

APPENDIX II-C

RULEMAKING NOTICE FORM

Notice Number _____

Rule Number **Pdab 100, Pdab 200, Pdab 300**

<p>1. Agency Name & Address: Prescription Drug Affordability Board c/o Dept. of Health and Human Services 129 Pleasant Street, Brown Building Concord, NH 03301</p>	<p>2. RSA Authority: <u>RSA 126-BB:6</u> 3. Federal Authority: _____ 4. Type of Action: Adoption <u> X </u> Repeal _____ Readoption _____ Readoption w/amendment _____</p>
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5. Short Title: **Prescription Drug Affordability Board Rules**

6. (a) Summary of what the rule says and of any proposed amendments:

The Prescription Drug Affordability Board was established under RSA 126-BB:2 on July 1, 2020 for the purpose of bringing greater transparency to an opaque pricing scheme used to set drug prices by the various entities involved in the industry and to identify opportunities for public entities such as the state, counties, municipalities, and school districts to save money on what they pay for drugs - being good stewards of taxpayers money.

The Prescription Drug Affordability Board (Board) is proposing to adopt Pdab 100 establishing the Board’s organizational rules and Pdab 200 establishing the Board’s practice and procedure rules. The Board is also proposing to adopt Pdab 300 which establishes rules on the Prescription Drug Affordability Board to include requirements on the Board’s budget and funding and assessment on regulated entities.

6. (b) Brief description of the groups affected:

This rule affects public entities, the state, counties, municipalities, and school districts, and state tax payers who are prescribed and purchase prescription drugs.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	Specific State or Federal Statute the Rule Implements
PDAB 100	RSA 126-BB:2; RSA 126-BB:4; RSA 126-BB:5; RSA 126-BB:6; RSA 126-BB:7; RSA 126-BB:9; and RSA 514-A:16, I(a)
PDAB 200	RSA 126-BB:6; RSA 126-BB:8; RSA 126-BB:9; RSA 126-BB:10; RSA 91-A RSA 541-A:16, I(b); and RSA 541-A:30-a through RSA 541-A:38
PDAB 300	RSA 126-BB:6 and RSA 126-BB:8

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7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Allyson Zinno** Title: **Administrator- Administrative Rules Unit**
 Address: **Dept. of Health and Human Services** Phone #: **(603) 271-9604**
Administrative Rules Unit Fax#: **(603) 271-5590**
129 Pleasant Street, 2nd Floor E-mail: Allyson.E.Zinno@dhhs.nh.gov
Concord, NH 03301

TTY/TDD Access: Relay NH 1-800-735-2964
or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:
<https://www.dhhs.nh.gov/doing-business-dhhs/legal-services/administrative-rules/nh-administrative-rules-public-comment>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Thursday, June 23, 2022**

Fax E-mail Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, June 16, 2022 at 11:00am**
Place: [**DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 22:090, dated May 17, 2022

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):
Not applicable, as these are new rules.

2. Cite the Federal mandate. Identify the impact on state funds:
No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

To the extent that the Board assesses civil fines, all fines collected would be transferred to the state general fund. The benefit is indeterminable. With respect to special funds, the Board has requested that the joint Fiscal Committee approve the creation of a special account for the Board. All assessments collected would be deposited into that account, and the intent is that the fund would not exceed 125% of the cost of funding the Board.

B. To State citizens and political subdivisions:

None.

C. To independently owned businesses:

Proposed PDAB 301.01 requires the imposition of several assessments, fees, and civil penalties, which will impact independently owned businesses to an indeterminable extent. To the extent that assessments are mandated by RSA 126-BB:8 (which requires certain assessments on health insurance carriers, prescription drug manufacturers, wholesale drug distributors, and others) the assessments are attributable to statute rather than to the rule.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

Adopt PDAB 100 to read as follows:

CHAPTER PDAB 100 ORGANIZATIONAL RULES

Statutory Authority RSA 126-BB:1-10

PART PDAB 101 DEFINITIONS

PDAB 101.01 "Board" means the New Hampshire prescription drug affordability board.

PDAB 101.02 "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

PDAB 101.03 "Generic drug" means a prescription drug, whether identified by its chemical, proprietary, or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance, and intended use. "Generic drug" includes a biosimilar product.

PDAB 101.04 "Manufacturer" means a manufacturer of prescription drugs that are distributed in the state. A manufacturer excludes a packager, repackager, labeler, and relabeler.

PDAB 101.05 "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed.

PDAB 101.06 "Public payor" means any division of state, county, or municipal government that administers a health plan for its employees or an association of state, county, or municipal employers that administers a health plan for its employees.

