

PART XXX 201 GENERAL INFORMATION

XXX 201.01 Scope. The rules in this chapter shall govern all proceedings before the prescription drug affordability board.

XXX 201.02 Authority. The rules have been promulgated pursuant to RSA 126-BB:6. The board's intention is these rules are necessary to fully implement this Chapter.

PART XXX 202 DEFINITIONS

XXX 202.01 Definitions.

(a) "Adjudicative proceeding" means an appeal of the board's decision to impose an assessment in accordance with RSA 126-BB:8 or a civil fine in accordance with RSA 126-BB:10.

(b) "Board" means prescription drug affordability board.

(c) "Confidential document" means a document that is confidential in its entirety because it contains confidential information, and there is no practicable means of filing a redacted version of the document.

(c) "Confidential information" means:

(1) Information that is not public pursuant to state or federal statute, administrative or court rule, a prior court order placing the information under seal, or case law; or

(2) Information which the board finds, if publicly disclosed, would substantially impair:

a. The privacy interests of an individual; or

b. The business, financial, or commercial interests of an individual or entity.

(d) "Contested case" means "contested case" as defined in RSA 541-A:1 IV.

(e) "Declaratory ruling" means "declaratory ruling" as defined in RSA 541-A:1, V.

(f) "Hearing" means the formal or informal receipt by the board of data or argument, or both, from persons.

(g) "Motion" means any application by a party to a proceeding for an order relating to the proceeding.

(h) "Order" means "order" as defined in RSA 541-A:1, XI.

(i) "Party" means "party" as defined in RSA 541-A:1, XII.

(j) "Person" means "person" as defined in RSA 541-A:1, XIII.

(k) "Remote hearing" means a hearing conducted via telephone, computer, or other electronic means.

(l) "Rule" means "rule" as defined in RSA 541-A:1, XV.

*Drafting Note – other definitions expected as appropriate and necessary

PART XXX 203 APPEARANCES BEFORE THE BOARD

XXX 203.01 Who May Appear.

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(a) A person or party may appear before the board in person, through a representative, or both.

(b) A person or party requesting to appear before the board shall notify the board at least three (3) weeks prior to the next scheduled board meeting.

(c) Notwithstanding (b) above, a person may request to appear at a date later than the next scheduled board meeting.

(d) A person or party requesting an appeal of the board's decision to impose an assessment in accordance with RSA 126-BB:8 or RSA 126-BB:10 shall submit the appeal in writing to the board within 30 days after the date of the notice. Such appeal shall include the specific reasons why the person or party believes the board's decision is unlawful or unreasonable.

(e) The board may waive the requirements of this part at its discretion.

(f) The board shall retain sole discretion to set its own agenda, including, but not limited to, the matters it hears and discusses and the timing of said hearings and discussions.

XXX 203.02 Representatives.

(a) A representative shall be either an attorney-at-law, licensed in New Hampshire, or an officer or employee designated to represent a business entity.

(b) Designation of an attorney-at-law or other representative shall:

(1) Be in writing; and

(2) Contain the following information:

a. Name, address, and telephone number of designee;

b. Title or name of matter pending before the department; and

c. Duration of designation.

(c) No such form need be filed by officers or employees of the person.

(d) An attorney from another jurisdiction shall be permitted to participate in the proceedings if the attorney files a motion for leave to appear providing proof the attorney is in good standing in his or her home jurisdiction.

(e) Nothing in this rule shall be interpreted as permitting the unauthorized practice of law, nor shall this rule be construed to restrict or limit the right of any person to conduct his or her own business with the board.

XXX 203.03 Right to Counsel. Any person in an appearance before the board may be represented by counsel at the person or party's own expense.

XXX 203.04 Prohibited Conduct and Representation.

(a) "Misconduct" means any act or non-act which would constitute misconduct of an attorney-at law as defined in the New Hampshire supreme court rules of professional conduct.

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(b) The board shall, after notice and opportunity for hearing, upon a finding of misconduct as defined in this section, prohibit an individual from acting as representative for any and all pending or future matters, or any combination thereof, before the board.

(c) Upon a finding of misconduct by any attorney admitted to practice in New Hampshire, the matter shall be referred to the New Hampshire supreme court, committee on professional conduct, for such determination as they find appropriate.

PART XXX 204 PROCEEDINGS BEFORE THE BOARD

XXX 204.01 Adjudicative Proceedings.

(a) In any adjudicative proceeding before the board, all motions, requests, and actions shall be conducted pursuant to RSA 541-A:31 through 38.

(b) Hearings shall be conducted with the person or party and any witnesses physically present before the board. A remote hearing shall be conducted upon motion of any party if the board determines that:

- (1) There is good cause as set forth in paragraph (c), below; and
- (2) Conducting the hearing with one or more parties participating remotely would not violate any law or rule or constitutional protections, and would promote the fair, accurate, and efficient resolution of issues pending before the board.

(c) Good cause shall include:

- (1) Excessive distance to the hearing location;
- (2) Physical disability or impairment of the respondent;
- (3) Transportation difficulties;
- (4) The physical presence of the respondent would threaten the health or safety of the respondent or any other individual; or
- (5) Other circumstance that would prevent the respondent or other parties from being able to appear and participate in person at the hearing.

XXX 204.02 Waiver of Procedural Rules. The board, upon its own initiative or upon the motion or petition of any interested person, shall waive any requirement or limitation imposed by this chapter not otherwise contrary to law, upon reasonable notice to affected persons, when the proposed waiver appears to be lawful and would be more likely to promote the fair, accurate, and efficient resolution of issues pending before the board than would adherence to a particular rule or procedure.

