

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. The term "generic drug" includes a biosimilar product as defined by 42 U.S.C. § 262(i)(2).

Pdab 101.04 "Manufacturer" means a manufacturer of prescription drugs that are distributed in the state. This term does not include a packager, repackager, labeler, or relabeler unless the packager, repackager, labeler, or relabeler sets the price or controls the price of the prescription drug.

Pdab 101.05 "Pricing unit" means the smallest available package that can be used to dispense the smallest amount of a prescription drug.

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) Two alternate members 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 or is absent.

(b) When any members appointed to the board are absent or have recused themselves from a matter before the board and an 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.

(c) When an alternate is appointed due to a recusal, the alternate shall only serve as a full member for the matter requiring recusal.

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 3 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 or recused 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 14 days in advance and materials for the meeting shall be made public at least one week in advance.

(c) Public meetings and materials in (b) above shall be found at the board's website presently located at <https://www.dhhs.nh.gov/programs-services/medicaid/new-hampshire-prescription-drug-affordability-board>.

(d) 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.

(e) Meetings shall be held at a location specified by the chairman and included in the announcement in (b) above.

(f) The board may, in accordance with RSA 91-A:3, meet in non-public session upon the motion of a board member, duly seconded, and a quorum vote of the members of the board.

(g) The board may allow expert testimony at any public meeting or any meeting conducted in non-public session.

(h) Any decision made by the board in non-public 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 Executive Director. The board shall employ an executive director pursuant to RSA 126-BB:2, VI.

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.

- (a) This chapter sets forth the rules of practice and procedure for the prescription drug affordability board.
- (b) 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) "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.

(d) "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;

(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; or

(3) Other information designated as confidential by the owner of the information prior to receipt by the board.

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

(f) "Day" means a calendar day.

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

(h) "Hearing" means the receipt and consideration by the board of data or argument, or both, by methods which are appropriate to the nature and scope of the issues being decided by the board..

(i) "Motion" means any request 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) "Presiding officer" means the board chairman or other member to whom the board chairman has delegated authority to preside over some or all aspects of a hearing.

(n) "Physical appearance" means to physically appear before the board.

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

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

Pdab 201.03 Presiding Officer Authority. The presiding officer shall as necessary:

- (a) Regulate and control the course of a hearing;
- (b) Facilitate informal resolution of an appeal;
- (c) Receive relevant evidence at hearings and exclude irrelevant, immaterial, or unduly repetitious evidence;
- (d) Question any person who testifies;
- (e) Cause a complete record of the hearing to be made; and
- (f) Take any other action consistent with applicable statutes and rules necessary to conduct the hearing and complete the record in a fair and timely manner.

Pdab 201.04 Withdrawal of Presiding Officer or Board Members.

- (a) Upon his or her own initiative or upon the motion of any party, the presiding officer or any other board member shall withdraw from any hearing when good cause exists.
- (b) Good cause shall exist if the presiding officer or board member:
 - (1) Has a direct interest in the outcome of a proceeding, including but not limited to a financial or family relationship;
 - (2) Has made statements or engaged in behavior which objectively demonstrates that they have prejudged the facts of a case; or
 - (3) Personally believes that they cannot fairly judge the facts of the case.
- (c) Mere knowledge of the issues, the parties, or any witness shall not constitute good cause for withdrawal.

Pdab 201.05 Waiver or Suspension of Procedural Rules or Orders. The board, upon its own initiative or upon the motion of any interested person shall, upon approval by a quorum vote of the members of the board, suspend or waive any procedural requirement or limitation imposed by this chapter provided:

- (a) A 10-day notice is given to all affected persons;
- (b) The proposed waiver or suspension appears to be lawful, and would be more likely to promote the fair, accurate, and efficient resolution of issues properly pending before the board than would adherence to a particular procedural rule or requirement; and
- (c) No party or intervenor objects to the waiver or suspension.

Pdab 201.06 Appearances Before The Board For Non-Adjudicative Hearings.

- (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 shall be made to the board at least 10 days prior to scheduled board meeting pursuant to Pdab 202.05.

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

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

Pdab 201.07 Appearances Before the Board for Adjudicative Proceedings.

(a) A person may appear in an adjudicative proceeding by personal attendance or through the attendance of a representative appointed by the person.

(b) Representatives shall be knowledgeable about the subject matter of the appeal.

(c) The representative shall present to the board prior to the commencement of the hearing a letter signed by the person they are representing giving them the authority to act as representative.

(d) An attorney from another jurisdiction shall be permitted to participate in the proceedings if the attorney files a motion pursuant to Pdab 202.05 for leave to appear providing proof the attorney is in good standing in their 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 their own business with the board.

