

BEFORE THE COMMISSIONER OF INSURANCE

STATE OF GEORGIA

IN THE MATTER OF:)
)
CHAPTER 120-2-97) **DOCKET NUMBER I-10-R-3**
PHARMACY BENEFITS MANAGERS)
REGULATION)
)
)

ORDER

I. STATEMENT OF PROCEEDINGS

On November 15, 2010, Notice of Intent to Adopt Rule Changes and Notice of Hearing were given regarding the proposed adoption of Regulation Chapter 120-2-97 entitled “Pharmacy Benefits Managers Regulation”. (Record, Exhibits 1 & 2). The proposed regulation is necessary due to the recent enactment of Chapter 64 of Title 33 (as part of Senate Bill 310) providing for the licensure and regulation of Pharmacy Benefits Managers (“PBMs”).

By letter dated November 30, 2010, the Office of the Attorney General opined that the proposed regulation was within this office’s scope of authority. (See Record, “Exhibit 4”). Pursuant to O.C.G.A. § 50-13-4(e), the proposed regulation was transmitted to Sewell Brumby, Legislative Counsel, for assignment to the appropriate standing committees of the Senate and House of Representatives. (Record, Exhibits 5 & 6).

Interested persons were given the opportunity to participate in the proposed rulemaking by submitting their written comments by December 15, 2010 and by making oral comments at the public hearing held on December 17, 2010. Two interested parties, the Georgia Pharmacy

Association and Healthsystems submitted written comments on December 15, 2010. CVS Caremark and the Georgia Pharmacy Association submitted late-filed written comments after December 15, 2010 and these comments were also made a part of the record. (Record, Exhibit 7). One interested party, the Georgia Pharmacy Association, made an oral presentation at the December 17, 2011 hearing.

II. CONSIDERATION OF INTERESTED PARTIES' COMMENTS

CVS Caremark

In its late-filed written comments, CVS Caremark argues that Chapter 120-2-97-.06 (regarding the examination of PBMs) “overreaches” the Commissioner’s authority because O.C.G.A. § 33-64-7 states that the “Commissioner may not enlarge upon or extend the provisions of this chapter through any act, rule or regulation.” (Record, Exhibit 7).

While O.C.G.A. § 33-64-7 provides that the Commissioner may not promulgate PBM licensure requirements beyond those authorized under Chapter 64 (just as any other rule must be founded upon authority provided by the legislature), CVS Caremark provides no evidence that the General Assembly intended thereby to limit the Commissioner’s authority under Chapter 2 to examine all licensees (which is the stated basis of authority for Chapter 120-2-97-.06) or solely exempt PBMs from examination by the Commissioner. (See O.C.G.A. § 33-2-12(a)(1) providing that the Commissioner “when he deems it necessary . . . may examine the affairs, accounts, records, documents, and transactions” of any person licensed under Title 33.) In fact, the plain language of O.C.G.A. § 33-64-7 itself, which simply delineates the Commissioner’s authority to enlarge upon or extend “the provisions of this chapter”, makes clear that O.C.G.A. 33-64-7 provides for no such limitation or exemption.

Healthsystems

Healthsystems proposes that Chapter 120-2-97-.06 should be amended to provide that the Commissioner must provide no less than a 45 day notice of intent to conduct an on-site examination and may only examine records “within the state of Georgia.” (Record, Exhibit 7).

However, under O.C.G.A. § 33-2-12 the Commissioner may conduct an examination “when he deems it necessary” and O.C.G.A. § 33-2-13(a) requires every person being examined to “produce and make freely accessible to the Commissioner the accounts, records, documents, and files in his possession or control” without regard to location. Neither the provisions of Chapter 64 nor Healthsystems offers any indication that the General Assembly intended to provide otherwise.

Healthsystems seeks modification of the proposed requirement for audited financial statements set forth at 120-2-97-.03(3) and 120-2-97-.05(3). (Record, Exhibit 7). Upon review, the Commissioner of Insurance’s Third Party Administrator regulation imposes a \$200,000 net worth requirement but does not limit applicants to audited financial statements. (See Chapter 120-2-49-.03(2)(d),(f) and 120-2-49-.11(4)). Therefore, proposed Chapter 120-2-97-.03(3) and Chapter 120-2-97-.05(3) shall be similarly revised.

Georgia Pharmacy Association

In its written and oral comments, the Georgia Pharmacy Association contends that the provisions of Chapter 64, either alone or in conjunction with other provisions of Title 33, make it plain that: (1) “[P]harmacy benefits management” constitutes the business of insurance subjecting PBMs to the unfair trade practices provisions of Chapter 6 of Title 33; (2) The Commissioner of Insurance can and should define “mail service pharmacy” and therein require

PBMs to comply with the Pharmacy Practice Act as codified in Title 26; (3) The Commissioner of Insurance can and should provide that a PBM imposing requirements for a valid prescription that exceed the Title 26 Pharmacy Practice Act's definition of a valid prescription has committed an unfair trade practice under Title 33; and (4) The Commissioner of Insurance can and should seek to enforce the Pharmacy Audit Bill of Rights because O.C.G.A. § 33-64-5 states that PBMs shall be subject to the Pharmacy Audit Bill of Rights under Title 26. (Record, Exhibit 7; Tr., pp. 7-11). The actions requested by the Georgia Pharmacy Association are inappropriate for the following reasons.

Although the Georgia Pharmacy Association asserts that each of the activities included within Chapter 64's definition of "pharmacy benefits management" (such as claims processing) constitutes "an agreement" to pay "a specified amount or benefit upon determinable contingencies" and thus meets the definition of "insurance" under O.C.G.A. § 33-1-2, the Georgia Pharmacy Association does not address (or cite) the essential element of "insurance" under Georgia law; that is, "a contract which is an integral part of a plan for distributing individual losses". (O.C.G.A. § 33-1-2(2) (emphasis provided)). Moreover, Chapter 64 defines "pharmacy benefits management" as "[a] service provided to a health plan". (O.C.G.A. § 33-64-1(6)).

Similarly, Chapter 64 does not provide a basis for the additional regulatory and enforcement provisions the Georgia Pharmacy Association seeks to include in the proposed regulation. In its oral comments, the Georgia Pharmacy Association notes that "Title 26 allows mail order [pharmacy]" in certain circumstances. (Tr., p. 9). Title 26 vests the Georgia State Board of Pharmacy with the authority to establish rules and regulations governing such activities and is therefore the proper venue for addressing issues regarding mail order pharmacy practices.

(See O.C.G.A. § 26-4-27). Likewise, the fact that Chapter 64 subjects PBMs to provisions of Title 26 by cross-reference does not, without more, evidence legislative intent to grant the Commissioner of Insurance enforcement authority over violations of the Georgia Pharmacy Act or the Pharmacy Audit Bill of Rights. To that end, if as the Georgia Pharmacy Association states, “neither the PBM Legislation nor the Pharmacy Audit Bill of Rights provides Georgia’s pharmacists with a clear avenue for relief” then such relief cannot be manufactured within the proposed regulation. (Record, Exhibit 7).

WHEREAS, IT IS HEREBY ORDERED that Regulation Chapter Section 120-2-97 entitled, “Pharmacy Benefits Managers Regulation”, a copy of which is attached hereto and made a part hereof by reference, is adopted.

Given under my Hand and Official Seal this ____ day of March, 2011.

**RALPH T. HUDGENS
COMMISSIONER OF INSURANCE
STATE OF GEORGIA**