XXX 204.03 Burden and Standard of Proof for Matters Before the Board.

(a) For purposes of this section, "proof by a preponderance of the evidence" means what is sought to be proved is more probable than not.

(b) It shall be presumed that board assessments are made in accordance with this law, subject to appeal as defined herein. It shall be the burden of any person challenging any assessment to overcome this presumption.

(c) In a hearing held to determine whether the board's assessment in accordance with RSA 126-BB:8 is reasonable, a person or party shall prove by a preponderance of the evidence that the entity was not subject to an assessment based upon its legal status or that the assessment was reasonable based upon the facts and circumstances.

(d) The executive director shall propose to the board the imposition of civil fines in accordance with RSA 126-BB:10 and the administrative rules adopted thereunder. The board shall review said proposal and impose civil fines (subject to board adjustment as to amount) reviewed upon a preponderance of the evidence whether the civil fine was reasonable under the circumstances.

(e) Civil fines are subject to appeal before the board in accordance within the time frames set forth XXX 203.01(d) and the procedures set forth herein. Appeals of board decisions shall be in accordance with RSA 541.

Commented [BR1]: Who bears the burden of proof?

XXX 204.04 Date of Issuance or Filing of Documents.

(a) All decisions, orders, notices, or other written correspondence or documents issued by or at the direction of the board shall be rebuttably presumed to have been issued on the date noted on the document.

(b) All written documents governed by these rules shall be deemed to have been filed with or received by the board on the actual date of receipt by the board, as evidenced by a date stamp placed on the document by the board in the normal course of business.

(c) A decision, order, notice, or other written correspondence or document issued by the board shall be deemed to have been received on the day it is:

- (1) Delivered to a party or left at the physical address of that person, if delivery is by personal delivery;
- (2) Deposited in a depository of the United States Postal Service, if delivery is by first class mail; or
- (3) Faxed or sent electronically, if delivery is by electronic mail.

XXX 204.05 Format and Filing of Documents.

(a) All correspondence, pleadings, motions, or other documents filed under these rules shall:

- (1) Be clearly printed on durable paper, 8½ by 11 inches in size; and
- (2) Be signed by the party or proponent of the document or, if the party appears by a representative, by the representative.

(b) The signature on a document filed with the board shall constitute certification that:

- (1) The signer has read the document;
- (2) The signer is authorized to file it; and
- (3) To the best of the signer's knowledge, information, and belief there are good and sufficient grounds to support it.

(c) All correspondence, filings, or communications intended for the board shall be addressed to:

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Executive Director
NH Prescription Drug Affordability Board
129 Pleasant Street
Concord, NH 03301

XXX 204.06 Computation of Time.

- (a) Unless otherwise specified, all time periods referenced in this chapter shall be calendar days.
- (b) Computation of any period of time referred to in this chapter shall begin with the day after the action which sets the time period in motion and shall include the last day of the period so computed.
- (c) If the last day of the period so computed falls on a Saturday, Sunday, or legal holiday, then the time period shall be extended to include the first business day following the Saturday, Sunday, or legal holiday.
- (d) Except where the time has been fixed by statute, the board shall for good cause, upon request or upon the board's own initiative, lengthen or shorten the time provided for the filing of any document. Good cause shall include the unavailability of information, parties, witnesses, or attorneys necessary for the filing of the document, the likelihood that the filing will not be necessary because the parties anticipate a settlement, or any other circumstances that demonstrate that a postponement would assist in resolving the case fairly.

XXX 204.07 Motions and Response Thereto.

- (a) Unless presented during an oral session of a proceeding, motions and all replies thereto shall be in written form and filed with the board, unless made in response to a matter asserted for the first time at the hearing or on the basis of information which was not received in time to prepare a written motion.
- (b) Oral motions and any oral objection to such motions shall be recorded in full in the record of the hearing. If the board finds that the motion requires additional information in order to be fully and fairly considered, the board shall direct the moving party to submit the motion in writing, with supporting information, before any deadline established by the hearing officer.
- (c) All motions shall state:
 - (1) The purpose of the motion;
 - (2) The relief sought by the motion;
 - (3) The statutes, rules, orders, or other authority sanctioning the relief sought by the motion; and
 - (4) The facts claimed to constitute grounds for the relief requested by the motion.
- (d) Replies to motions shall state:
 - (1) The defense of the party filing the reply;
 - (2) The action which the party filing the reply wishes the department to take on the motion;
 - (3) The statutes, rules, orders, or other authority relied upon in defense of the motion; and
 - (4) Any facts which are additional to or different from the facts stated in the motion.
- (e) Motions shall be decided upon the writings submitted. Repetitious motions shall not be accepted.

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(f) Replies to motions shall be filed within 10 days after the filing of the motion. Failure to reply to a motion within the time allowed shall constitute a waiver of objection to the motion but shall not in and of itself constitute grounds for granting the motion. The board may, but need not, reply to motions.

(g) The board shall rule upon a motion after full consideration of all objections and other factors relevant to the motion in accordance with this chapter.

(h) The board may, at its discretion, consider and dispose of matters through motions, memoranda, or briefs, without hearing.

XXX 204.08 Confidential Documents and Confidential Information.

(a) Except as otherwise provided by statute or rule, all pleadings, attachments to pleadings, and exhibits submitted at meetings shall be available for public inspection.

(b) A confidential document shall not be accepted in a pleading if it is neither required for filing nor material to the matter to be heard by the board.

(c) If a confidential document is required or is material to the matter to be heard by the board, it shall be filed in the manner prescribed by paragraph (d) below.

