Impact Analysis – 11 NCAC 24 Pharmacy Benefits Management

Agency:	North Carolina Department of Insurance
Rule Citation(s):	11 NCAC 24 .0101, .0102, .0103, .0104, .0105, .0106, .0107, .0108
Agency Contact:	**Alisha Benjamin** alisha.benjamin@ncdoi.gov 919-807-6654
Rulemaking Authority:	G.S. 58-2-40; 58-56A-2
Impact Summary:	**State Government: YES** **Local Government: NO** **Private Entities: YES** **Substantial Impact: NO**

I. Purpose

The purpose of the proposed rules is to establish a licensure application process for licensing pharmacy benefits managers (PBM or PBMs) as required by SL 2021-161 (Senate Bill 257) – now codified in Article 56A of Chapter 58 of the General Statutes. The proposed rules also establish an application fee and annual renewal fee, as authorized by GS. § 58-56A-2.

SL 2021-161 created a new license for entities that operate as PBMs for health benefit plans in North Carolina. PBMs are private entities that administer or manage prescription drug benefits for health benefit plans. Prior to SL 2021-161, these entities were required to be licensed – or, in limited circumstances, registered -- as third-party administrators (TPA or TPAs) under Article 56 of Chapter 58 of the General Statutes.

PBMs and some of their business practices have been coming under review in a number of states. Legislatures in these states have passed licensing laws similar to North Carolina's. Some states have gone further, passing laws that also address specific business practices by PBMs. Establishing a separate licensure requirement specific to PBMs should enable incrementally more efficient regulation of PBMs versus under the current TPA rules. It is the Department's understanding that additional legislation is possible in the future that would build off these licensing requirements and further regulate PBMs. Presumably, actions taken to regulate PBMs would be for the broader purpose of improving transparency and reducing health care costs.

II. **Description of Proposed Rules** *(Text of proposed rules is in Appendix A)*

The proposed rules are drafted such that the license application and renewal process for PBMs will be roughly equivalent to the current application and renewal process required for TPAs. PBMs are a specific type, or subset, of TPAs. As compared to the existing TPA rules, the proposed rules will: 1) provide clarity about the license application procedure specific to PBMs; 2) incorporate specific elements required by SL 2021-161; and 3) establish licensure application and renewal fees that are higher than existing TPA fees.

11 NCAC 24 .0101 Definitions: License Applications

- Defines relevant terms and incorporates G.S. § 58-56A-1 by reference.
- Lists items required to constitute a complete application for initial or renewal PBM licensure.
- This rule is modeled on 11 NCAC 21 .0101 which applies to license applications for TPAs.
    - The additional defined terms are additional terms defined in G.S. § 58-56-2 but not included in G.S. 58-56A-1 that are used in the proposed rules.
    - The additional items to be filed with the license application follow what is listed in 11 NCAC 21 .0101(b) and G.S. § 58-56-51(b).
    - The time for reporting material modifications has been increased to 30 days based on feedback on the draft rules from interested parties.

11 NCAC 24 .0102 Fees

- G.S. § 58-56A-2(b) gives the Commissioner the discretion to establish an application fee of $2,000 and a renewal fee of $1,500. This rule establishes those fees. Regulated entities will be required to pay these PBM fees instead of the TPA fees.
- G.S. § 58-56-51 currently requires TPAs to pay an application fee of $300 and a renewal fee of $300. Regulated PBMs will no longer have to pay these TPA fees.

11 NCAC 24 .0103 Financial Statements

- Lists and clarifies the required financial statements of 11 NCAC 24 .0101(c)(6) and explains the preparation process.
- The proposed rule is essentially identical to what is applicable to TPAs pursuant to 11 NCAC 21 .0102.

11 NCAC 24 .0104 Determination of Financial Responsibility

- Lists the items the Department of Insurance shall consider in determining the financial responsibility of an applicant for PBM licensure.

- The proposed rule is the same as what is applicable to TPAs pursuant to 11 NCAC 21 .0103.

