contract entered into by a carrier shall contain specific provisions which shall require the carrier to adhere to and comply with the following minimum fair business standards in the processing and payment of claims for health care services:

1. A carrier shall pay any claim within 40 days of receipt of the claim except where the obligation of the carrier to pay a claim is not reasonably clear due to the existence of a reasonable basis supported by specific information available for review by the person submitting the claim that:

a. The claim is determined by the carrier not to be a clean claim due to a good faith determination

674 or dispute regarding (i) the manner in which the claim form was completed or submitted, (ii) the
675 eligibility of a person for coverage, (iii) the responsibility of another carrier for all or part of the claim,
676 (iv) the amount of the claim or the amount currently due under the claim, (v) the benefits covered, or
677 (vi) the manner in which services were accessed or provided; or

678 b. The claim was submitted fraudulently.

679 Each carrier shall maintain a written or electronic record of the date of receipt of a claim. The
680 person submitting the claim shall be entitled to inspect such record on request and to rely on that record
681 or on any other admissible evidence as proof of the fact of receipt of the claim, including without
682 limitation electronic or facsimile confirmation of receipt of a claim.

683 2. A carrier shall, within 30 days after receipt of a claim, request electronically or in writing from
684 the person submitting the claim the information and documentation that the carrier reasonably believes
685 will be required to process and pay the claim or to determine if the claim is a clean claim. Upon receipt
686 of the additional information requested under this subsection necessary to make the original claim a
687 clean claim, a carrier shall make the payment of the claim in compliance with this section. No carrier
688 may refuse to pay a claim for health care services rendered pursuant to a provider contract which are
689 covered benefits if the carrier fails timely to notify or attempt to notify the person submitting the claim
690 of the matters identified above unless such failure was caused in material part by the person submitting
691 the claims; however, nothing herein shall preclude such a carrier from imposing a retroactive denial of
692 payment of such a claim if permitted by the provider contract unless such retroactive denial of payment
693 of the claim would violate subdivision 6 of this subsection. Nothing in this subsection shall require a
694 carrier to pay a claim which is not a clean claim.

695 3. Any interest owing or accruing on a claim under § 38.2-3407.1 or 38.2-4306.1 of this title, under
696 any provider contract or under any other applicable law, shall, if not sooner paid or required to be paid,
697 be paid, without necessity of demand, at the time the claim is paid or within 60 days thereafter.

698 4. a. Every carrier shall establish and implement reasonable policies to permit any provider with
699 which there is a provider contract (i) to confirm in advance during normal business hours by free
700 telephone or electronic means if available whether the health care services to be provided are medically
701 necessary and a covered benefit and (ii) to determine the carrier's requirements applicable to the provider
702 (or to the type of health care services which the provider has contracted to deliver under the provider
703 contract) for (a) pre-certification or authorization of coverage decisions, (b) retroactive reconsideration of
704 a certification or authorization of coverage decision or retroactive denial of a previously paid claim, (c)
705 provider-specific payment and reimbursement methodology, coding levels and methodology,
706 downcoding, and bundling of claims, and (d) other provider-specific, applicable claims processing and
707 payment matters necessary to meet the terms and conditions of the provider contract, including
708 determining whether a claim is a clean claim. If a carrier routinely, as a matter of policy, bundles or
709 downcodes claims submitted by a provider, the carrier shall clearly disclose that practice in each
710 provider contract. Further, such carrier shall either (i) disclose in its provider contracts or on its website
711 the specific bundling and downcoding policies that the carrier reasonably expects to be applied to the
712 provider or provider's services on a routine basis as a matter of policy or (ii) disclose in each provider
713 contract a telephone or facsimile number or e-mail address that a provider can use to request the specific
714 bundling and downcoding policies that the carrier reasonably expects to be applied to that provider or
715 provider's services on a routine basis as a matter of policy. If such request is made by or on behalf of a
716 provider, a carrier shall provide the requesting provider with such policies within 10 business days
717 following the date the request is received.