PDAB 101.07 "Wholesale acquisition cost" means a manufacturer's listed price for sale to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

PART PDAB 102 DESCRIPTION OF BOARD

PDAB 102.01 Members of the Prescription Drug Affordability Board.

(a) The prescription drug affordability board shall consist of 5 voting members with expertise in health care economics or clinical medicine and shall be appointed as follows:

- (1) Two members appointed by the president of the senate;
- (2) Two members appointed by the speaker of the house of representatives;
- (3) One member appointed by the governor; and
- (4) One alternate member appointed by each, the senate president, the speaker of the house of representatives, and the governor, who shall participate in deliberations of the board in the event any member appointed elects to be recused as provided in RSA 126-BB:3.

(b) When any member appointed to the board are absent and the alternate member is present, the chair shall elevate the alternate member to become a full member of the board with all rights and privileges of a full member of the board including the right to vote.

PDAB 102.02 Terms.

(a) Members shall be appointed to 5-year terms except for the initial appointments described in this section.

(b) Of the initial appointees, the member appointed by the governor shall serve an initial term of 5 years.

(c) One member appointed by the president of the senate and one member appointed by the speaker of the house of representatives shall serve an initial term of 4 years.

(d) One member appointed by the president of the senate and one member appointed by the speaker of the house of representatives shall serve an initial term of 3 years.

PDAB 102.03 Quorum. A quorum of the board for the purpose of conducting business shall consist of a majority of its members present. For a quorum, alternate members shall not be included as part of the quorum unless the chair has elevated them to replace an absent member.

PDAB 102.04 Chair. The board shall elect a chairman by an affirmative vote of at least 4 of the 5 members of the board.

PDAB 102.05 Meetings.

(a) The board shall hold meetings in public session at least once every 12 weeks.

(b) Each public meeting shall be announced 2 weeks in advance, and materials for the meeting shall be made public at least one week in advance.

(c) Each public meeting shall provide opportunity for comment from the public in attendance at the meeting, and for the public to submit written comments on pending decisions.

(d) Meetings shall be held at a location specified by the chairman.

(e) The board may meet in executive session upon the motion of a board member, duly seconded and a majority vote of the members of the board present at the meeting.

(f) The board may allow expert testimony at any meeting conducted in executive session.

(g) Any decision made by the board in executive session shall be made public.

PDAB 102.06 Advisory Council.

(a) A 12-member advisory council shall be established to advise the board on establishing annual spending targets pursuant to RSA 126-BB:5, I and determining methods for meeting those spending targets pursuant to RSA 126-BB:5, III.

(b) The advisory council shall consist of the following members:

- (1) The governor, or designee;
- (2) The commissioner of the department of administrative services, or designee;
- (3) The commissioner of the department of corrections, or designee;
- (4) The commissioner of department of health and human services, or designee;
- (5) The attorney general, or designee;
- (6) The director of the division or risk and benefits, department of administrative services, or designee;
- (7) The president of the New Hampshire State Employees Association, or designee;
- (8) The president of the New Hampshire Education Association, or designee;
- (9) The executive director of the New Hampshire Municipal Association or designee;
- (10) The chancellor of the university system of New Hampshire, or designee;
- (11) The chancellor of the New Hampshire community college system, or designee; and
- (12) A representative of consumer interests, appointed by the governor who shall serve a 3 year term.

PDAB 102.07 Powers and Duties of Board.

(a) In consultation with the advisory council, the board shall identify strategies that optimize spending by public payors for pharmaceutical products while reasonably ensuring subscriber access to needed pharmaceutical products.

(b) To achieve this goal in (a) above, the board shall determine annual spending targets for prescription drugs purchased by public payors based upon a 10-year rolling average of the medical care services component of the United States Department of Labor, Bureau of Labor Statistics Consumer Price Index, medical care services index, plus a reasonable percentage for inflation and minus a spending target for pharmacy savings as determined by the board.

(c) The board shall determine spending targets on specific prescription drugs that may cause affordability challenges to enrollees in a public payor health plan. Such targets shall consider any medical cost offsets achieved by utilization of the drug.

(d) The board shall determine which public payors are likely to exceed the spending targets determined in (a) above.