(d) When a person files a document, the person shall omit or redact confidential information from the filing when the information is not required to be included for filing and is not material to the proceeding; and

(1) If none of the confidential information is required or material to the proceeding, only the version of the document from which the omissions or redactions have been made shall be filed; and

(2) At the time the document is submitted to the hearing clerk, the party shall clearly indicate on the document that the document has been redacted or information has been omitted pursuant to XXX 204.05.

(e) It is the responsibility of the filing party to ensure that confidential information is omitted or redacted from a document before the document is filed.

(f) If confidential information is required for filing or is material to the proceeding and must be included in the document, the filer shall file:

(1) A motion to seal as provided in paragraph (g);

(2) For inclusion in the public file, the document with the confidential information redacted by blocking out the text or using some other method to clearly delineate the redactions; and

(3) An unredacted version of the document clearly marked as confidential.

(g) A motion to seal a confidential document or a document containing confidential information shall state the authority for the confidentiality or circumstance that requires confidentiality. An agreement of the parties that a document is confidential or contains confidential information shall not be sufficient basis alone to seal the record but must be ruled so, pursuant to paragraph (h) below.

(h) The board shall:

(1) Review the motion to seal and any objection to the motion to seal that may have been filed and determine whether the unredacted version of the document shall be confidential; and

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(2) Issue an order setting forth the board's ruling on the motion to seal, which order shall include the duration that the confidential document or document containing confidential information shall remain under seal, and the reasons for the ruling.

- Drafting Note – decisions of the board should be made publicly available on its website for guidance and instructions to registrants and other necessary entities.

XXX 204.09 Continuances.

(a) The board shall for good cause, upon request or upon the board's own initiative, advance or postpone the time and date set for any hearing.

(b) If a postponement is requested by a party to the hearing, it shall be granted if the board determines that good cause has been demonstrated.

(c) Good cause shall include the unavailability of information, parties, witnesses, or attorneys necessary to conduct the hearing, the likelihood that the hearing will not be necessary because the parties anticipate settlement, or any other circumstances that demonstrate that a postponement would assist in resolving the case fairly.

(d) If the date, time, and place of the continued hearing are known, the date, time, and place shall be stated on the record. If the date, time, and place of the continued hearing are not known, the board shall issue a written scheduling order stating the date, time, and place of the postponed hearing as soon as possible.

XXX 204.10 Evidence.

(a) Receipt of evidence shall be governed by RSA 541-A:33.

(b) All documents, materials, and objects offered as exhibits shall be admitted into evidence unless excluded by the presiding officer as irrelevant, immaterial, unduly repetitious, or legally privileged.

(c) All objections to the admissibility of evidence shall be stated as early as possible.

(d) Transcripts of testimony and documents or other materials admitted into evidence shall be public records unless the board determines that all or part of a transcript or document is exempt from disclosure under RSA 91-A:5 or applicable case law.

XXX 204.11 Record. The record in a contested case shall include all of the following that are applicable in that case:

(a) All pleadings, motions, objections, and rulings;

(b) Evidence received or considered;

(c) A statement of matters officially noticed;

(d) Any decision, opinion, or report by the board;

(e) The tape recording or stenographic notes or symbols prepared for the hearing by the board, together with any transcript of all or part of the hearing considered before final disposition of the adjudicative proceeding;

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(f) Staff memoranda or data submitted to the board, except advisory memoranda prepared and submitted to the board by staff of board or others designated by the board to act as advisor or assistant to the hearing officer; and

(g) Matters placed on the record after an ex parte communication.

(h) Safeguarding PII See confidential information tab

XXX 204.12 Consolidation. Upon motion or the board's own initiative, if 2 or more proceedings involve common questions of law or fact, and the board determines consolidation is fair and efficient, the board shall consolidate those proceedings for hearing, decision, or both, after providing the parties notice and an opportunity for hearing on the proposed consolidation.

XXX 204.13 Severance. Whenever it shall appear to the board, upon motion or its own initiative, that injury to the substantial rights of a party or undue delay might be thereby avoided, the board shall, as fairness and efficiency permit, sever one or more issues from a proceeding and dispose of those issues in another proceeding, after providing the parties notice and an opportunity for hearing on the proposed severance.

XXX 204.14 Limiting Number of Witnesses. To avoid unnecessary cumulative evidence in any proceeding, the board may limit the number of witnesses or the time for testimony upon a particular issue in the course of any hearing.

PART XXX 205 SETTLEMENT, DECISIONS, AND REHEARING

XXX 205.01 Settlement.

(a) Settlements between the parties shall be encouraged in accordance with RSA 541-A:38. Parties shall attempt to settle a matter before it is scheduled for a hearing and may settle a matter at any stage of the proceedings.

(b) All settlement agreements shall:

- (1) Be in writing, describing the agreement's material terms; and
- (2) Be signed by both parties and their attorneys or agents.

XXX 205.02 Reopening the Record.

(a) At any time prior to the issuance of the decision on the merits, the board, on its own motion or on the motion of any party, shall reopen the record to receive relevant, material, and non-duplicative testimony, evidence, arguments, or exhibits not previously received.

(b) Requests to reopen the record made after one or more parties have left the hearing shall be made in writing.

(c) The board shall give written notice of such further proceedings if the parties are no longer present. The board shall also specify a date by which other parties shall respond to or rebut the newly received evidence.

XXX 205.03 Motion for Reconsideration.

- (a) A motion for reconsideration shall be filed within 30 days of the final decision.
- (b) A motion for reconsideration shall:
 - (1) Identify each error of fact, error of reasoning, or error of law which the moving party wishes to have reconsidered;
 - (2) Describe how each error causes the final decision to be unlawful, unjust, unreasonable, or illegal in respect to jurisdiction, authority, or observance of the law, an abuse of discretion, or is arbitrary, unreasonable, or capricious;
 - (3) State concisely the factual findings, reasoning, or legal conclusion proposed by the moving party; and
 - (4) Include any argument or memorandum of law the moving party wishes to file.
- (c) Any objections to a motion for reconsideration shall be filed within 5 days.