Pdab 201.08 Disqualification.

(a) After notice and opportunity for a hearing and a finding of misconduct by any individual relating to representation before the board, the individual shall be disqualified from acting as a representative before the board.

(b) A finding of misconduct shall be based on the following actions or behaviors:

- (1) Obstruction of fair, due process;
- (2) Disruption of the orderly conduct of procedure; or
- (3) Willful action which results in prejudice to other parties.

(c) If a representative is disqualified, the board shall postpone the matter to allow the party being represented to procure alternative representation.

Pdab 201.09 Intervention.

(a) A non-party may intervene in any matter pending before the board under the provisions of RSA 541-A:32, by filing a motion stating facts demonstrating that:

- (1) The non-party's rights or other substantial interests might be affected by the proceeding; or
- (2) That the non-party qualifies as an intervenor under any provision of law.

(b) If the presiding officer determines that such intervention would be in the interest of justice and would not impair the orderly and prompt conduct of the hearing, a motion for intervention shall be granted.

Pdab 201.10 Right to Counsel. Any person in an appearance before the board may be represented by counsel at the person or party's own expense.

Pdab 201.11 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 extend to include the first business day following the Saturday, Sunday, or legal holiday.

PART PDAB 202 PROCEEDINGS BEFORE THE BOARD FOR APPEALS

Pdab 202.01 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 shall be conducted in person.

Pdab 202.02 Issuance of Civil Fines Proceedings.

(a) The board shall issue notice of an imposed civil fine for the following:

- (1) Failure to register with the board annually;
- (2) Failure to pay the assessment fee on time; and
- (3) Failure to report data to the board.

(b) The civil fine imposed for any violation identified in (a) above shall be up to \$1000 per day and not to exceed a total of \$25,000 for any one occurrence.

(c) The executive director or presiding officer shall, at least 30 days prior to the next scheduled board meeting, provide written notice to the affected party of the basis for the proposed issuance of a civil fine in accordance with RSA 126-BB:10 and contemporaneously notify the board.

(d) The party shall have 15 calendar days to provide a written response to the notice in (a) above.

(e) The board shall review the proposal together with any response by the affected party.

(f) The board shall determine whether a preponderance of evidence supports the imposition of a civil fine subject to board adjustment as to amount in accordance with RSA 126-BB:10.

(g) The board may, if additional investigation or fact-finding is necessary, assign the advisory council to investigate the facts and circumstances related to the proposed imposition of the civil fine.

(h) If assigned per (g) 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.

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

(j) A person or party may appeal the imposition of a civil fine.

(k) 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.

(l) 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 to withdraw, uphold, or adjust the amount of the civil fine.

Pdab 202.03 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) Not in compliance with due process as required by RSA 126-BB in cases of appeals related to denials of assessment waivers.

Pdab 202.04 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 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 202.05 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, 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 202.06 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.

(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 shall, if it is determined that there is no material issue of fact, consider and dispose of matters through motions, memoranda, or briefs, without the person or party appearing before the board.

Pdab 202.07 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 202.04.

(e) It shall be 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 shall 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 might have been filed and determine, pursuant to RSA 91-A, 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) Parties disagreeing with the board's decision as to the confidential nature of documents may seek relief in any court of competent jurisdiction.

(k) The board shall not make public any documents or any other materials subject to any legal proceeding regarding confidentiality.

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

Pdab 202.08 Continuances.

(a) The board shall for good cause pursuant to (c) below, 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 pursuant to (c) below, 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 202.09 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 202.10 Record.

(a) The record in a proceeding shall include all of the following that are applicable in that case:

- (1) All pleadings, motions, objections, and rulings;
- (2) Evidence received or considered;
- (3) A statement of matters officially noticed;
- (4) Any decision, opinion, or report by the board;
- (5) 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;
- (6) Staff memoranda or data submitted to the board; and
- (7) Matters placed on the record after an ex parte communication.

(b) The record in part or in its entirety shall be exempt from public disclosure if it is identified as confidential information as defined in Pdab 201.02(d) in accordance with RSA 91-A:5.

Pdab 202.11 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 202.12 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 202.13 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 203 SETTLEMENT, DECISIONS, AND REHEARING

Pdab 203.01 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 203.02 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 to the proceeding, shall reopen the record to receive relevant, material, and non-duplicative testimony, evidence, arguments, or exhibits not previously received if the board, through the presiding officer, determines that such testimony, evidence or arguments are necessary to a full and fair consideration of the issues to be decided.

(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 203.03 Motion for Rehearing.