11 NCAC 24 .0105 Claims Processing by PBMs

- Clarifies that a license is not required of a PBM or an employee of a PBM to adjust insurance claims for an insurer.
- The proposed rule is the same as 11 NCAC 21 .0105 which provides the same clarification for TPAs.

11 NCAC 24 .0106 Payment of Claims

- Requires a PBM or the insurer to mail a claims status report to the claimant if a claim has not been paid within 30 days of receipt.
- Follows the requirements of G.S. § 58-3-225 that applies to insurers who write health benefit plans, whose claims PBMs process.
- The proposed rule mirrors 11 NCAC 21 .0106.

11 NCAC 24 .0107 General Administration

- As a condition of licensure and license renewal, sets minimum standards relating to a PBM's administration. Requires PBMs to have a governing body set policy, securely maintain corporate records, employ a management information system, and set internal policies and procedure for contract management.
- This is the same as what is required for TPAs under 11 NCAC 21 .0107.

11 NCAC 24 .0108 Claims Processing

- Sets minimums standards for claims processing procedures that PBM must maintain to be licensed and to remain licensed.
- Subsections (a) and (b) are the same as requirements for TPAs in 11 NCAC 21 .0108, and subsection (c) mirrors the requirement for TPAs in 11 NCAC 21 .0110(b).

III. Analysis of Impacts

The rules, as proposed, largely mirror the licensure application and renewal process for TPAs and apply them to the subset of TPAs that are PBMs. Once the proposed rules are in effect, entities that are currently licensed or registered as TPAs will instead need to be licensed as PBMs. Since the application and renewal processes for TPAs and PBMs are so similar, there will be minimal impacts (benefits or costs) to regulated PBMs from the proposed rules other than from increased application and renewal fees. There will be minimal impacts, if any, to the local government or the public. Further, any impacts would be more appropriately attributed to SL 2021-161 itself which mandated the creation of a license specific to PBMs. Nevertheless, this analysis attempts to capture the incremental impacts most likely to result from the proposed PBM license and associated fees.

Generally, TPAs that provided services to health benefit plans that were not regulated by the Department, like where ERISA preempts state insurance laws, were only required to register with the Department. The Department's understanding of the intent of SL 2021-161 was for PBMs that would have only registered as TPAs to obtain PBM licenses with the other PBMs. This was based, in part, on a United States Supreme Court decision that indicated that states could, to some extent, regulate the conduct of PBMs providing administrative services to ERISA exempt plans. The extent of states' ability to regulate PBMs providing services to ERISA exempt plans continues to be defined through new court cases, but it does appear, at a minimum, that states can require them to be licensed. This is why PBMs that currently only have to register as TPAs will be required to get a PBM license.

Application and Renewal Fees

The main impact from the proposed rules will be related to the amount that regulated PBMs pay in licensing fees. G.S. § 58-56A-2 states that the Commissioner "may charge an initial application fee of two thousand dollars ($2,000) and an annual renewal fee of one thousand five hundred dollars ($1,500)." The language of the statute appears to give no flexibility in the amount of the fee that can be charged.

Currently, entities that are licensed or registered as TPAs pay $300 in one-time application fees and $300 in annual renewal fees. The proposed PBM license and renewal fees will replace these TPA fees. It is unlikely that there will be many entities not already licensed or registered as TPAs seeking a PBM license. For this reason, for licensed TPAs, we consider the proposed PBM fee amounts relative to the current TPA fee amounts.

<u>As of 11/20/24</u>

368 *licensed* TPAs
- TPAs currently pay a $300 application fee for initial applications and annual renewals.
- 368 licensed TPAs x $300 = $110,400 in TPA fees (total fees paid by TPAs under existing rule)
- 32 of these licensed TPAs are PBMs and will apply to become licensed PBMs. These 32 entities will pay the proposed PBM license fee instead of the current TPA fee.

139 r*egistered* TPAs
- There is no fee to register as a TPA.
- 20 of these registered TPAs are PBMs and will apply to become licensed PBMs. These 20 entities will begin paying the proposed PBM license fee.