XXX 205.04 Stay of Board Orders.

- (a) A stay of board action shall be specifically requested. The mere filing of a motion for reconsideration shall not operate as a stay of any order, but a motion for stay may be combined with a motion for reconsideration.
- (b) If the board, acting on the board's own motion, stays the effect of any final order, the board shall do so with or without a corresponding order to reconsider or reopen the proceeding.
- (c) Consent agreements shall be encouraged and shall provide a legitimate conclusion to the hearing process. When the consent agreement is issued, the signatories to it shall thereby waive their right to a motion to reconsider. Intervenors shall have no standing to contest the consent agreement.

XXX 205.05 Record Retention. The board shall keep a decision or order on file in its records for at least 6 years following the date of the final decision or the date of the decision on any appeal, unless otherwise required by law.

PART XXX 206 PETITION FOR DECLARATORY RULING

XXX 206.01 Petitions.

- (a) Any person may request a declaratory ruling from the board on matters within its jurisdiction by filing an original and 4 copies of the petition, and the petition for declaratory ruling shall set forth the following information:
 - (1) The exact ruling being requested, including any rule or statute implicated;
 - (2) The statutory and factual basis for the ruling, including any supporting affidavits or memoranda of law; and
 - (3) A statement as to how the language of the rule or statute applies to the circumstances of the petitioner's case.

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(b) Any petition for declaratory ruling which does not contain the information required in (a) above shall be inadequate.

XXX 206.02 Action on Petitions.

(a) If examination of a petition for declaratory ruling reveals that other persons would be substantially affected by the proposed ruling, the board shall require service of the petition on such persons and advise them that they may file a reply.

(b) The petitioner and any persons served with notice of the petition shall provide such further information or participate in such evidentiary or other proceedings as the board may direct after reviewing the petition and any replies received.

(c) The board shall act on the petition as follows:

(1) Issue a written ruling within 30 days after receipt of all information or the conclusion of any evidentiary or other proceeding; or

(2) Reject the petition if:

a. It is inadequate;

b. It involves a hypothetical situation or otherwise seeks advice as to how the board would decide a future case;

c. It does not implicate the legal rights or responsibilities of the petitioner;

d. It is beyond the scope of the board's statutory authority;

e. There is pending legislation or rulemaking, a pending administrative or judicial proceeding, or a pending investigation or examination that will address the petition; or

f. Other procedural options are available to the interested parties or the board.

PART XXX 301 SPENDING TARGETS CALCULATIONS

XXX 301.01 Retail Drug Spending Target

(a) Beginning in 2023, the board shall, in consultation with the advisory council, set the prospective spending targets for the retail pharmacy benefit of public payors.

(1) Spending targets shall be expressed as a percentage year-on-year increase in pharmacy benefit spending. The percentage will be calculated using the 10-year rolling average of New England Division medical price component of the federal New England Division Consumer Price Index. The resulting medical price component growth percentage shall be indexed for the upcoming spending target year by a three-year rolling average in the New England region CPI-U. If the 3-year rolling average of the New England region CPI-U is greater than the most recent New England Division CPI medical component, then the spending target for the upcoming year will be indexed to the most recent New England CPI-medical percentage.

a. Spending targets will be annual without regard to the biennial state budget process. The spending target(s) will be announced 6 months prior to the start of the target spending year.

b. The Board may set payor-specific spending targets if there is a pattern of highly differentiated total retail pharmacy benefit year on year spending growth among the payors in the 3 years prior to 2022 which is not correlated to differences in covered populations. The Board can request detailed spending data to verify the differential if there is reason to believe that Rx spending growth among public payors is substantially different.) This determination shall be made prior to the first year of spending targets. In subsequent years, all public payors will be aligned with a single pharmacy benefit spending target.

XXX 301.02 Retail Drug Spending Targets Attainment

- (a) Each public payor shall provide the Board an analysis of its ability to meet the target year spending target. The analysis shall capture spending up to the end of the third quarter of the calendar year and project spending through the end of the fourth quarter of the spending target year.
- (b) To the extent a public payor expects to exceed targets, the payor shall identify drug products contributing the most to growth in excess of spending targets and the role of product price and utilization in spending growth of each product.

XXX 301.03 Additional Retail Drug Public Payor Reports

- (a) Public payors shall submit to the board verifiable pharmacy spending totals for the target year. The report shall include the top 10 highest spend brand and top 10 highest spend generic products. Each report shall break out volume and average reimbursement amount for the drug component of the medical claim. Public payors shall also supply net spending (after rebates and other price concessions) for each of the 10 products.
- (b) Payors shall report enrollee cost-sharing requirements (copay amount, coinsurance percentage, etc.) for each of the 10 reported highest spend drug products.
- (c) In consultation with the advisory council and the All-Payor Claims Database, the board will establish a reporting template.

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XXX 301.04 Exclusions from Retail Drug Spending Target Calculations

- (a) In determining whether a public payor can meet and has met the spending target, outpatient retail drugs launched in the spending target year with an annualized WAC of at least \$100,000 (or per course of treatment if not a chronic disease medicine) shall not be included in the analysis for that specific spending target year. Newly launched, costly, retail drugs shall be included in public payor spending target analyses in the calendar year that begins 12 months after the drug product launch year.

