120-2-97 Pharmacy Benefit Managers Regulation

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120-2-97-.01

Authority

This Regulation is promulgated by the Commissioner of Insurance pursuant to the authority set forth in O.C.G.A. §§ 33-2-9 and 33-64-1 et seq. All terms defined in O.C.G.A. § 33-64-1, hereinafter referred to as the Pharmacy Benefits Manager Act, which are used in this Regulation, shall have the same meaning as in the Act.

120-2-97-.02

Scope and purpose

(1) This Regulation applies to any pharmacy benefits manager as defined in O.C.G.A. §~~Section~~ 33-64-1.

(2) The purposes of this Regulation include:

(a) Providing the regulation and licensure of pharmacy benefits managers;

(b) Promoting the financial responsibility of pharmacy benefits managers;

(c) To protect the interests of the enrolled public;

(d) To provide means by which to govern, regulate, and monitor the conduct of pharmacy benefits managers;

(e) Subjecting those business entities defined in O.C.G.A. § 33-64-1 to the jurisdiction of the Commissioner of Insurance; and

(f)~~(d)~~ Regulating pharmacy benefits managers' practices in conformity with the general purposes of the Georgia Insurance Code.

120-2-97-.03

License; application; issuance; renewal; net worth; probationary license

(1) It is unlawful for any person, business entity, or other entity to act as or hold itself out to be a pharmacy benefits manager in this State without a valid license issued by the Commissioner of Insurance. To qualify for and hold a license to act as a pharmacy benefits manager in this State, a pharmacy benefits manager must otherwise be in compliance with Chapter 64 of Title 33 of the Official Code of Georgia Annotated and this Regulation.

(2) The pharmacy benefits manager shall file with the Commissioner an application for a license upon a form to be furnished by the Commissioner.

(3) An audited financial statement or such other information as the Commissioner may require that demonstrates that the applicant possesses a minimum net worth of $200,000. Letters of credit, backstop guarantees and special corporate structures will not be taken into consideration by the Commissioner in determining the net worth requirement.

(4) A Bond and proof of Errors and Omissions coverage must be included in the application and maintained by the pharmacy benefits manager.

(5) An application for a pharmacy benefits manager's license shall be accompanied by a fee of $2000.00~~500.00~~.

(6) The Commissioner shall not issue a license or renew an existing license if he or she determines that the pharmacy benefits manager has:

(a) Misrepresented or concealed any material fact in the application for the license;

(b) Has obtained or attempted to obtain the license by misrepresentation, concealment, or other fraud; ~~or~~

(c) Has committed fraud;

(d) Has failed to obtain for initial licensure or retain for annual renewal a net worth of at least $200,000; or.

(e) Has violated any provision of this chapter while on probation, if for license renewal.

(7) A license issued under this section may be issued on a probationary basis in the discretion of the Commissioner. The probationary license may be issued for not longer than 12 months and not less than 3 months and is subject to revocation without a hearing. The Commissioner, at his or her discretion, shall prescribe the terms of probation, may extend the probationary period, or refuse to grant a license at the end of any probationary period.

120-2-97-.04

Pharmacy benefits managers bond; and errors and omissions coverage

(1) Every pharmacy benefits manager shall file a bond with the Commissioner. The pharmacy benefits manager shall file a certificate of such bond, in a form acceptable by a corporate surety insurer authorized to transact insurance in this state in favor of Commissioner of Insurance of the state of Georgia, continuous in form and in an amount $100,000.

(2) The bond shall inure to the benefit of any person damaged by any fraudulent act or conduct of the pharmacy benefits manager and must be conditioned upon faithful accounting and application of all money coming into the pharmacy benefits manager's possession in connection with its activities as an pharmacy benefits manager.