718 b. Every carrier shall make available to such providers within 10 business days of receipt of a
719 request, copies of or reasonable electronic access to all such policies which are applicable to the
720 particular provider or to particular health care services identified by the provider. In the event the
721 provision of the entire policy would violate any applicable copyright law, the carrier may instead
722 comply with this subsection by timely delivering to the provider a clear explanation of the policy as it
723 applies to the provider and to any health care services identified by the provider.

724 5. Every carrier shall pay a claim if the carrier has previously authorized the health care service or
725 has advised the provider or enrollee in advance of the provision of health care services that the health
726 care services are medically necessary and a covered benefit, unless:

727 a. The documentation for the claim provided by the person submitting the claim clearly fails to
728 support the claim as originally authorized; or

729 b. The carrier's refusal is because (i) another payor is responsible for the payment, (ii) the provider
730 has already been paid for the health care services identified on the claim, (iii) the claim was submitted
731 fraudulently or the authorization was based in whole or material part on erroneous information provided
732 to the carrier by the provider, enrollee, or other person not related to the carrier, or (iv) the person
733 receiving the health care services was not eligible to receive them on the date of service and the carrier
734 did not know, and with the exercise of reasonable care could not have known, of the person's eligibility
735 status.

6. No carrier may impose any retroactive denial of a previously paid claim unless the carrier has provided the reason for the retroactive denial and (i) the original claim was submitted fraudulently, (ii) the original claim payment was incorrect because the provider was already paid for the health care services identified on the claim or the health care services identified on the claim were not delivered by the provider, or (iii) the time which has elapsed since the date of the payment of the original challenged claim does not exceed the lesser of (a) 12 months or (b) the number of days within which the carrier requires under its provider contract that a claim be submitted by the provider following the date on which a health care service is provided. Effective July 1, 2000, a carrier shall notify a provider at least 30 days in advance of any retroactive denial of a claim.

7. Notwithstanding subdivision 6 of this subsection, with respect to provider contracts entered into, amended, extended, or renewed on or after July 1, 2004, no carrier shall impose any retroactive denial of payment or in any other way seek recovery or refund of a previously paid claim unless the carrier specifies in writing the specific claim or claims for which the retroactive denial is to be imposed or the recovery or refund is sought. The written communication shall also contain an explanation of why the claim is being retroactively adjusted.

8. No provider contract may fail to include or attach at the time it is presented to the provider for execution (i) the fee schedule, reimbursement policy or statement as to the manner in which claims will be calculated and paid which is applicable to the provider or to the range of health care services reasonably expected to be delivered by that type of provider on a routine basis and (ii) all material addenda, schedules and exhibits thereto and any policies (including those referred to in subdivision 4 of this subsection) applicable to the provider or to the range of health care services reasonably expected to be delivered by that type of provider under the provider contract.

9. No amendment to any provider contract or to any addenda, schedule, exhibit or policy thereto (or new addenda, schedule, exhibit, or policy) applicable to the provider (or to the range of health care services reasonably expected to be delivered by that type of provider) shall be effective as to the provider, unless the provider has been provided with the applicable portion of the proposed amendment (or of the proposed new addenda, schedule, exhibit, or policy) at least 60 calendar days before the effective date and the provider has failed to notify the carrier within 30 calendar days of receipt of the documentation of the provider's intention to terminate the provider contract at the earliest date thereafter permitted under the provider contract.

10. In the event that the carrier's provision of a policy required to be provided under subdivision 8 or 9 of this subsection would violate any applicable copyright law, the carrier may instead comply with this section by providing a clear, written explanation of the policy as it applies to the provider.

11. All carriers shall establish, in writing, their claims payment dispute mechanism and shall make this information available to providers.

