# New Mexico Register / Volume XXXIII, Issue 4 / February 22, 2022

TITLE 13 INSURANCE

CHAPTER 10 HEALTH INSURANCE

PART 30 PHARMACY BENEFITS MANAGERS

**13.10.30.1 ISSUING AGENCY:** Office of Superintendent of Insurance ("OSI").

[13.10.30.1 NMAC – Rp, 13.10.30.1 NMAC, 3/1/2022]

**13.10.30.2 SCOPE:** This rule applies to every pharmacy benefits manager ("PBM") and health insurance carrier subject to the jurisdiction of the office of superintendent of insurance. [13.10.30.2 NMAC – Rp, 13.10.30.2 NMAC, 3/1/2022]

**13.10.30.3** STATUTORY AUTHORITY: Section 59A-2-9 NMSA 1978 and Subsection C of Section 59A-61-3 NMSA 1978.

[13.10.30.3 NMAC – Rp, 13.10.30.3 NMAC, 3/1/2022]

**13.10.30.4 DURATION:** Permanent.

[13.10.30.4 NMAC - Rp, 13.10.30.4 NMAC, 3/1/2022]

**13.10.30.5 EFFECTIVE DATE:** March 1, 2022, unless a later date is cited at the end of a section. [13.10.30.5 NMAC – Rp, 13.10.30.5 NMAC, 3/1/2022]

**13.10.30.6 OBJECTIVE:** This rule establishes operating standards, licensing, reporting and record retention requirements for PBMs to implement and promote the objectives and policies of the Pharmacy Benefits Manager Regulation Act, Chapter 59A, Article 61 NMSA 1978.

[13.10.30.6 NMAC – Rp, 13.10.30.6 NMAC, 3/1/2022]

- **13.10.30.7 DEFINITIONS:** For puRposes of this rule and the Pharmacy Benefits Manager Regulation Act:
- **A.** "Clean claim" has the definition found in Paragraph (1) of Subsection A of Section 59A-16-21.1 NMSA 1978.
- **B.** "Client" means any person with whom a PBM contracts to provide pharmacy benefits management services arising out of or relating to pharmacy operations in New Mexico.
- **C.** "Formulary" is a list of prescription drugs that has been developed by a health insurance carrier or its designee that the carrier or health plan in determining applicable prescription drug coverage and benefit levels.
- **D.** "Health insurance carrier" or "carrier" has the definition found in Paragraph (2) of Subsection C of Section 59A-16-21.2 NMSA 1978.
- **E. "Health plan"** has the definition found in Paragraph (3) of Subsection A of Section 59A-16-21.1 NMSA 1978.
  - **F.** "NCPDP" means the national council for prescription drug program.
  - **G.** "NDC" means national drug code.
- **H.** "Network pharmacy" means a pharmacy with whom a payor or PBM has contracted to provide pharmacy services to persons with an expectation of receiving payment directly or indirectly from the carrier.
- **I.** "**Prescription drug claim administration**" is administrative services performed in connection with the processing, adjudicating and auditing of claims relating to pharmacy services.
- **J.** "Similarly situated" refers to a network pharmacy whose PBM contract is subject to the same reimbursement for a claim as a pharmacy whose appeal was granted. [13.10.30.7 NMAC Rp, 13.10.30.7 NMAC, 3/1/2022]
- **13.10.30.8 REQUIREMENTS FOR LICENSURE:** A PBM shall not conduct any operation or provide any service in New Mexico unless it holds a valid PBM license issued by the superintendent.
- **A.** A PBM shall apply for a license by submitting a complete application package on a form, and pursuant to the directions, prescribed by the superintendent. The application package shall include:
- (1) The non-refundable filing fee prescribed by Paragraph (1) of Subsection AA of Section 59A-6-1 NMSA 1978 for filing an application for a license.