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Lines 128-130 of HB 946

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(3) The bond remains in force until released by the Commissioner or canceled by the surety. Without prejudice to any liability previously incurred, the surety may cancel the bond upon thirty (30) days' advance notice to the pharmacy benefits manager and the Commissioner. A pharmacy benefits manager's license shall be suspended if it does not file with the Commissioner a replacement bond before the date of cancellation of the previous bond. A replacement bond must meet all requirements of this section for the initial bond.

(4) Each pharmacy benefits manager shall obtain errors and omissions coverage or other appropriate liability insurance, written by an insurer authorized to transact insurance in this state, in an amount of at least $250,000.

(5) Any policy written in accordance with paragraph (4) of this Rule shall be for a term of at least one year and shall contain provisions that:

(a) Cancellation or termination of the policy is not effective except upon sixty (60) days' written notice by registered or certified mail to the other party to the policy and to the Commissioner; and

(b) The policy is automatically renewable at the expiration of the policy period except upon sixty (60) days' written notice by registered or certified mail by the party not renewing the policy to the other party to the policy and to the Commissioner.

(6) Compliance by the pharmacy benefits manager with paragraphs (1) and (4) of this Rule is a prerequisite to approval of its application by the Commissioner.

(7) Any bond and errors and omissions coverage required for licensure and renewal purposes shall be maintained in place by the pharmacy benefits manager for a period of at least one year immediately following the surrender, non-renewal or revocation of the license.

120-2-97-.05

Annual renewal

(1) Each authorized pharmacy benefits manager shall file with the Commissioner an annual renewal of its license on a form prescribed by the Commissioner. The statement shall be filed annually on or before May 1. The annual renewal shall be in such form and contain such matters as the Commissioner prescribes and shall be verified by at least one officer of the pharmacy benefits manager. For good cause shown the Commissioner may extend the time for filing of the annual renewal of the license conditioned upon payment of a late fee of $15.00 per day as prescribed by law at O.C.G.A. § 33-8-1(W). In the event the pharmacy benefits manager does not timely renew its license prior to the expiration of its license, June 30, the pharmacy benefits manager will cease to have a valid license and will need to reapply for a new license prior to commencing its business or initiating new business in Georgia. If the pharmacy benefits manager fails to renew its license the Commissioner shall provide notice to the pharmacy benefits manager and the pharmacy benefits manager may invoke the right to a hearing.

(2) At the time of filing its annual renewal, the pharmacy benefits manager shall pay a filing fee of $1000.00~~400.00~~.

(3) The pharmacy benefits manager shall at all times maintain a net worth of $200,000. If the pharmacy benefits manager fails to maintain a net worth of $200,000 the Commissioner, in his or her discretion, may enter any disciplinary order as he or she deems appropriate pursuant to Title 33. In order to verify the net worth of the pharmacy benefits manager, proof that the applicant possesses a minimum net worth of $200,000 must be included in the annual renewal filing that represents the calendar year end or fiscal year end of the pharmacy benefits manager.

120-2-97-.06

Examination by eCommissioner; ~~and~~ on-site visits; access to records; and expenses

(1) The Commissioner or his or her designated representative is authorized to conduct financial examinations, compliance audits, and investigate complaints~~make a complete on-site examination~~ of the affairs of each pharmacy benefits manager as often as is deemed necessary. Whenever the Commissioner shall deem it expedient, he or she shall examine, either directly or by use of an examiner duly authorized by him or her, the affairs, transactions, accounts, records, documents, assets, liabilities, of a pharmacy benefits manager and any other facts relative to its business methods, management, and dealings with a health plan or covered entity.

(2) Any pharmacy benefits manager being examined shall provide to the Commissioner or his or her designee convenient and free access, at all reasonable hours at their offices, to all books, records, documents and other papers relating to such pharmacy benefits manager's business affairs. In addition to on-site access to records, a pharmacy benefit manager shall, upon written request, make its records available to the Commissioner or the Commissioner's designee, unless otherwise directed by the Commissioner.