C. Without limiting the foregoing, in the processing of any payment of claims for health care services rendered by providers under provider contracts and in performing under its provider contracts, every carrier subject to regulation by this title shall adhere to and comply with the minimum fair business standards required under subsection B, and the Commission shall have the jurisdiction to determine if a carrier has violated the standards set forth in subsection B by failing to include the requisite provisions in its provider contracts and shall have jurisdiction to determine if the carrier has failed to implement the minimum fair business standards set out in subdivisions B 1 and B 2 in the performance of its provider contracts.

D. No carrier shall be in violation of this section if its failure to comply with this section is caused in material part by the person submitting the claim or if the carrier's compliance is rendered impossible due to matters beyond the carrier's reasonable control (such as an act of God, insurrection, strike, fire, or power outages) which are not caused in material part by the carrier.

E. Any provider who suffers loss as the result of a carrier's violation of this section or a carrier's breach of any provider contract provision required by this section shall be entitled to initiate an action to recover actual damages. If the trier of fact finds that the violation or breach resulted from a carrier's gross negligence and willful conduct, it may increase damages to an amount not exceeding three times the actual damages sustained. Notwithstanding any other provision of law to the contrary, in addition to any damages awarded, such provider also may be awarded reasonable attorney's fees and court costs. Each claim for payment which is paid or processed in violation of this section or with respect to which a violation of this section exists shall constitute a separate violation. The Commission shall not be deemed to be a "trier of fact" for purposes of this subsection.

F. No carrier (or its network, provider panel or intermediary) shall terminate or fail to renew the employment or other contractual relationship with a provider, or any provider contract, or otherwise penalize any provider, for invoking any of the provider's rights under this section or under the provider contract.

G. This section shall apply only to carriers subject to regulation under this title.

797 H. This section shall apply with respect to provider contracts entered into, amended, extended or
798 renewed on or after July 1, 1999.

799 I. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and
800 regulations as it may deem necessary to implement this section.

801 J. If any provision of this section, or the application thereof to any person or circumstance, is held
802 invalid or unenforceable, such determination shall not affect the provisions or applications of this section
803 which can be given effect without the invalid or unenforceable provision or application, and to that end
804 the provisions of this section are severable.

805 K. The Commission shall have no jurisdiction to adjudicate individual controversies arising out of
806 this section.

807 § 38.2-4209.1. Pharmacies; freedom of choice.

808 A. Notwithstanding any provision of § 38.2-4209, no corporation providing preferred provider
809 subscription contracts, *nor any pharmacy benefits manager who provides services, including services*
810 *provided as an agent or contractor under a subscription contract*, shall prohibit any person receiving
811 pharmaceutical benefits thereunder from selecting, without limitation, the pharmacy of his choice to
812 furnish such benefits. This right of selection extends to and includes pharmacies that are nonpreferred
813 providers and that have previously notified the corporation *or pharmacy benefits manager*, by facsimile
814 or otherwise, of their agreement to accept reimbursement for their services at rates applicable to
815 pharmacies that are preferred providers, including any copayment consistently imposed by the
816 corporation *or pharmacy benefits manager*, as payment in full. Each corporation *or pharmacy benefits*
817 *manager* shall permit prompt electronic or telephonic transmittal of the reimbursement agreement by the
818 pharmacy and ensure payment verification to the pharmacy of the terms of reimbursement. In no event
819 shall any person receiving a covered pharmacy benefit from a nonpreferred provider which has
820 submitted a reimbursement agreement be responsible for amounts that may be charged by the
821 nonpreferred provider in excess of the copayment and the corporation's *or pharmacy benefits manager's*
822 reimbursement applicable to all of its preferred pharmacy providers.