Reduction in TPA Fees
- TPA fees, in total, will be reduced by $9,600 annually.
- 32 licensed TPAs that are also PBMs x $300 per licensed TPA = $9,600

- Total TPA fees under the proposed rule = $100,800 ($110,400 - $9,600).

New Fees from Proposed PBM licensing

- PBMs will pay a $2,000 initial application fee and a $1,500 annual renewal fee.
- Year 1:
    - 52 new applications to license PBMs (32 licensed TPAs + 20 registered TPAs) x $2,000 per application = $104,000 in new PBM fees
- Year 2 (and each year thereafter)
    - 52 renewals from licensed PBMs x $1,500 per renewal = $78,000 in new PBM fees
- Difference in total fees
    - Year 1: $94,400 net in additional fees
    - Year 2 (and each subsequent year): $68,400 net in additional fees

Total New Fees: $94,400 (Year 1), $68,400 (Year 2 and subsequent years)

In total, regulated PBMs will incur estimated new costs of $94,400 in the first year and $68,400 in subsequent years. For PBMs that are currently *licensed* as TPAs, each will have to pay an additional $1,700 in Year 1 and $1,200 in subsequent years to be licensed. For PBMs that are currently *registered*, each will have to now pay $2,000 in Year 1 and $1,500 in subsequent years to be licensed.

These funds will generate revenue to the Department. Unless otherwise specified, fees collected by the Commissioner are paid into the State treasury and credited to the General Fund (G.S. §§ 58-6-1, 58-6-5). Separately, the Insurance Regulatory Trust Fund is used to reimburse the General Fund for appropriations related to regulating the insurance industry (G.S. § 58-6-25). Similar entities licensed by the Department pay fees to be licensed. The proposed licensing fee is justified, particularly in the long term, as it will reduce the likelihood that there will be a shortfall of funds to pay for staffing and operating expenses related to the licensing program.

Workload/Time Costs

For PBMs that are already licensed as TPAs, there would not be much difference in workload since the licensing and renewal processes would be so similar. There is likely to be a minimal one-time increase in workload in Year 1, as the initial licensure process is more involved than the renewal process. There will also be a small increase in overall workload for the 20 PBMs that will have to become licensed as the application and renewal process is more involved than what is required for a TPA to register with the Department.

For those entities pursuing licensure for the first time, there are likely to be additional one-time costs associated with the application process. These costs could include hiring an independent certified public accountant to prepare financial statements (11 NCAC 24 .0103) and preparing documents that may incur legal fees such a power of attorney (11 NCAC 24 .0101). The Department does not have data on how much time would be spent by a PBM to perform these activities or the costs to pay for these services. The amount of time and costs incurred will vary depending on factors such as the size of the PBM, whether they had already compiled similar documentation for TPA licensing, and if the PBM is domiciled out of state. It should be noted that Department staff will be available to provide guidance to minimize the time burden on all regulated entities.

Similarly, the Department expects an increase in its workload in terms of time and volume of work. As compared to the status quo, the Department will spend more time reviewing applications in the first year because all applications will be initial applications, which require more time to review than a renewal application, and because entities that previously were only required to register will now have to apply to be licensed. In subsequent years, the Department's workload will also be slightly increased due to the higher number of renewals.

Currently, the regulation of TPAs, including PBMs, are part of the job duties of three Life and Health Division employees: a Regulatory Insurance Analyst Manager (NC22), a Regulatory Insurance Analyst I (NC17), and an Administrative Associate II (NC02). Roughly fifty percent of the Regulatory Insurance Analyst Manager's time is spent on TPA/PBM matters. The Regulatory Insurance Analysts I and Administrative Associate II spend about seventy percent of their time on TPA/PBM matters. In addition to processing applications, there is constant work responding to inquiries from licensees, reviewing, and updating information required to be reported by the licensees. The Financial Analysis Division also assists in reviewing financial statements. The financial review is conducted by either an Insurance Company Examiner I (NC12) or Insurance Company Examiner II (NC17). For the Life and Health Division employees, assuming salaries at the midpoint and 10 years of service, the estimated annual time cost of regulating TPAs is $215,738.