(a) A motion for rehearing shall be filed within 30 calendar days of the board's final decision.

(b) A motion for rehearing 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 rehearing shall be filed within 10 calendar days of the date of filing of the motion for rehearing.

Pdab 203.04 Standard for Granting Motion for Rehearing. A motion for rehearing a case subject to appeal to the New Hampshire supreme court under RSA 541 shall be granted if it demonstrates that the board's decision is unlawful, unjust, or unreasonable.

Pdab 203.05 Decision on Motion for Rehearing. The board shall grant or deny a motion for rehearing or suspend the order or decision pending further consideration within 30 days of the filing of the motion for rehearing.

Pdab 203.06 Stay of Board Orders.

(a) A stay of board action shall be specifically requested by a party to the proceeding.

(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 becomes aware of additional information that was unavailable or was not discovered prior to hearing that would change the final order, the board shall stay the final order for reconsideration by affirmative vote of the members of the board.

(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 203.07 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 204 PETITION FOR DECLARATORY RULING

Pdab 204.01 Petitions.

(a) Any person or party may request a declaratory ruling from the board on matters within its jurisdiction by filing an original petition and a copy for each member of the board, 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 not be accepted by the board.

Pdab 204.02 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 might 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.

(d) 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 incomplete;
 - 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 Pdab 205 PETITIONS FOR RULEMAKING

Pdab 205.01 Petition for Rulemaking.

- (a) Any person may request the board to commence a proceeding for the purpose of adopting, amending, or repealing a rule by filing a written petition that contains:
 - (1) A statement of the petitioner's request for the proposed rule;
 - (2) The text of the proposed rule or a statement of the particular results intended by the petitioner's interest in the subject matter of the proposed rule;
 - (3) An identification of the particular rule sought to be amended or repealed;
 - (4) Any data or argument the petitioner believes would be useful to the board in deciding whether to commence a rulemaking proceeding; and
 - (5) The name, address, signature of petitioner, and date of the petition request.

Pdab 205.02 Disposition of Petition.

- (a) The board shall consider all petitions for rulemaking and proceed pursuant to RSA 541-A:4.
- (b) The board shall request additional data, or argument from the petitioner, or other interested persons to clarify the argument.
- (c) Such petitions shall be received and handled in the following manner:
 - (1) Petitions shall be submitted to the board; and
 - (2) Within 30 days of the receipt of the petition, the board shall take one of the following actions:
 - a. Commence rulemaking in accordance with RSA 541-A:3, if the requested action is:
 - 1. Within the board's authority; and
 - 2. Consistent with and best implements state statutes affecting the board; or
 - b. Deny the petition, in writing, stating fully the reasons for denial.

PART Pdab 206 RULEMAKING PUBLIC COMMENT HEARINGS

Pdab 206.01 Purpose. The purpose of this part shall be to provide a uniform procedure for the conduct of public hearings at which comment from the general public shall be solicited for evaluation and consideration by the board relative to rulemaking.

Pdab 206.02 Rulemaking Public Comment Hearing. A public comment hearing shall be held by the board when proposing to adopt, amend, or repeal a rule or rules.

Pdab 206.03 Notice. Notice of the date, time, and place of public comment hearing for a rulemaking shall comply with RSA 541-A:6, I.

Pdab 206.04 Record. A record of the public comment hearing shall be kept by electronic recording or other method that will provide a verbatim record.

Pdab 206.05 Presiding Officer. The presiding officer at a public comment hearing in a rulemaking proceeding shall be the board chairman or a designee.

Pdab 206.06 Opening the Hearing.

(a) The presiding officer shall open a public comment hearing by describing in general terms the purpose of the hearing and procedures governing its conduct.

(b) After the opening statement the presiding officer shall receive comments from the persons attending the hearing.

Pdab 206.07 Testimony.

(a) Written testimony or exhibits may be submitted any time from the time notice has been published until the record has been closed, which shall not be less than 7 calendar days after the hearing.

(b) Anyone wishing to testify at a public comment hearing shall submit in writing to the presiding officer the person's name, address or email address, and whom, if anyone, that person represents.

(c) The presiding officer shall call each person to present testimony.

(d) The presiding officer shall rule any comments, questions, or discussions that the presiding officer determines not to be relevant to the subject of the public comment hearing out of order, and proceed to the next speaker.

Pdab 206.08 Closing the Hearing. When the presiding officer determines that no person has further questions or comments that are relevant to the subject of the hearing, the presiding officer shall close the hearing.

Pdab 206.09 Postponements; Relocation.