823 B. No such corporation *or pharmacy benefits manager* shall impose upon any person receiving
824 pharmaceutical benefits furnished under any such contract:

825 1. Any copayment, fee or condition that is not equally imposed upon all individuals in the same
826 benefit category, class or copayment level, whether or not such benefits are furnished by pharmacists
827 who are nonpreferred providers;

828 2. Any monetary penalty that would affect or influence any such person's choice of pharmacy; ~~or~~

829 3. Any reduction in allowable reimbursement for pharmacy services related to utilization of
830 pharmacists who are nonpreferred providers; *or*

831 4. *A different copayment, fee, or condition for persons wishing to have prescriptions filled at a*
832 *participating pharmacy other than a mail order pharmacy, regardless of the number of months for*
833 *which the prescription is written.*

834 C. For purposes of this section, a prohibited condition or penalty shall include, without limitation: (i)
835 denying immediate access to electronic claims filing to a pharmacy which is a nonpreferred provider and
836 which has complied with subsection D below or (ii) requiring a person receiving pharmacy benefits to
837 make payment at point of service, except to the extent such conditions and penalties are similarly
838 imposed on preferred providers.

839 D. Any pharmacy which wishes to be covered by this section shall, if requested to do so in writing
840 by a corporation *or pharmacy benefits manager*, within thirty days of the pharmacy's receipt of the
841 request, execute and deliver to the corporation *or pharmacy benefits manager* the direct service
842 agreement or preferred provider agreement which the corporation *or pharmacy benefits manager* requires
843 all of its preferred providers of pharmacy benefits to execute. Any pharmacy which fails to timely
844 execute and deliver such agreement shall not be covered by this section with respect to that corporation
845 unless and until the pharmacy executes and delivers the agreement.

846 E. The Commission shall have no jurisdiction to adjudicate controversies arising out of this section.

847 § 38.2-4214. Application of certain provisions of law.

848 No provision of this title except this chapter and, insofar as they are not inconsistent with this
849 chapter, §§ 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-218 through 38.2-225, 38.2-230,
850 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through
851 38.2-515, 38.2-600 through 38.2-620, 38.2-700 through 38.2-705, 38.2-900 through 38.2-904, 38.2-1017,
852 38.2-1018, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.) and 2
853 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1315.1, 38.2-1317 through
854 38.2-1328, 38.2-1334, 38.2-1340, *Article 10 (§ 38.2-1365 et seq.) of Chapter 13*, 38.2-1400 through
855 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3400, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3405.1,
856 38.2-3407.1 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3409, 38.2-3411 through
857 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3501, 38.2-3502, subdivision 13 of § 38.2-3503,
858 subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, §§ 38.2-3516 through 38.2-3520 as they

apply to Medicare supplement policies, §§ 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3541, 38.2-3542, 38.2-3543.2, 38.2-3600 through 38.2-3607, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall apply to the operation of a plan.

§ 38.2-4312.1. Pharmacies; freedom of choice.

A. Notwithstanding any other provision in this chapter, no health maintenance organization providing health care plans *nor any pharmacy benefits manager who provides services, including services provided as an agent or contractor under a health care plan* shall prohibit any person receiving pharmaceutical benefits thereunder from selecting, without limitation, the pharmacy of his choice to furnish such benefits. This right of selection extends to and includes pharmacies that are not participating providers under any such health care plan and that have previously notified the health maintenance organization *or pharmacy benefits manager*, by facsimile or otherwise, of their agreement to accept reimbursement for their services at rates applicable to pharmacies that are participating providers, including any copayment consistently imposed by the plan *or pharmacy benefits manager*, as payment in full. Each health maintenance organization *or pharmacy benefits manager* shall permit prompt electronic or telephonic transmittal of the reimbursement agreement by the pharmacy and ensure prompt verification to the pharmacy of the terms of reimbursement. In no event shall any person receiving a covered pharmacy benefit from a nonparticipating provider which has submitted a reimbursement agreement be responsible for amounts that may be charged by the nonparticipating provider in excess of the copayment and the health maintenance organization's *or pharmacy benefits manager's* reimbursement applicable to all of its participating pharmacy providers.