- (b) Outpatient physician administered prescription drugs shall not be subject to the retail drug spending target and are addressed separately (below).
- (c) Pursuant to provision of I.C., spending on retail drugs with separate, specific targets that may increase spending shall be excluded from the total spend target calculation for two (2) subsequent spending target years.

XXX 301.05 Outpatient Physician-Administered Products Spending Targets

- (a) Spending Target Formula: Beginning in 2023, in consultation with the advisory council, the board shall set prospective spending targets for the outpatient, medical benefit, physician-administered prescription drugs of public payors.
 - (1) Spending targets shall be expressed as a percentage year-on-year increase in pharmacy benefit spending. The percentage shall be calculated using the 10-year rolling average of New England Division medical price component of the federal New England Division Consumer Price Index. The resulting medical price component growth percentage shall be indexed for the upcoming spending target year by a three-year rolling average in the New England region CPI-U. If the 3-year rolling average of the New England region CPI-U is greater than the most recent New England Division CPI medical component, then the spending target for the upcoming year will be indexed to the most recent New England CPI-medical percentage.
 - (2) Spending targets shall be annual without regard to the biennial state budget process. The spending target(s) shall be announced six (6) months prior to the start of the target spending year.
 - (3) The board may set payor-specific spending targets if there is a pattern of highly differentiated total outpatient physician administered prescription drug spending growth (expressed as a year on year percentage) among the payors in the 3 years prior to spending target implementation year that is not correlated to differences in covered populations. The board may request detailed spending data to verify the differential if there is reason to believe that outpatient physician administered drug spending growth among public payors is substantially different. This determination shall be made prior to the first year of spending targets. In subsequent years, all public payors shall be aligned with a single medical benefit outpatient physician administered spending target.

XXX 301.06 Outpatient Physician Administered Spending Target Attainment

- (a) Each public payor shall provide the board an analysis of its ability to meet the spending target. The analysis shall capture spending up to the end of the third quarter of the calendar year and project spending through the end of the fourth quarter.
- (b) To the extent a public payor expects to exceed target in a year, the payor shall identify drug products contributing the most to growth in excess of spending targets and the role of price and utilization in growth of each of those products.

XXX 301.07 Exclusions from Outpatient Physician Administered Drug Spending Target

- (a) In determining whether a public payor can meet and has met the spending target, outpatient physician administered drugs launched in the spending target year with an annualized Wholesale Acquisition Cost (WAC) of at least \$800,000 (or per course of treatment if less than a year shall not be included in the analysis for that specific spending target year. Newly launched, costly, physician-administered drugs shall be included in public payor spending target analyses beginning in the calendar year that begins twelve (12) months after the drug product launch year.
- (b) Pursuant to provision XXX 301.08, spending on outpatient physician administered drugs with specific targets that may increase spending shall be excluded from the total spend target calculations for two (2) subsequent spending target years.

XXX 301.08 Additional Outpatient Physician Administered Drug Public Payor Reports

- (a) Public payors shall submit to the board verifiable outpatient physician administered drug spending totals for the target year. The report shall provide volume and average product reimbursement in addition to total product spend data. Public payors shall also supply net spending (after rebates and other price concessions) for each of the ten (10) products. The data will be aggregated to include all dosage forms and strengths (9-digit NDC).
- (b) For each of the ten (10) top spend outpatient physician administered products, plans will report patient cost sharing and utilization management policies applied to the product.
- (c) The board shall present the data back to the advisory council arrayed to show each plan's top spend outpatient physician administered drug lists highlighting the drugs common to two or more plans.

XXX 301.09 Spending Targets for Drugs Which Create Enrollee Affordability Challenges

- (a) In consultation with the advisory council, the board shall determine if there are drugs among the retail and outpatient physician administered top spend products, or drugs beyond the top spend products, which create affordability challenges for enrollees of public plans.

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- (b) The Board shall require public payors to annually survey their enrollees about retail and outpatient physician administered drugs that create financial challenges for enrollees, if any. Employee responses are voluntary, and the survey shall provide information about the respondent's employer to evaluate the response relative to the benefit design of the respondent's health plan.
- (c) For drugs found to create enrollee affordability challenges under (a) or (b), the law requires the board to establish a spending target for each identified drug. The spending target may provide for an increase in spending to address enrollee affordability challenges.
 - (1) The board may establish a spending target under this section for a specific public payor plan if the board determines that the affordability challenge is the result of the benefit design of a particular plan.
 - (2) A drug-specific spending target percentage that reduces spending on that drug cannot be promulgated in the absence of specific recommendations to public payors on how to constrain spending growth for the retail drug, based on the study required by 126-BB:5.III.

XXX 301.10 Criteria by Which to Assess Affordability Challenge

- (a) Assessing a financial challenge of a prescription drug to public payor plan enrollees may include the following indicators:
 - (1) The existence of manufacturer-sponsored copay assistance programs that reduce patient cost sharing to de minimis amounts throughout the calendar year, whether or not the assistance program is offered to public plan enrollees in the State.
 - (2) The extent to which public payors have shifted costs to patients using the product for the purpose of managing overall public payor spending.
 - (3) The extent to which public payors have applied utilization management strategies to the drug product to manage spending on the drug product.
 - (4) The extent to which residents of New Hampshire cannot afford to access the drug product due to cost.
 - (5) The extent to which the condition for which the drug is indicated is estimated to be un- or under-treated among public program enrollees due to cost.
 - (6) Other assessment criteria as adopted by the board.