(a) A public comment hearing shall be postponed in accordance with RSA 541-A:11, IV when:

(1) The weather is so inclement that it is reasonable to conclude that people wishing to attend the hearing will be unable to do so; or

(2) Postponement will facilitate greater participation by the public.

(b) A public comment hearing shall be moved to another location in accordance with RSA 541-A:11, V when the original location is not able to accommodate the number of people who wish to attend.

(c) A public comment hearing shall be continued past the scheduled time or to another date in accordance with RSA 541-A:11, III when:

- (1) The time available is insufficient to give each person who wishes to speak a reasonable opportunity to do so; or
- (2) The capacity of the room in which the hearing is to be held does not accommodate the number of people who wish to attend and it is not possible to move the hearing to another location.

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

Adopt Pdab 300 to read as follows:

CHAPTER PDAB 300 PRESCRIPTION DRUG AFFORDABILITY BOARD

Statutory Authority: RSA 126-BB

PART PDAB 301 BOARD OPERATIONS

Pdab 301.01 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 (a) above, the board shall determine annual spending targets for prescription drugs purchased by public payors using the following:

(1) 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 available at <https://www.bls.gov/cpi/factsheets/medical-care.htm>;

(2) Plus a percentage for inflation; and

(3) An adjusted spending target based on projected savings as determined by the board which might include drug rebates, lower medical costs, and drug utilization.

(c) The board shall determine spending targets on specific prescription drugs that might 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 (b) above.

(e) The board shall consider the following data to accomplish its duties in (a) through (d) of this section, including but not limited to:

(1) Expenditures and utilization data for prescription drugs for each plan offered by a public payor;

(2) The formulary for each plan offered by a public payor and prescription drugs common to each formulary;

(3) Pharmacy benefit management services and other administrative expenses of the prescription drug benefit for each plan offered by a public payor;

(4) Enrollee cost sharing for each plan offered by a public payor;

(5) Aggregate net spending on the prescription drug benefit;

(6) Data compiled by the department of health and human services; and

(7) Claims databases, including but not limited to the all payors claims database, New Hampshire comprehensive health information system (NH-CHIS), all prescription drug spending whether billed under the prescription drug benefit or the medical benefit.

(f) Prescription drug spending data provided to the board under this section shall be confidential to the same extent it is confidential while in the custody of the entity that provided the data to the board;

(g) 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).

(h) 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.

(i) 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.

(j) The report in (i) 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.

Pdab 301.02 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 possible and other personnel pursuant to RSA 126-BB.
- (b) Members of the board, advisory council, employees, or contractors who utilize the board's data shall be liable under federal and state law and shall be subject to penalties for violations of patient confidentiality concerning electronic data.
- (c) Members of the board, advisory council, employees, or contractors of the board's data shall execute non-disclosure agreements.
- (d) Violations shall be reported in writing directly to the board and to the New Hampshire department of justice.
- (e) 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 prior to receipt by the board.
- (f) The board shall limit access to confidential information as provided in Pdab 301.02(a) to members of the board, employees, or contractors where the data is directly relevant to the research and investigation authorized by the board.
- (g) Anyone who suspects violations of trade secrets laws by the board, board staff, any member of the advisory council, or any individual who has access to the data, shall be referred to the New Hampshire department of justice in writing for investigation and remediation.
- (h) All confidential information, as defined in Pdab 201.01(d), shall be stored in a secure location and accessible only during such time as needed for the individual's work assignment.

PART PDAB 302 BOARD FUNDING AND ASSESSMENT ON REGULATED ENTITIES

Pdab 302.01 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 board's annual budget:

- (1) Health insurance carriers providing fully insured products, administrative services only, or dental-only plans;
- (2) Health maintenance organizations;
- (3) Third-party administrators;
- (4) Prescription drug manufacturers of products intended for sale in the state;
- (5) Wholesale drug distributors; and
- (6) Pharmacy benefits managers, including those that process and pay claims on the basis of claims processed or paid for each plan sponsor.

(b) All entities in (a) selling products or services for the benefit of residents and businesses in the state of New Hampshire shall 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 302.01(a)(1) through (4) shall be subject to an annual assessment of not less than \$100 and not more than \$200 due annually on or before July 1 of each calendar year;

(2) The entities in Pdab 302.01(a)(5) through (7) shall be subject to an annual assessment of not less than \$500 and not more than \$1,000 due annually on or before July 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 , that person or entity shall be subject to a fine of \$1,000 per calendar day, per violation;

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

(f) All fees, assessments, civil fines, and penalties shall be deposited into a non-lapsing dedicated fund, known as the New Hampshire prescription drug affordability board administration fund.

(g) 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 300	RSA 126-BB:6 and RSA 126-BB:8