B. No such health maintenance organization *or pharmacy benefits manager* shall impose upon any person receiving pharmaceutical benefits furnished under any such health care plan:

1. Any copayment, fee or condition that is not equally imposed upon all individuals in the same benefit category, class or copayment level, whether or not such benefits are furnished by pharmacists who are not participating providers;

2. Any monetary penalty that would affect or influence any such person's choice of pharmacy; ~~or~~

3. Any reduction in allowable reimbursement for pharmacy services related to utilization of pharmacists who are not participating providers; *or*

4. *A different copayment, fee, or condition for persons wishing to have prescriptions filled at a participating pharmacy other than a mail order pharmacy, regardless of the number of months for which the prescription is written.*

C. For purposes of this section, a prohibited condition or penalty shall include, without limitation: (i) denying immediate access to electronic claims filing to a pharmacy which is a nonparticipating provider and which has complied with subsection E below or (ii) requiring a person receiving pharmacy benefits to make payment at point of service, except to the extent such conditions and penalties are similarly imposed on participating providers.

D. The provisions of this section are not applicable to any pharmaceutical benefit covered by a health care plan when those benefits are obtained from a pharmacy wholly owned and operated by, or exclusively operated for, the health maintenance organization providing the health care plan.

E. Any pharmacy which wishes to be covered by this section shall, if requested to do so in writing by a health maintenance organization *or pharmacy benefits manager*, within thirty days of the pharmacy's receipt of the request, execute and deliver to the health maintenance organization *or pharmacy benefits manager* the direct service agreement or participating provider agreement which the health maintenance organization *or pharmacy benefits manager* requires all of its participating providers of pharmacy benefits to execute. Any pharmacy which fails to timely execute and deliver such agreement shall not be covered by this section with respect to that health maintenance organization *or pharmacy benefits manager* unless and until the pharmacy executes and delivers the agreement.

F. The Commission shall have no jurisdiction to adjudicate controversies arising out of this section.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1017 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, *Article 10* (§ 38.2-1365 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through 38.2-3418.14, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1

920 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.),
921 Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be
922 applicable to any health maintenance organization granted a license under this chapter. This chapter shall
923 not apply to an insurer or health services plan licensed and regulated in conformance with the insurance
924 laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health
925 maintenance organization.

926 B. Solicitation of enrollees by a licensed health maintenance organization or by its representatives
927 shall not be construed to violate any provisions of law relating to solicitation or advertising by health
928 professionals.

929 C. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful
930 practice of medicine. All health care providers associated with a health maintenance organization shall
931 be subject to all provisions of law.

932 D. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health
933 maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to
934 offer coverage to or accept applications from an employee who does not reside within the health
935 maintenance organization's service area.

936 E. For purposes of applying this section, "insurer" when used in a section cited in subsection A of
937 this section shall be construed to mean and include "health maintenance organizations" unless the section
938 cited clearly applies to health maintenance organizations without such construction.

939 § 38.2-4509. Application of certain laws.

940 A. No provision of this title except this chapter and, insofar as they are not inconsistent with this
941 chapter, §§ 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229,
942 38.2-316, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620,
943 38.2-900 through 38.2-904, 38.2-1038, 38.2-1040 through 38.2-1044, Articles 1 (§ 38.2-1300 et seq.)
944 and 2 (§ 38.2-1306.2 et seq.) of Chapter 13, §§ 38.2-1312, 38.2-1314, 38.2-1315.1, Article 4
945 (§ 38.2-1317 et seq.) of Chapter 13, *Article 10 (§ 38.2-1365 et seq.) of Chapter 13*, §§ 38.2-1400
946 through 38.2-1444, 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3404, 38.2-3405, 38.2-3407.10,
947 38.2-3407.13, 38.2-3407.14, 38.2-3407.15, 38.2-3415, 38.2-3541, 38.2-3600 through 38.2-3603, Chapter
948 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall apply to the
949 operation of a plan.

950 B. The provisions of subsection A of § 38.2-322 shall apply to an optometric services plan. The
951 provisions of subsection C of § 38.2-322 shall apply to a dental services plan.

952 C. The provisions of Article 1.2 (§ 32.1-137.7 et seq.) of Chapter 5 of Title 32.1 shall not apply to
953 either an optometric or dental services plan.