(3) ~~At the direction of the Commissioner the~~A pharmacy benefits manager shall pay the fees and expenses of the examination whether conducted by the Commissioner or contracted examiner designated by the Commissioner. A consolidated account for the examination shall be filed by the examiner with the Commissioner. When a pharmacy benefits manager is examined as a result of a complaint filed against it and the Commissioner determines that the complaint was not justified, the expenses incurred as a result of the examination shall not be levied against the pharmacy benefits manager.

(4) Nothing in this rule shall limit or abridge any other investigatory powers of the Commissioner vested in him or her by Title 33 of the Official Code of Georgia Annotated.

120-2-97-.07

Forms; reports; and required documentation

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Line 130 of HB 946

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(1)Standard pharmacy benefits manager forms are required and will be supplied upon request by the Commissioner's office either in paper form or electronically over the internet. Applicants and licensed pharmacy benefits managers shall utilize all applicable forms in preparing applications, statements, notices of required information, and other required submissions required under Chapter 64 of Title 33 of the Official Code of Georgia Annotated.

(2) A pharmacy benefits manager shall file all methodologies utilized in determining multi-source generic drug pricing reimbursement to pharmacies in this state within 30 days of their use and upon receiving a notice of complaint by the Commissioner in connection with O.C.G.A. § 33-64-9, a pharmacy benefits manager shall within five business days:

(a) Identify the methodology and source or sources used to determine the multi-source generic drug price for the drug which is the subject of the complaint; and

(b) Identify the reason for the denial of any pharmacy reimbursement appeal and produce relevant documentation in connection with the reimbursement price of the drug the day the claim at issue in the complaint was adjudicated and the preceding 5 days prior to the day the claim was adjudicated including source pricing records as well the national drug code of an equivalent drug product that could have been purchased by the complainant pharmacy at a price at or below the amount the pharmacy was reimbursed;

(3) A pharmacy benefits manager shall annually file a disclosure statement identifying all affiliate pharmacies holding a Georgia license or non-resident pharmacy and upon receiving a notice of complaint by the Commissioner in connection with steering or a mail order mandate, a pharmacy benefits manager shall provide within five business days:

(a) Any and all communications sent to the insured within the previous 12 months advertising, marketing, promoting an affiliate pharmacy or the affiliate pharmacy of another pharmacy benefits manager; any communication ordering an insured to use an affiliate pharmacy benefits manager or indicating that an insured's costs will increase when using a non-affiliate pharmacy; and

(b) Any and all communications sent to a non-affiliate pharmacy when an insured attempted to fill a prescription including any on-screen rejections or other messaging directing an insured to an affiliate pharmacy or affiliate of another pharmacy benefits manager.

(4) As required by O.C.G.A. Section 33-64-9.1 (a)(2), a pharmacy benefits manager shall annually file on a form provided by the Commissioner:

(a)The required NADAC report for the months of January through March no later than May 15, for the months May through July no later than September 15, and for the

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HB 946 Lines 96-115

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months of September through December no later than January 15 of the following year; and

(b) on or before March 1, the website domain name where the public can access the pharmacy benefits manager's NADAC reports. Any changes to the domain name thereafter shall be filed with the Commissioner within 3 days of the change.

(5) As required by O.C.G.A. Code Section 33-64-10 (a), a pharmacy benefits manager shall, for each health plan client, annually, on or before the first day of March, on a form provided by the Commissioner report all rebates and other payments it received in the preceding calendar year from pharmaceutical manufacturers on behalf of the health plan.

(6) As required by O.C.G.A. Code Section 33-64-10 (d), a pharmacy benefits manager shall, report for any health plan administered on behalf of a state agency or political subdivision of the state, state department or subdivision of the state, on or before March first, the aggregate difference between what the pharmacy benefits manager reimbursed pharmacies and what the pharmacy benefits managers we paid by the health plan. Nothing herein shall be construed to authorize a pharmacy benefits manager charging a state health plan or political subdivision of the state health plan more for a prescription drug than it reimburses a pharmacy after July of 2021.