Review of both initial and renewal applications involve staff from two divisions in the Department. The Department's Life & Health Division receives the applications and handles the majority of the tasks related to the review of an application but an entity's financial statements are reviewed by the Department's Financial Evaluation Division.

It is estimated that Life & Health's review of an initial application will take approximately 2.5 hours and review of a renewal application will take approximately 2 hours. It is also estimated that the Department's Financial Evaluation Division will spend approximately 15 minutes reviewing the financial statements for a single application.

Because all entities currently licensed or registered as TPAs will have to make an initial application to be licensed as PBMs the increased workload for Department staff is estimated to be about 143 hours (52 applications x 2.75 hrs per application). Using an hourly total compensation rate of $60.48 (based on the midpoint salary of an NC17 position with 10 years of service[1]), the additional time cost to the Department in the first year will be about $8,648 ($60.48 per hr x 143 hrs). In subsequent years, the additional time cost to the Department to

[1] NC OSHR: Total Compensation Calculator

review renewal applications for 52 licensed PBMs (2.25 hr per renewal) will be about $7,076 ($60.48 per hr x 117 hrs) .

Given the overall small number of entities affected by the change in licensure, the Department anticipates that the additional work can be managed by the existing staff. It should be noted that even with the additional revenue from PBM fees, the total fee revenue collected by PBMs and the remaining TPAs ($204,800 Year 1, $178,800 Year 2) will not surpass the estimated annual time cost to the Department for regulating TPAs and PBMs (about $215,000 for FY2025).

Improved Rule Clarity/Groundwork for Future Regulation

As compared to the regulatory baseline, the proposed rules are expected to produce incremental benefits to the regulated community, state government, and the public. Establishing a separate licensure requirement specific to PBMs should enable slightly more efficient regulation of PBMs versus current regulation under the TPA rules, which could save time for regulated entities and Department staff. It is the Department's understanding that additional legislation is possible in the future that would build off these licensing requirements and further regulate PBMs. If that were to occur, it would likely require additional rulemaking and associated regulatory impact analyses. Presumably, actions taken to regulate PBMs would be for the broader purpose of improving transparency and reducing health care costs for consumers.

IV. Summary

<u>Regulated Entities (PBMs)</u>

Net costs of $94,400 in Year 1, $68,400 in subsequent years for licensing, plus unquantified, one-time costs associated with preparing application materials.

<u>State Government</u>

Net increase in revenue of $94,400 in Year 1; $68,400 in subsequent years.

Net increase of $8,648 in Year 1 and $7,076 in subsequent years in Department staff time costs for application and renewal processing. These costs will likely increase over time as salary and compensation costs increase.

<u>Local Government</u>

The proposed rules are not expected to result in impacts to local government.

<u>Public</u>

Although not directly attributable to the proposed rules, regulating PBMs should improve transparency and reduce health care costs for consumers.

APPENDIX A – Proposed Rule Text

CHAPTER 24 – PHARMACY BENEFITS MANAGEMENT

SECTION .0100 - GENERAL PROVISIONS

11 NCAC 24 .0101 DEFINITIONS: LICENSE APPLICATIONS

(a) The definitions in G.S. 58-56A-1 are incorporated into this Chapter by reference.

(b) The following definitions apply in this Chapter:

(1) "Control." Defined in G.S. 58-19-5(2).

(2) "Insurance." Any coverage offered or provided by an insurer.

(3) "Material modification." Any material change in a PBM's ownership, control, or other fact or circumstance affecting the PBM's qualification for a license in this State.