XXX 301.11 Study of Different Public Payor Cost Containment Approaches

- (a) Rebate negotiations (or supplemental rebates) for drugs contributing the most to spending that exceeds spending targets:
 - (1) In order to determine if there are cost savings in working with public payors on rebates, the board shall understand the baseline of public payor price concessions as a component of cost containment. Public payors and their vendors shall provide to the board for retail and outpatient physician administered drugs as appropriate:
 - a. Specific unit rebate amounts on a drug-by-drug basis for top spend drugs as reported under xxxx.
 - b. The percentage of rebates retained by vendor expressed as a percentage of total rebates.

- c. The percentage discount/rebate on total pharmacy spend vendor has guaranteed to the public payor (if any). Applies only to retail, pharmacy benefit drugs.
 - d. The list of drugs excluded from a plan coverage (if any)
 - e. The percentage of covered drugs to which plan utilization management tools are applied.
- (b) Establishing a unified formulary for use among all NH public payors:
- (1) The board shall collect payor/plan-specific formulary information in electronic form:
 - a. Covered drugs, organized by alphabetically organized therapeutic class, drugs listed alphabetically within the class.
 - b. For each listed drug, notation on tier placement/patient cost sharing associated with the tier, and utilization management policies applied to the drug.
 - (2) The board shall compare the formularies, highlighting differences in:
 - a. Scope of drug coverage within each therapeutic class
 - b. Significant differences in tiering of therapeutically important or high-utilization drugs
 - (3) The board shall review, with the advisory council, the range of coverage among the different plans and the extent to which plans might have to change their coverage or management if formularies are unified.
 - (4) Results of the study concerning rebates together with formulary structure information shall allow the board and advisory council to evaluate the potential financial benefits of a unified formulary relative to the payor financial costs of change and potential enrollee disruption.
- (c) Formulary management tools for drugs for which there are insufficient price concessions or drugs which drive spending growth.
- (1) The findings of the study of rebates and the information generated from the formulary study in shall be the basis of this review of insufficient price concessions.
 - (2) The board shall consult with public payors for input on which covered drugs are perceived by payors to have insufficient price concessions and review plan reports where spending growth is expected to exceed the year's target.
 - (3) The board shall review the utilization management tools applied by each public plan to drugs identified in xxx. The board shall develop best practices for managing drugs perceived to have insufficient price concessions, including the extent to which there are therapeutic alternates available in the market.
- (d) Requiring that all public payors' administrative services providers apply the utilization management tools adopted by the public payors to their other books of business.
- (1) The board shall determine if requiring a subset of State contractors to administer their employee benefits by reference to New Hampshire state employee coverage and benefit design is legal under NH or federal law, and if this has precedent in NH.
 - (2) The Board shall hold hearings and solicit public input prior to making a recommendation.
- (e) Unified purchasing prescription drugs in bulk for enrollees of public payors.
- (1) The board shall issue a request for information to better understand:
 - a. Whether the program should be a literal bulk purchase program among public payors;
 - b. Which drugs would be appropriate – retail and/or physician administered;
 - c. Who owns the bulk product;
 - d. Should a wholesaler manage distribution to retail pharmacies/providers in the state;

- e. How would pharmacy-specific or provider-specific quantities be determined so that public employees can be supplied in their local pharmacy or other provider without product coverage that could expire before being dispensed;
 - f. Can pharmacies/providers separately shelf public employee products;
 - g. Should the program be a figurative bulk purchase that is a volume-based rebate agreement with a manufacturer (or manufacturers) which does not require government ownership of product or a distinct distribution system;
 - h. Which drugs would be appropriate;
 - i. How is this different from current operations of public payors; and
 - j. The implications of a literal or figurative bulk purchase for the rest of the New Hampshire healthcare economy.
- (f) Collaborating with other states and state prescription drug “purchasing” consortia to purchase prescription drugs in bulk or to jointly negotiate rebates.
- (1) The board shall conduct an environmental scan of existing multi-state prescription drug initiatives and assess applicability to New Hampshire public payors.
 - (2) The Board shall conduct an environmental scan of new prescription drug market participants including non-profit generic manufacturing and non-profit pharmacy benefit managers and assess applicability to New Hampshire public payors.
 - (3) The Board shall release the results of the two analyses and consult with the advisory council about potential opportunities for New Hampshire public payors.
- (g) Encouraging small market and individual market payors to participate in a multi-agency drug coverage arrangement for a fee.
- (1) The board shall solicit input from small and individual market payors on key concerns and expectations for their participation with public payors administering pharmacy benefits.
 - (2) After the initial consultation, the board shall pend analysis of private plan participation in public payor cost containment strategies until the board and advisory council have reviewed the different studies in this subsection and determined which approaches will be most effective. Input from private payors shall inform board strategic decisions.
- (h) Procuring actuarial and/or pharmacy benefit management services from a single entity that serves all New Hampshire public payors. Multi payor, unified pharmacy benefit administration will be analyzed in conjunction with exploring a unified formulary. The board shall obtain additional information:
- (1) Existing public payor vendor contract termination dates, termination clauses, administrative cost structure, remuneration, and other features of each contract relevant to a recommendation that would affect existing contract provisions.
 - (2) The board’s contract review and analysis will maintain payor-specific confidentiality of those key contract provisions.
 - (3) How non-profit PBMs are differentiated from for-profit PBMs and how that differentiation may or may not benefit State public payors
- (i) How drug-specific spending targets create affordability for plan enrollees.
- (1) The board shall impose spending targets on those drugs that create financial challenges to public payor plan enrollees.
 - a. The board shall study the extent to which targets that reduce spending on the costly drug can improve access of enrollees to a costly drug product.

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- b. The board shall also analyze the extent to which targets that increase plan spending on costly drugs can improve access of enrollees to a costly drug.