(e) The board shall consider the following data to accomplish its duties in (a) through (d) of this section if:

- (1) A public payor's prescription drug spending data, provided to the board by the 3rd-party administrator or insurer for the public payor's health plan, on behalf of the public payor upon request notwithstanding any provision of law to the contrary, includes:
- a. Expenditures and utilization data for prescription drugs for each plan offered by a public payor;
 - b. The formulary for each plan offered by a public payor and prescription drugs common to each formulary;
 - c. Pharmacy benefit management services and other administrative expenses of the prescription drug benefit for each plan offered by a public payor;
 - d. Enrollee cost sharing for each plan offered by a public payor; and
 - e. Aggregate net spending on the prescription drug benefit.
- (f) Data compiled by the department of health and human services shall be confidential.
- (g) Prescription drug spending data provided to the board under this subparagraph shall be confidential to the same extent it is confidential while in the custody of the entity that provided the data to the board;
- (h) Based upon the prescription drug spending data received in accordance with (e) above, the board, in consultation with a representative of each public payor shall determine methods for the public payor to meet the spending targets established in (a) through (d).
- (i) While continuing to ensure adequate access by subscribers to needed prescribed pharmaceutical products, the board shall determine whether the following methods reduce costs to individuals purchasing prescription drugs through a public payor and allow public payors to meet the spending targets established in (a) through (d):
- (1) Negotiating specific rebate amounts on the prescription drugs that contribute most to spending that exceeds the spending targets;
 - (2) Changing a formulary when sufficient rebates cannot be secured under (1);
 - (3) Establishing a common prescription drug formulary for all public payors;
 - (4) Prohibiting health insurance carriers in the state administering benefits for a public payor from offering on their formularies prescription drugs when the method described in (2) is implemented;
 - (5) Purchasing prescription drugs in bulk or through a single purchasing agreement for use among public payors;
 - (6) Collaborating with other states and state prescription drug purchasing consortia to purchase prescription drugs in bulk or to jointly negotiate rebates;

(7) Allowing health insurance carriers providing coverage to small businesses and individuals in the state to participate in the public payor prescription drug benefit for a fee; and

(8) Procuring common expert services for public payor, including but not limited to pharmacy benefit management services and actuarial services.

(j) By November 1 of each year the board shall report its recommendations, including prescription drug spending targets, its strategies for optimization of affordability of prescription drugs for the state and all of its residents, the progress of implementing those recommendations, as well as the annual net spending by public payors on prescription pharmaceutical products as a measure of the efficacy of implementation of those recommendations to date, to the standing committees of the general court with jurisdiction over health coverage and insurance matters and to the governor.

(k) The report in (j) above shall also contain the following information about prescription drugs, both brand name and generic:

(1) The 25 most frequently prescribed drugs in the state as reflected in the New Hampshire All Payor Claim database or such like database then in use in New Hampshire at that time;

(2) The 25 costliest drugs as determined by the total amount spent on those drugs in the state; and

(3) The 25 drugs with the highest year-over-year cost increases as determined by the total amount spent on those drugs in the state.

(j) The board may apply for and receive funds, grants, or contracts from public and private sources.

PDAB 102.08 Data Reporting Compliance, Data Management

(a) 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.

(1) 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 electronic data.

(2) Users of the board's data shall execute non-disclosure agreements.

(3) Violations may be reported directly to the board or to the appropriate state authority.

(b) The board shall safeguard and keep confidential:

(1) Commercial or proprietary information provided to the board;

(2) Trade secret information; and

(3) Other information designated as confidential by the owner of the information.

(c) The board shall limit access to confidential information as provided in PDAB 102.08(b) to employees or contractors where the data is directly relevant to the research and investigation authorized by 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.

Adopt PDAB 200 to read as follows:

CHAPTER PDAB 200 PRACTICE AND PROCEDURE

Statutory Authority: RSA 126-BB:1-10

PART PDAB 201 PURPOSE, SCOPE, AND DEFINITIONS

PDAB 201.01 Purpose and Scope. This chapter sets forth the rules of practice and procedure for the prescription drug affordability board. The rules in this chapter shall govern all proceedings before the prescription drug affordability board.

PDAB 201.02 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) "Advisory council" means the advisory council established in RSA 126-BB:4.
- (c) "Board" means prescription drug affordability board.
- (d) "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.
- (e) "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.
- (f) "Contested case" means "contested case" as defined in RSA 541-A:1 IV.
- (g) "Declaratory ruling" means "declaratory ruling" as defined in RSA 541-A:1, V.
- (h) "Hearing" means the formal or informal receipt by the board of data or argument, or both, from persons.
- (i) "Motion" means any application by a party to a proceeding for an order relating to the proceeding.
- (j) "Order" means "order" as defined in RSA 541-A:1, XI.
- (k) "Party" means "party" as defined in RSA 541-A:1, XII.
- (l) "Person" means "person" as defined in RSA 541-A:1, XIII.
- (m) "Physical Appearance" means to physically appear before the board.