- (2) The name of the legal entity, federal employer identification number ("FEIN"), business address, phone number and state of residency.
- (3) The name, business address, phone number and e-mail address of a contact person designated by the PBM to respond to grievances.
- (4) The name, business address, phone number and e-mail address of a contact person designated by the PBM to respond to inquiries by the superintendent.
- (5) Proof of current authority from the controlling New Mexico regulator to conduct business in New Mexico.
- (6) For each partner, managing member, and director, as applicable, the application package shall include a background investigation report through a vendor approved by OSI upon initial application. Changes in leadership shall submit a background investigation report at the time of renewal of license.
  - (7) For the preceding 10 years, a statement of whether the application has:
- (a) been refused a registration, license or certification to act as or provide the services of a PBM or third-party administrator; or
- (b) had any registration, license or certification denied, suspended, revoked or non-renewed for any reason by any state or federal entity; and
- (c) if either (a) or (b) apply, the PBM shall separately attach the details of each such action, including the date, nature and disposition of the action.
- (8) A statement of whether the applicant in the most recent 10 years had a business relationship terminated for any admission, legal finding, or judgement of fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan and a description of each termination.
  - (9) A list of all New Mexico clients serviced by the PBM.
- (10) A list of each regulatory enforcement action against the PBM in any other state for the previous 10 years.
- (11) The application shall be shall be signed and verified by an officer, director, managing member, or partner, as applicable, of the PBM.
- (12) Any other information that is deemed necessary by the superintendent in evaluating the application to evidence compliance with Chapter 59A, Article 61 NMSA 1978 or the requirements of rules promulgated by the superintendent.
- (13) Confidentiality requests by an applicant are governed by the superintendent's bulletin 2022-001 or any superseding bulletin or rule.
- (14) The application package, except for the application fee, shall be submitted as directed by the superintendent. After the application has been approved or rejected by the PBM program coordinator, the applicant shall pay the application fee through NIPR. Failure to pay the application fee for a rejected application will preclude licensure or renewal.
- **B.** Review and approval process for initial licensure. Within 30 days of receipt of an application pursuant to Subsection A of this section, the superintendent will review the application and:
- (1) if the application is incomplete, notify the applicant in writing that additional information is needed, and allow the applicant 30 days to cure any deficiency in the application.
- approve the application and issue a PBM license to the applicant if the superintendent determines that the applicant meets the requirements for licensure; or
- (3) deny the application if the superintendent determines that the applicant does not meet the requirements for licensure.

# C. Content and scope of license.

- (1) Content. A license issued by the superintendent under this rule shall identify the PBM by name and business address; the capacity of the licensee to act as a PBM in New Mexico; and the effective and expiration dates of the license.
- (2) Scope. A license issued under this regulation entitles the PBM to act for one or more authorized insurance carriers, health plans, workers' compensation insurers, Medicaid MCO, multiple employer welfare arrangement or government plan or persons that self-insure without being required to obtain a separate license.
- **D.** License renewal. To continue a license a PBM shall submit a renewal application by March 1, of each year pursuant as directed by the superintendent After the application has been approved or rejected by the PBM program coordinator, the applicant shall pay the required application fee through NIPR and shall pay the annual report fee as directed by the superintendent. Failure to pay the application fee will preclude renewal. A renewal application shall include updates to any items required by the initial application for licensure.

- **E. Review and approval process for renewal of license.** Within 60 days of receipt of a renewal license application, the superintendent will review the application and:
- (1) if the application is incomplete, notify the applicant in writing that additional information is needed, and allow the applicant 30 days to cure any deficiency in the application.
- approve the application and issue a PBM license to the applicant if the superintendent determines that the application meets the requirements for licensure; or
- (3) deny the application if the superintendent determines that the applicant does not meet the requirements for licensure. For disapprovals or denials of an application for renewal the superintendent will notify the applicant of the denial or rejection and state the basis or reason for the denial.
- **F. Corrective action plan.** In lieu of a denial for initial licensure or renewal, the superintendent may require the PBM to submit a plan to cure or correct deficiencies in its application. [13.10.30.8 Rp, 13.10.30.8 NMAC, 3/1/2022]

# 13.10.30.9 PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION ("PSAO") REGISTRATION:

- **A. Registration required.** A PSAO shall not provide any service in New Mexico unless it is registered with the register with the superintendent.
- **B.** A PSAO's registration application shall be submitted on a form provided by the superintendent and shall include:
  - (1) full business name of PSAO;
  - (2) name, business address, phone number and e-mail address for primary contact;
- name, business address, phone number and e-mail address for contact designated to handle grievances; and
  - (**4**) FEIN.