XXX 301.12 Reports to the Legislature

- (a) The board shall report to the standing committees of the legislature on its activities of the prior year, including its analysis of different prescription drug cost containment strategies list in section 126-BB:5.III by November 1. The board shall hold hearings and accept written comments about the recommendations produced from its research and analysis.
- (b) Annually thereafter, the board shall report on progress implementing its recommendations and report if and how public payors achieved the spending targets of the prior year. The annual report shall provide prior year net pharmaceutical spending for each public payor relative to the spending target for that year.
- (c) To meet the additional requirements of 126-BB:5.IV, the Board shall annually request of the New Hampshire **APCD** non-confidential statewide data concerning:
 - a) The 25 most prescribed prescription drugs in New Hampshire.
 - b) The 25 prescription drugs with the highest spend in New Hampshire with analysis of the extent to which price and volume affected placement in the top 25.
 - c) The 25 prescription drugs with the largest spending increase relative to the prior year with analysis of the extent to which price and volume affected placement in the top 25.
- (d) The board will compare drugs reported by the APCD to similar reports in other states where the same data is reported.

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XXX 301.13 Grant Funding

- (a) The board may periodically solicit public input on sources of grant funding to assist in the work of the board and public payors.

PART XXX 401 DATA

XXX 401.01 Data Collection

- (a) The board shall develop and implement policies and procedures for the collection, processing, storage, and analysis of clinical, financial, quality restructuring, and prescription drug price data.
- (b) Data collection shall meet the following purposes:
 - (1) To use, build, and improve, upon and coordinate existing data sources and measurement efforts through integration of data systems and standardized of concepts.
 - (2) To coordinate the development of a linked public and private sector information system.
 - (3) To emphasize data that is useful, relevant, and not duplicative of existing data.
 - (4) To minimize the burden on entities that provide data.
 - (5) To preserve the reliability, accuracy, and integrity of collected data.
- (c) The board shall engage with the medical community, the business employer community, the New Hampshire APCD, the Department of Insurance, the Board of Pharmacy, and the University of New

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Hampshire College of Engineering Department of Computer Science Research Group (as applicable) and the Computer Science Interoperability Lab.

- (1) The board shall engage with each group individually to gather basic input on the concepts (a) and (b) of this section.
- (2) The board shall convene a meeting of the entities listed above as well as other stakeholders.
- (3) The board shall appoint a work group, staffed by the DMAS to create an interoperable database.
- (d) In the interim, the board will work with the All Payor Claims Database to gather basic information from the claims-based reporting system.
 - (1) The five most prevalent medical conditions in the State
 - a. Identified as acute or chronic conditions
 - b. Compare condition prevalence of each disease state among state employees to the prevalence in the general state population.
 - c. The average per capita annual prescription drug cost of each of the five most prevalent conditions in state employee benefit programs and the general state population.
 - d. The most prescribed drugs used to treat each condition in the state population at large and the most prescribed drug used to treat each condition in each state employee benefit program.
 - (2) The board shall issue a public report relative to the results of the study in this section.

XXX 401.02 Data Reporting Compliance, Data Management

- (a) The Board shall assure:
 - (1) Prescription drug manufacturers file data required under 126-BB:9 concerning price increase notifications and disclosures. The board will assure that payors, providers, wholesale drug distributors, and pharmacy benefit managers supply any other information the board may request concerning drugs reported by manufacturers. 126-BB:10 provides that failure to provide information required by law or required per request of the board is civil violation subject to fines of \$1000/day/record requested, up to a maximum of \$25,000 per occurrence. Penalties are levied on the 61st day following the board request and are imposed retroactive to the date on which the entity received the board's request or, in the case of manufacturers, retroactive to the date that is seven (7) days after the new drug was launched or the price increase subject to reporting became effective.
 - (2) Users that obtain health data and information from the board safeguard the identification of patients and health care practitioners.
 - (3) Payors, providers, prescription drug manufacturers, wholesale drug distributors, and pharmacy benefits managers pay all assessments.
- (b) The board shall limit access to any information that it receives pursuant to this section to the smallest number of employees and other personnel possible. Users of the board's data are liable under federal and state law and may be subject to penalties for violations of patient confidentiality concerning

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electronic data. Users of the board's data shall execute non-disclosure agreements. Violations may be reported directly to the board or to the appropriate state authority.

- (c) The board shall safeguard and keep confidential commercial or proprietary information provided to the board.
- (d) Suspected violations of trade secrets laws by the board, board staff and any adjacent individuals shall be referred to the appropriate state authority for investigation and remediation. The board will limit access of trade secret information to employees or contractors on a 'need to know' basis where the data is directly relevant to the research and investigation authorized by the board.

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PART XXX 501 BOARD FUNDING AND ASSESSMENT ON REGULATED ENTITIES

XXX 501.01 Board Budget and Funding

- (a) The expenses of the board shall be funded by assessments on the following entities:
 - (1) Health carriers providing fully insured products, administrative services only, or dental-only plans, health maintenance organizations, pharmacy benefit managers operating in the state in any capacity for a health plan operating in the state, and third-party administrators.
 - (2) Prescription drug manufacturers of products intended for sale in the state, wholesalers, and pharmacy benefits managers.
 - (3) All entities in (1) and (2) selling product or services for the benefit of residents and businesses in the State must be registered and licensed by the appropriate state agency, office, or board.
- (b) The board shall develop an annual budget to fund ongoing duties of the board.
- (c) The board shall determine from the board of pharmacy and department of insurance and other appropriate agencies, the numerical count of licensed entities subject to the provisions of this section. The board will fund itself on the following schedule
 - (1) sliding scale assessments of \$100 to \$500 based on revenue for entities listed in (a)(1) and
 - (2) sliding scale assessments of at least \$500 based on revenue for entities listed in (a)(2).
- (d) Researchers and the public requesting specific data not otherwise on the board website may be charged for costs of providing the requested data.
- (e) Assessments may be waived by the board in situations where the interest of the board and the interest of the entity requesting the waiver are served.