(n) "Remote Appearance" means an appearance before the board conducted via telephone, computer, or other electronic means.

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

PART PDAB 202 APPEARANCES BEFORE THE BOARD

PDAB 202.01 Who May Appear.

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

(b) A person or party, excluding individuals providing public testimony, may request to appear before the board provided the request is made to the board at least 5 weeks prior to a scheduled board meeting.

(c) Notwithstanding (b) above, a person or party 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 calendar days after the date of the notice.

(e) The appeal in (d) above shall include the specific reasons why the person or party believes the board's decision is unlawful or unreasonable.

(f) The chair may waive the requirements of this part at its discretion.

(g) 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.

PDAB 202.02 Representatives in Adjudicative Proceedings.

(a) A representative, in an adjudicative proceeding, shall be either an attorney-at-law licensed in New Hampshire, or a duly authorized officer or employee designated to represent that 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 and scope of authority.

(c) 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 their home jurisdiction.

(d) 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 their own business with the board.

PDAB 202.03 Right to Counsel. Any person in an appearance before the board may be represented by counsel at the person or party's own expense.

PART PDAB 203 PROCEEDINGS BEFORE THE BOARD

PDAB 203.01 Proceedings Before the Board.

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

(b) Proceedings may be conducted, remotely or in person, with the person or party and any witnesses appearing before the board. The board shall make its decision on remote or in person appearance based upon the following:

- (1) There is good cause to conduct a proceeding remotely as set forth in paragraph (c), below; and
 - (2) Conducting the proceeding 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 to conduct a proceeding remotely shall include:
- (1) Excessive distance to the proceeding 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 proceeding.

PDAB 203.02 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.

PDAB 203.03 Issuance of Civil Fines Proceedings.

(a) 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.

(b) The board shall review the proposal and impose a civil fine subject to board adjustment as to amount based upon a preponderance of the evidence whether the civil fine was reasonable under the circumstances.

(c) The board may assign the advisory council to investigate the facts and circumstances related to the proposed imposition of the civil fine.

(d) If assigned per (c) above, the advisory council shall, within 90 calendar days, issue a written recommendation to the board as to the merits of imposing the civil fine and a recommended amount of the civil fine.

(e) The board shall vote whether to accept the recommendations in (d) above of the advisory council in whole or in part and issue a final written decision detailing its findings of fact and conclusions.

(f) A person or party may appeal the imposition of a civil fine in accordance within the time frames set forth PDAB 202.01(d) and the procedures set forth herein.

(g) A person or party appealing the imposition of a civil fine shall provide any additional evidence to the board that the person or party believes is relevant to determining the merits and amount of the imposition of the civil fine.

(h) The board shall, after the person or party has had an opportunity to present evidence and be heard, determine based upon a preponderance of the evidence, whether the imposition of the civil fine is just and fair under the facts and circumstances.

(i) Appeals of board decisions shall be in accordance with RSA 541.

PDAB 203.04 Board Proceedings Relative to Assessments and Registration.

(a) A person or party may request an appeal of the board's notice requiring:

- (1) Registration of the person or party with the board; or
- (2) Annual assessment amounts including the board's denial of a waiver of an assessment.

(b) A person or party appealing a notice in accordance with this part shall provide any additional evidence to the board that the person or party believes is relevant to determining the merits of the appeal.

(c) The board shall, after the person or party has had an opportunity to present evidence and be heard, determine, based upon a preponderance of the evidence, whether the notice was:

- (1) Required by RSA 126-BB in cases of appeals of notice of registration; or
- (2) Just and fair in cases of appeals related to denials of assessment waivers.

PDAB 203.05 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 refutably 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) Sent by certified or registered mail; or

(2) Faxed or sent electronically, if delivery is by electronic mail.

PDAB 203.06 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, including appeal requests, intended for the board shall be addressed to:

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

PDAB 203.07 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 proceeding 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 proceeding. 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 board.

(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.
- (f) Repetitious motions shall not be accepted.
- (g) Replies to motions shall be filed within 10 calendar days after the filing of the motion.
- (h) 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.
- (i) 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.
- (j) The board may, at its discretion, consider and dispose of matters through motions, memoranda, or briefs, without the person or party appearing before the board.

PDAB 203.08 Confidential Documents and Confidential Information in Adjudicative Proceedings.

- (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 in accordance with RSA 91-A.
- (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 PDAB 203.05.
- (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.

(h) 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 (i) below.

(i) 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

(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.

(j) Decisions of the board shall be made publicly available on its website for guidance and instructions to registrants and other necessary entities.