(c) The following items shall be filed in order to constitute a complete application submission for initial or renewal PBM licensure:

(1) Transmittal form;

(2) A completed pharmacy benefits application form;

(3) Biographical form(s) completed by principal officers;

(4) All organizational documents of the PBM, including any articles of incorporation, articles of association, partnership agreement, trade name certificate, or trust agreement, any other applicable documents, and all amendments to these documents;

(5) The bylaws, rules, regulations, or similar documents regulating the internal affairs of the PBM;

(6) Annual financial statements or reports for the two most recent years that prove that the applicant is solvent and any other information the Commissioner may require in order to review the current financial condition of the applicant;

(7) A general description of the business operations, including information on staffing levels and activities proposed in this State and nationwide. The description must provide details setting forth the PBM's capability for providing a sufficient number of experienced and qualified personnel in the areas of claims processing and record keeping;

(8) A power of attorney duly executed by the PBM, if not domiciled in North Carolina, appointing the Commissioner as attorney for the PBM in and for this State, upon whom process in any legal action or proceeding against the PBM on a cause of action arising in this State may be served; and

(9) Evidence of maintenance of a fidelity bond, errors and omissions liability insurance or other security.

(d) Each applicant shall make available for inspection by the Commissioner copies of all contracts with insurers or other persons using the services of the PBM.

(e) An applicant or PBM shall notify the Commissioner of any material modification within 30 business days after the change.

(f) Copies of all forms may be obtained from the Department.

History Note: Authority G.S. 58-2-40; 58-16-30; 58-19-5; 58-56A-2;

11 NCAC 24 .0102 FEES

(a) The initial application fee for a PBM license shall be $2,000.

(b) The annual renewal fee for a PBM license shall be $1,500.

History Note: Authority G.S. 58-2-40; 58-56A-2.

11 NCAC 24 .0103 FINANCIAL STATEMENTS

The financial statements required by 11 NCAC 24 .0101(c)(6) shall include a balance sheet, a statement of operations, and a statement of cash flows for the PBM's two most recent fiscal years. Financial statements shall be prepared by an independent certified public accountant. Financial statements of a PBM's parent company are acceptable if those statements contain consolidating schedules that include a breakout of the finances of the PBM, and if the certified public accountant's opinion letter does not disclaim association with the consolidating schedules.

History Note: Authority G.S. 58-2-40; 58-2-205; 58-56A-2.

11 NCAC 24 .0104 DETERMINATION OF FINANCIAL RESPONSIBILITY

In determining the financial responsibility of an applicant for a PBM license, the Department shall require that an applicant be solvent. In addition, the Department shall consider:

(1) Liquidity;

(2) Any internal controls the applicant may have in place to afford protection for benefit plans, which may include the manner in which benefit plan fund accounts are established; and

(3) Segregation of duties.

History Note: Authority G.S. 58-2-40; 58-56A-2.

11 NCAC 24 .0105 CLAIM PROCESSING BY PBMS

A PBM or an employee of a PBM does not have to have a license to adjust insurance claims for an insurer with which the PBM has a written agreement to provide claims processing services.

History Note: Authority G.S. 58-2-40; 58-56A-1(4); 58-56A-2.

11 NCAC 24 .0106 PAYMENT OF CLAIMS

If claims filed with a PBM or insurer are not paid within 30 days after receipt of the initial claim by the PBM or the insurer, the PBM or the insurer shall at that time mail a claim status report to the claimant.

History Note: Authority G.S. 58-2-40; 58-3-225; 58-56A-2.

11 NCAC 24 .0107 GENERAL ADMINISTRATION

Every PBM shall:

(1) Establish a governing body that is authorized to set policy for the organization.

(2) Maintain complete corporate records in a secure and accessible location.

(3) Employ a management information system that is able to provide information on all areas of the PBM operations.

(4) Set internal policies and procedures for contract management.

History Note: Authority G.S. 58-2-40; 58-56A-2.

11 NCAC 24 .0108 CLAIMS PROCESSING

(a) Each PBM's claims processing service shall be supported by a set of written policies, procedures, and performance standards related to timeliness in payment of claims and its financial operations.

(b) Each PBM shall develop and implement a claims processing internal audit and a quality assurance program to monitor and improve claims processing services.

(c) Each PBM shall be accessible to insureds, insurers, and pharmacist by telephone to respond to inquiries about claims payments.

History Note: Authority G.S. 58-2-40;58-56A-1(4); 58-56A-2.