(7) As required by O.C.G.A. Section 33-64-12, a pharmacy benefits manager and a person operating a health plan under Title 33 shall:

(a) Annually, on or before March 1, file on a form provided by the Commissioner, an attestation indicating whether or not, in the previous calendar year, it or its contracted pharmacy benefits manager engaged in the practice of steering or imposed point of sale or retroactive fees in connection with its health plans and Georgia insureds; and

(b) Annually, on or before March 1, file a report detailing all prescription drug claims it or its contracted pharmacy benefits manager administered for Georgia insureds on behalf of each health plan including the date each claim was administered, the amount the pharmacy was reimbursed for the claim, and the aggregate dollar amount it reimbursed pharmacies in the previous calendar year for prescriptions drugs for Georgia insureds on behalf of all its health plan clients.

(c) If it has engaged in the practice of steering or has imposed point of sale or retroactive fees, annually, on or before April 1, render to the state of Georgia, a surcharge equal to 10% of the aggregate dollar amount it or its contracted pharmacy benefits manager reimbursed pharmacies in the previous calendar year for prescriptions drugs for Georgia insureds.

(d) Any and all claims administered pursuant to the Medicare program shall be exempt from reporting requirements and shall be exempt from the surcharge calculation. All other claims administered on behalf of a Georgia insured shall be subject to reporting

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and, when a pharmacy benefits manager has engaged in the practice of steering or has imposed a point of sale or retroactive fee, the surcharge.

(8) upon receiving a notice of complaint by the Commissioner regarding an audit in connection with O.C.G.A. Code Section 26-4-118, a pharmacy benefits manager shall identify within five business days, on a form provided by the Commissioner, the notice given to the pharmacy, the number of claims audited during the audit at issue, the number of claims audited within the past 12 months, the number of audits of the pharmacy within the past 12 months, the discrepancies identified in the audit at issue, the basis for the denial of any internal appeal, and the basis for recoupment.

120-2-97-.08

Penalties; Commissioner actions; and reimbursements

(1) Any person, business entity, or other entity acting as a pharmacy benefits manager without a license shall be subject to a monetary penalty of up to $2000.001,000.00 for each and every transaction in violation of the chapter. Any person, business entity, or other entity willfully acting as a pharmacy benefits manager without a license shall be subject to a monetary penalty of up to $10,000.005,000.00 for each and every act in violation.

(2) In addition to all other penalties provided for under this title, the Commissioner shall have the authority to place any pharmacy benefits manager on probation for a period of time not to exceed one year for each and every act in violation of theeis chapter and may subject such pharmacy benefits manager to a monetary penalty of up to $2000.001,000.00 for each and every act in violation of this chapter. If the pharmacy benefits manager willfully acted in violation of this chapter the monetary penalty may be increased up to $10,000.005,000.00 for each and every act in violation.

(3) In the event a pharmacy benefits manager is in violation of the chapter while on probation, the Commisioner may suspend the license.

(4) When a pharmacy benefits manager is taking or threatening to take action in violation of the chapter the Commissioner may issue a cease and desist order.

(5) Whenthe action of a pharmacy benefits manager is in violation of the chapter the Commissioner may order reimbursement to an insured, pharmacy, or other dispenser for any monetary loss arising as a result of the violation or violations as well as order payment of a fine not to exceed $1,000.00 per violation to an insured, pharmacy, or other dispenser who has been aggrieved. Such a fine shall be in addition to and not to preclude any other penalties pursuant to the chapter.

120-2-97-.09

Severability

If any provision of this Regulation Chapter, or the application thereof to any person, business entity, or other entity or circumstance, is held invalid by a court of competent

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Lines 183-187

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jurisdiction, the remainder of the Regulation Chapter or the applicability of such provision to other persons or circumstances shall not be affected.