PDAB 203.09 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.

(e) 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.

PDAB 203.10 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.

PDAB 203.11 Record. The record in a proceeding 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 recording or stenographic notes or symbols prepared for the proceeding by the board, together with any transcript of all or part of the hearing considered before final disposition of the adjudicative proceeding;
- (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.

PDAB 203.12 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.

PDAB 203.13 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.

PDAB 203.14 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 PDAB 204 SETTLEMENT, DECISIONS, AND REHEARING

PDAB 204.01 Settlement.

- (a) Settlements between the parties shall be encouraged in accordance with RSA 541-A:38.
- (b) 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.
- (c) 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.

PDAB 204.02 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.

(d) The board shall also specify a date by which other parties shall respond to or rebut the newly received evidence.

PDAB 204.03 Motion for Reconsideration.

(a) A motion for reconsideration shall be filed within 30 calendar 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 10 calendar days.

PDAB 204.04 Stay of Board Orders.

(a) A stay of board action shall be specifically requested.

(b) 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.

(c) 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.

(d) Consent agreements shall be encouraged and provide a legitimate conclusion to the hearing process.

(e) When the consent agreement is issued, the signatories to it shall thereby waive their right to a motion to reconsider.

(f) Intervenors shall have no standing to contest the consent agreement.

PDAB 204.05 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 PDAB 205 PETITION FOR DECLARATORY RULING

PDAB 205.01 Petitions.

(a) Any person or party may request a declaratory ruling from the board on matters within its jurisdiction by filing an original and a copy for each member of the board of the petition, which includes 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.

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

PDAB 205.02 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) For the purposes of (a) and (b), service of the petition shall be, at a minimum, completed by sending a copy of the petition to the affected persons via certified mail.

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

- (1) Issue a written ruling within 30 calendar 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.

Adopt PDAB 300 to read as follows:

CHAPTER PDAB 300 PRESCRIPTION DRUG AFFORDABILITY BOARD

PART PDAB 301 BOARD FUNDING AND ASSESSMENT ON REGULATED ENTITIES

PDAB 301.01 Board Budget and Funding.

(a) The expenses of the board shall be funded by assessments fees on the following entities and not exceed 125 percent of the annual budget:

- (1) Health insurance carriers providing fully insured products, administrative services only, or dental-only plans;
- (2) Health maintenance organizations;
- (3) Pharmacy benefit managers operating in the state in any capacity for a health plan operating in the state;
- (4) Third-party administrators;
- (5) Prescription drug manufacturers of products intended for sale in the state;
- (6) Wholesale drug distributors; and
- (7) Pharmacy benefits managers.

(b) All entities in (a) selling products or services for the benefit of residents and businesses in the state of New Hampshire must register with the board.

(c) The board shall work with the board of pharmacy and department of insurance and other state agencies, to determine the numerical count of entities subject to the provisions of this section.

(d) The board shall apply the following assessments, fees and civil penalties:

- (1) The entities in PDAB 301.01(a)(1) through (4) shall be subject to an annual assessment of \$100 due on or before February 1 of each calendar year;
- (2) The entities in PDAB 301.01(a)(5) through (7) shall be subject to an annual assessment of \$500 due on or before February 1 of each calendar year;
- (3) Researchers and members of the public requesting data in accordance with RSA 91-A shall be assessed a fee of \$0.25 per page for physical copies;
- (4) When a person or party that is a health care facility payor, prescription drug manufacturer, wholesale drug distributor, or pharmacy benefits manager violates any requirement of RSA 126-BB or the rules adopted thereunder, that person or entity shall be subject to a fine of \$1,000 per day;

(e) A fine imposed by (4) above shall not exceed \$25,000 for any one occurrence.

(f) Assessments may be waived by the board in situations where the person or party demonstrates a financial hardship.

(g) All civil fines and penalties collected by the board shall be transferred to the general fund.

(h) The total sum of all assessments, fees collected by the board shall not exceed 125 percent of the board's operating cost for a state fiscal year.

Appendix

Rule	Specific State or Federal Statute the Rule Implements
PDAB 100	RSA 126-BB:2; RSA 126-BB:4; RSA 126-BB:5; RSA 126-BB:6; RSA 126-BB:7; RSA 126-BB:9; and RSA 514-A:16, I(a)
PDAB 200	RSA 126-BB:6; RSA 126-BB:8; RSA 126-BB:9; RSA 126-BB:10; RSA 91-A RSA 541-A:16, I(b); and RSA 541-A:30-a through RSA 541-A:38
PDAB 300	RSA 126-BB:6 and RSA 126-BB:8