[13.10.30.9 - Rp, 13.10.30.9 NMAC, 3/1/2022]

#### 13.10.30.10 PHARMACY GRIEVANCES:

- **A. Health plans subject to 13.10.16 NMAC:** a pharmacy grievance relating to a PBM who is performing services for a health plan or carrier subject to rule 13.10.16 NMAC shall be governed by that rule.
- **B.** Health plans not subject to 13.10.16 NMAC: A pharmacy with a grievance relating to a PBM who is performing services for health plan or carrier that is not subject to rule 13.10.16 NMAC may file a grievance against the PBM with the superintendent.
- (1) A grievance by a pharmacy against a PBM shall be in writing on a form provided by the superintendent.
- (2) A pharmacy shall submit a grievance within six months from the date the pharmacy new or should have known of alleged PBM misconduct.
  - (3) A grievance may allege multiple violations against a single PBM.
  - (4) A pharmacy shall provide supporting documentation.
- (5) The superintendent shall transmit any grievance, including supporting documentation to the e-mail contact designated by the PBM to receive grievance.
  - (6) The superintendent will specify the documentation necessary to address the grievance.
  - (7) A PBM shall have 14 business days from receipt of the grievance to respond in writing.
- (8) The superintendent may request additional documentation. The PBM shall provide any additional documentation in writing within 14 business days from the date of the superintendent's request.
  - (9) The superintendent may grant a PBM's request for an extension of time.
- (10) The superintendent will send a copy of all submissions received in connection to a grievance to the opposing party.
- C. Enforcement: If the superintendent finds probable cause that a PBM violated a law enforceable by the superintendent, the superintendent may issue a notice to show cause, why the superintendent should not take specified enforcement action against the PBM and its principal.

  [13.10.30.10 NMAC Rp, 13.10.30.10 NMAC, 3/1/2022]
- **13.10.30.11 PAYMENT OF CLAIMS:** Claims for reimbursement by a pharmacy are subject to the clean claims laws.

[13.10.30.11 NMAC – Rp, 13.10.30.11 NMAC, 3/1/2022]

# 13.10.30.12 MAXIMUM ALLOWABLE COST ("MAC") APPEALS:

- A. Submission of appeal. A network pharmacy that disputes a MAC reimbursement amount may submit a MAC appeal, to the PBM within 21 business days after a network pharmacy receives notice of the reimbursement amount. A PSAO may submit a MAC appeal on behalf of a network pharmacy.
- **B.** Appeals mechanism. A PBM shall provide a mechanism for submitting MAC appeals, including the dedicated phone number and electronic mail address or website. The phone number shall be manned at a minimum during the hours of 8:00 a.m. to 5:00 p.m., mountain time. Information about MAC appeals mechanisms shall be prominently displayed in any contract or manual provided by a PBM to a pharmacy.
- **C. Appeal instructions on website.** The PBM's website shall prominently display instructions for submitting a MAC appeal and instructions for seeking assistance in navigating the website. This link shall also be included in the PBM's provider manual.
  - **D. Response to denied appeal(s).** The PBM's response to a denied MAC appeal shall include:
- (1) the source or sources used, including NDC and name of supplier, to determine pricing for the maximum allowable cost list specific to that provider.
  - (2) the date of the last MAC list update for the drug which is the subject of the MAC appeal;
- (3) documentation evidencing that the drug was available for purchase by a pharmacy in New Mexico at the MAC price from a national or regional wholesaler at the time of claim submission; and
  - (4) any other information the PBM deems relevant to the MAC appeal.
- **E.** Nonresponse to appeal. The MAC appeal shall be deemed granted if the PBM does not respond within 14 business days of a complete appeal submission or its response does not include the items outlined in Subsection D of 13.10.30.12 NMAC.
  - **F. Notice of granting appeal.** If a MAC appeal is granted or deemed granted, a PBM shall:
- (1) within one day, notify by email the challenging pharmacy and any similarly situated network pharmacy and their PSAO(s) that a MAC appeal was granted, the NDC of the drug, the MAC price challenged and the updated MAC price; and
- (2) permit the appealing pharmacy and any similarly situated pharmacy to resubmit the claim at the updated price.
- **H. Request for MAC list.** A PBM shall provide a MAC list to a network pharmacy or the superintendent within seven business days upon request. [13.10.30.12 NMAC Rp, 13.10.30.12 NMAC, 3/1/2022]