PART XXX 601 DRUG PRICE NOTIFICATIONS AND DISCLOSURES, CONFIDENTIALITY, AND REGISTRATION

XXX 601.01 Manufacturer Drug Pricing Reporting

- (a) Annually by January 30th, prescription drug manufacturers shall notify the board of drug cumulative wholesale acquisition cost increases in the previous calendar year of:
 - (1) More than 20% in the event of a branded drug; and
 - (2) More than 20% for a generic drug costing at least \$10 per pricing unit.

- (b) Annually by January 30th, prescription drug manufacturers shall notify the board of a newly introduced drug with a wholesale acquisition cost greater than the Medicare Part D specialty drug price threshold already reported to the Department of Insurance.
- (c) In developing a reporting format for drugs reported under (a) and (b):
 - (1) The board may determine that the reporting format of another state or states will meet the needs of New Hampshire.
 - (2) If the board determines that an existing format will suffice, it will adjust the existing format or formats as needed for reporting criteria specific to New Hampshire or establish a new reporting format in consultation with manufacturers.
 - (3) If the board determines that a new reporting format is needed for New Hampshire, it shall consult with manufacturers and in-state experts to develop the format.
- (d) The board shall obtain or share a subscription to a pricing file which tracks manufacturer price increases and new drug launch prices to determine the accuracy of, or gaps in, manufacturer reporting.
- (e) The board will determine the efficiency of manufacturer price reporting relative to full reliance on a pricing file subscription for all pricing information.
- (f) A manufacturer, wholesale drug distributor, or pharmacy benefits manager that submits a notification or report to the board pursuant to this section shall submit with the notification or report a signed written certification of the notification's or report's accuracy.

XXX 601.02 Public Reports

- (a) The board shall produce a report annually by November 1st that synthesizes existing information on trends in drug prices in the prior calendar year. The board shall incorporate the list of drugs with reportable launch prices, price increases, and otherwise unreported information concerning drugs that meet the criteria of XXX 601.01(a) as well as:
 - (1) National pricing trends, including, but not limited to, any new reports of the prescription drug affordability boards of other states which review launch prices and price increases.
 - (2) Relevant reviews of new literature on drug pricing and pricing trends.
 - (3) Information about the role of the supply chain in drug pricing, drug costs, and explain how and why a retail drug price can be different depending on the pharmacy.
 - (4) The report will incorporate relevant information gathered under XXX 501.
- (b) The board shall request information from any part of the New Hampshire prescription drug supply chain, including healthcare facilities, and may request information from any state licensed health plan. The requests shall be made to the extent that data other than wholesale acquisition cost is needed to elucidate pricing and cost trends in New Hampshire which are to be included in the annual report.
 - (1) Regarding drugs identified under XXX 601.01 data requested should include the following information which is to be provided by pharmacy benefit managers contracted with state health plans.
 - a. The dollar amount of all manufacturer rebates or fees collected by each pharmacy benefits manager for drugs dispensed to enrollees of state-licensed plans and the

state employee benefit plans, including retirees for which the PBM contracts its services.

- (2) The information requested in (b) should be aggregated for all covered drugs and all health plans served by the PBM
 - a. Expressed in dollar terms and
 - b. Expressed as a percentage of spend for all covered drugs for all health plans served by the reporting PBM
 - (3) The information requested in XXX should be segregated and aggregated for all drugs reported XXX and
 - a. Expressed in dollar terms and
 - b. Expressed as a percentage of spend for all 1.2 drugs for all health plans served by the reporting PBM
 1. The percentage of all rebates and fees collected that are passed through to the state licensed health plans served by each reporting PBM.
 - c. The information requested shall exclude bona fide service fees as defined in federal regulation.
 - (4) All rebates and fees reported in accord with this provision shall be considered confidential and cannot be publicly reported in any manner that can identify the drug or health plan, or pharmacy benefit manager.
 - (5) All rebates and fees reported by any company in accord with this provision shall be certified by the company's Chief Financial Officer.
 - (6) All rebates and fees reported by any company in accord with this provision shall be subject to audit at the discretion of the board based on reasonable cause to believe the information is not accurate.
- (c) Prescription drug manufacturers may limit their reporting to information that is otherwise publicly available that is at least as revelatory as a Security and Exchange Commission quarterly or filing.
- (d) The board shall verify that all reporting entities are registered with the Board and registered with or licensed by the Board of Pharmacy or other State licensing agency.
- (e) The board may audit the data submitted by a manufacturer, wholesale drug distributor, or pharmacy benefits manager pursuant to this section. The audits shall only be conducted when the state has reasonable cause to believe information received is inaccurate. The board shall notify the entity to be audited with sufficient notice before conducting the audit. The costs of the audit shall be paid for by the manufacturer, wholesale drug distributor, or pharmacy benefits manager.
- b. The board may require a manufacturer, wholesale drug distributor, or pharmacy benefits manager subject to this section to develop a corrective action plan to correct any deficiencies the board finds with the manufacturer's, wholesale drug distributor's, or pharmacy benefits manager's compliance with this section.

XXX 601.03 Compliance with Reporting Under this Section

- (a) Entities reporting pursuant to XXX have 60 days from receipt of board request to provide the requested information.

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- (b) Failure to provide information requested pursuant to XXX commits a civil violation and may be fined not more than \$1000 per day, not to exceed \$25000 per violation. Each requested data element constitutes a violation.

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