# 13.10.30.13 SUBMISSION OF A MAC APPEAL:

- **A. Submission requirements.** A MAC appeal submission include:
  - (1) fill date;
  - (2) BIN number (six digits);
  - (3) NCPDP (seven digits):
  - (4) Rx number;
  - (5) NDC 11 (11 digits);
  - (6) drug name;
  - (7) drug strength;
  - (8) invoice price and net purchase price of drug (whole dollar with two decimal places);
  - (9) total reimbursement (whole dollar with two decimal places);
  - (10) reason for review;
  - (11) any information required by contract; and
  - (12) notes (optional).
- **B. No additional information required.** A PBM shall not require or request additional information to process a MAC appeal but shall accept and consider any additional information provided in a MAC appeal submission.

[13.10.30.13 NMAC - Rp, 13.10.30.13 NMAC, 3/1/2022]

#### 13.10.30.14 SEARCHABLE ONLINE DATABASE OF DRUG PRICES:

- **A. Update timeframe.** A PBM shall update its MAC list at least once every seven days.
- **B.** Searchable online database required. A PBM shall establish a searchable online database that will allow a network pharmacy to search MAC list prices for a particular drug for as long as the pharmacy has the right to file a MAC appeal or grievance concerning a specific fill. The PBM's provider manual shall include instructions for accessing the price list on the PBM's website. The provider manual shall be transmitted to a newly

joined pharmacy within 10 business days from the date of execution of a contract with the PBM. A PBM shall provide an updated version of its provider manual within 30 days of any revisions to all network pharmacies.

- **C. Search requirements.** The database shall be searchable by NDC or drug name, and specific plan identifier.
  - **D. Drug information.** The information provided for the drug shall contain:
    - (1) NDC:
    - (2) NDC description;
    - (3) MAC list price; and
    - (4) effective date.
- **E.** Instructions required. The provider manual shall contain instructions for searching the MAC list and contain instructions for requesting the name of the sources used to determine MAC pricing for the MAC list. A network pharmacy may request the name of the sources through a PBM's website, e-mail, facsimile or letter, if they are not already included in the provider manual. The PBM shall respond with the names of the sources within 10 business days from the date of the request.
- **F. Website requirements.** The PBM's website shall contain a prominent link to request the names of the sources used to establish the MAC price.
- **G. Accessibility.** Upon request a PBM shall provide the superintendent information contained in the database to determine compliance with these rules or to resolve a grievance. [13.10.30.14 NMAC Rp, 13.10.30.14 NMAC, 3/1/2022]

# 13.10.30.15 HISTORICAL MAC LIST DATABASE:

- **A. Searchable list of drugs.** A PBM shall maintain a searchable database containing all MAC list pricing for the preceding five years, but no earlier than January 14, 2021. The database shall be searchable by these criteria:
  - (1) NDC number;
  - (2) drug name;
  - (3) specific health plan; and
  - (4) removal data.
- **B.** Reason for removal. When a drug is removed from the MAC database, the database shall indicate the reason for its removal.
- **C. Obsolete drugs.** The database shall include obsolete drugs. If a drug is removed because it is obsolete, the database shall indicate the date it became obsolete.
- **D. List dated.** The database shall specifically indicate the date a drug price was updated and posted to the PBM's website.
- **E.** Accessibility. Upon request a PBM shall provide the superintendent information contained in the database for any regulatory or legislative puRpose.

[13.10.30.15 NMAC – Rp, 13.10.30.15 NMAC, 3/1/2022]

**13.10.30.16 ANNUAL REPORT BY PBM:** A PBM applying for license renewal shall submit an annual report to the superintendent's PBM program coordinator with the license renewal application. The annual report shall contain the items outlined in 13.10.30.8 NMAC. Failure to comply with these requirements shall result in nonrenewal of the license. Information submitted in the annual report is considered PBM data received by the superintendent pursuant to a specific request pursuant to 13.10.30.17 NMAC. [13.10.30.16 NMAC – Rp, 13.10.30.16 NMAC, 3/1/2022]

# 13.10.30.17 CONFIDENTIALITY AND CONFLICTS:

- **A.** Confidentiality. Any PBM data received by the superintendent in response to a specific request shall be deemed confidential, unless disclosure is required for a regulatory puRpose, enforcement, rulemaking, to respond to a legislative request, or is otherwise required by law or directed by court order. Notwithstanding the foregoing, the superintendent may publish aggregated data that cannot be traced to a specific PBM, provided any published data is at least 12 months old.
- **B.** Conflicts. The superintendent shall not share confidential data with a consultant or contractor unless that third-party:
  - (1) discloses all potential conflicts of interest;
  - (2) maintains appropriate data safeguards and firewalls; and
  - (3) executes an agreement prohibiting unauthorized disclosure or use of the confidential data.

- **13.10.30.18 COMPLIANCE REPORTING BY PBM:** PBMs shall submit the following information to determine compliance with New Mexico law according to the schedule provided by the superintendent:
- **A. Grievance and MAC appeal data**. The PBM shall file a log of grievance and MAC appeal data using a form specified by the superintendent.
- **B. Pharmacy and therapeutics ("P&T") committee data**. The PBM shall submit the following information for any P&T Committee:
  - (1) names of committee members and conflict disclosure statements;
  - dates and meeting minutes of the P&T committee from the prior plan year; and
  - (3) statement of the P&T committee's duties responsibilities, and goals.
- C. Confidentiality of P&T committee data. P&T committee minutes provided to the superintendent shall be deemed confidential.

[13.10.30.18 NMAC – Rp, 13.10.30.18 NMAC, 3/1/2022]

# 13.10.30.19 RETALIATION, DISCRIMINATION AND UNFAIR PRACTICES: A PBM shall not:

- **A. Retaliate.** Retaliate against a pharmacy for invoking its rights under these rules or the Pharmacy Benefits Manager Regulation Act. Selecting a pharmacy that has filed a grievance for audit at a rate disproportionately higher than for other network pharmacies may be considered retaliation.
  - **B. Discriminate.** Discriminate against any person or legal entity.
- (1) based on any class membership or characteristic protected under any state of federal antidiscrimination law or
- (2) that receives discounts on prescription drugs as a result of a state or federal program or law.
- **C. Unfair trade practice.** Engage in or commit any act or practice proscribed by any state or federal unfair practice law.
- **D. Steer.** Induce or attempt to induce, a health plan member to fill a prescription at a pharmacy benefits manager affiliate or transfer a prescription to any pharmacy benefits manager affiliated without an enrollee's express and informed consent.

[13.10.30.19 NMAC – Rp, 13.10.30.19 NMAC, 3/1/2022]

# **13.10.30.20 EXAMINATION:**

- **A. Examination.** Pursuant to the examination powers conferred by the Insurance Code, the superintendent may examine a PBM for compliance with any applicable New Mexico law.
- **B. Data calls.** Pursuant to the oversite and supervision powers conferred by the Insurance Code, the superintendent may issue a data call to a PBM or PSAO.

[13.10.30.20 NMAC – Rp, 13.10.30.20 NMAC, 3/1/2022]

**13.10.30.21 MAINTENANCE OF INFORMATION:** Every PBM shall maintain at its principal administrative office for the duration of the written agreement referred to in Section 59A-12A-4 NMSA 1978 and five years thereafter adequate books and records of all contracts and transactions. The superintendent shall have access to such books and records for the puRpose of examination, audit and inspection. A PBM may request that certain records be deemed confidential through the process established by OSI. The release of any confidential information shall only be made pursuant to law.

[13.10.30.21 NMAC – Rp, 13.10.30.21 NMAC, 3/1/2022]

**13.10.30.22 RULE NONCOMPLIANCE:** Failure to comply with any provision of these rules is a violation of the Insurance Code.

[13.10.30.22 NMAC – Rp, 13.10.30.22 NMAC, 3/1/2022]

# History of 13.10.30 NMAC:

History of Repealed Material.

13.10.30 NMAC, Pharmacy Benefits Managers filed 3/1/2021, was repealed and replaced by 13.10.30 NMAC, Pharmacy Benefits Managers, effective 3/1/2022.