



## **New York State Medicaid Drug Utilization Review Board Bylaws**

### **I. Introduction**

The name of this body is the New York State Medicaid Drug Utilization Review Board (hereinafter referred to as the DURB).

### **II. Purpose and Responsibilities of the DURB**

- A. The purpose and responsibilities of the DURB are established in Social Services Law Article 5, Title 11, Section 367-a (7) (e) (viii), Article 5, Title 11-C, Sections 369-AA, 369-BB, and 369-CC, and Public Health Law Article 2-A, Title 1, Sections 270, 272, 274, 277 and 280.
- B. The DURB provides clinical guidance to the Commissioner of the New York State Department of Health (hereinafter referred to as the Commissioner) regarding the utilization of pharmaceuticals and the evaluation of drug expenditures within the New York State Medicaid program. DURB activities include but are not limited to the following:
  - 1. Establishment and implementation of medical standards and criteria for the prospective and retrospective DUR program,
  - 2. Development, selection, application, and assessment of educational interventions for physicians, pharmacists and recipients that improve care,
  - 3. Administration of pharmacy programs, including the Preferred Drug Program and the Clinical Drug Review Program, and
  - 4. Evaluation of drugs which may be responsible for exceeding the Medicaid Drug Cap or identified as a high cost drug or gene therapy.
- C. The DURB is authorized to provide recommendations to the Commissioner. The DURB shall make its recommendations to the Commissioner or his or her designee. The Commissioner shall consider the DURB's recommendations and advice.

### **III. Composition**

- A. DURB members are appointed by the Commissioner and the Board consists of twenty- three members. Fifteen of the members shall be clinicians. The DURB is comprised of the following:
  - 1. One chairperson representing the New York State Department of Health (hereinafter referred to as the Department),
  - 2. Six persons licensed and actively engaged in the practice of medicine in the state, with expertise in the areas of mental health, HIV/AIDS, geriatrics,

- pediatrics or internal medicine,
3. Six licensed and actively practicing pharmacists,
  4. One licensed and actively practicing nurse practitioner or midwife,
  5. Two drug utilization review experts, at least one of whom is a pharmacologist,
  6. Three consumers or consumer representatives of organizations with a regional or statewide constituency and who have been involved in activities related to health care consumer advocacy, including issues affecting Medicaid or The Elderly Pharmaceutical Insurance Coverage (EPIC) program members,
  7. Two health care economists,
  8. One actuary, and
  9. One representative from the New York State Department of Financial Services.

#### IV. Meetings

##### A. Scheduling

DURB meetings are conducted in Albany, New York. The Chairperson reserves the right to allow meeting participation by way of a remote or virtual environment. The executive session requirements, as described in paragraph D of these Bylaws, must be sustained for any remote or virtual meeting participants. The Department shall post the agenda on its web site no later than thirty days prior to the date of a scheduled meeting, and the agenda and supporting documentation shall be sent to DURB members at least seven days prior to a scheduled meeting for their review and preparation. DURB meetings shall be held as often as necessary to carry out the responsibilities of the DURB. The DURB may convene for up to eight hours per meeting.

A meeting summary, including the recommendations of the DURB, shall be prepared by Department program staff and shall be posted on the Department's website prior to any final determination made by the Commissioner. The Department shall post the Commissioner's final determination within ten days of the Commissioner's decision.

##### B. Quorum

Each meeting of the DURB requires that quorum be met. Unless required otherwise by statute, quorum shall consist of a majority of DURB seats. Quorum shall not be achieved unless a majority of the attending members are clinicians.

##### C. Attendance

As each meeting of the DURB requires a quorum, in accepting appointment to the DURB, members commit themselves to regular attendance at the scheduled meetings. Meeting dates shall be scheduled sufficiently in advance to allow for requisite planning and scheduling for attendance by DURB members. Members unable to attend a meeting must notify the Commissioner or his or her designee prior to the meeting. Substitute members are not permitted. It is expected that each

member of the DURB should attend a majority of scheduled DURB meetings within the calendar year. Failure to attend a majority of meetings may result in removal from the DURB. New members shall be appointed to fill any vacancies in accordance with these Bylaws.

#### D. Conduct of Meetings

The DURB meetings shall be conducted by the Chairperson. The DURB shall not present its recommendations as the policy of the State. Confidential financial information shall only be presented or discussed during executive session. DURB members shall not release information that is made available to them by virtue of their participation on the DURB.

#### E. Public Comment

With prior notice to the Department, any interested party may request and may be permitted to provide oral comments or make a presentation to the DURB during a public comment segment of the meeting on any item under consideration by the DURB at that meeting. Individuals interested in providing public comments to the DURB may submit a request to the Department at least one week in advance of a meeting to be added to the agenda.

Before a request to provide public comment is granted, individuals shall be required to divulge any financial relationships with the pharmaceutical industry which may influence their comments. Before an individual is permitted to provide public comment, the Chairperson shall require that the individual attest as to the accuracy of the information on financial relationships provided. Individuals granted permission to address the DURB shall be notified of their inclusion on the public comment list when the list is deemed complete. The public comment period shall be at the beginning of the meeting. Up to ninety minutes may be devoted to public comments on issues to be considered by the DURB. If multiple speakers are proposing to address the same issue with the same point of view, and there is insufficient time to include all speakers, an individual may provide a brief written statement.

#### F. Decision Making

Every DURB member has one vote, and voting shall take place while the meeting is convened. Except for recommendations given per Public Health Law Section 280, DURB recommendations may be adopted by general consent, with adoptions made by majority vote if the Chairperson deems such a vote necessary. Recommendations given per Public Health Law § 280 shall be adopted by majority vote.

### V. Conditions of DURB Membership

#### A. Requirements

DURB members (except for the Chairperson, the consumer representatives, the financial and economic representatives, and the drug utilization review experts) are required to be New York State licensed practitioners in good standing. No DURB member may have Medicaid or Medicare sanctions against them.

## B. Conflicts of Interest and Financial Disclosure

Members should exercise their duties and responsibilities as DURB members in the public interest of the people of New York State, regardless of their affiliation with, or relationship to, any facility, agency or program, category of provider, or interest group. Members are required to disclose any interest, financial or otherwise, held by the member, his or her spouse/partner and minor children, in any entity that may have a direct interest in matters before the DURB. Members should address questions regarding conflicts of interest or the appearance of conflicts of interest to Department staff, the Department 's Ethics Officer, and the attorney for the DURB.

### 1. Code of Ethics

No DURB member should have any interest, financial or otherwise, direct or indirect, or engage in any business or transaction or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his or her DURB duties in the public interest. Members should also avoid the appearance of a conflict of interest. Members of the DURB must comply with the following Code of Ethics during their service on the DURB:

- a. No DURB member should accept employment which may impair his or her independence of judgment in the exercise of his or her official duties on the DURB.
- b. No DURB member should accept employment or engage in any business or professional activity which would require him or her to disclose confidential information which he or she has gained because of his or her official duties on the DURB.
- c. No DURB member should disclose confidential information acquired by him or her in the course of his or her duties on the DURB or use such information to further his or her personal interests.
- d. No DURB member should use or attempt to use his or her official position on the DURB to secure unwarranted privileges or exemptions for himself or herself or others, including but not limited to, the misappropriation to himself, herself or to others of the property, services or other resources of the State for private business or other compensated non-governmental purposes.
- e. No DURB member should engage in any transaction as representative or agent of the state with any business entity in which he or she has a direct or indirect financial interest that might reasonably tend to conflict with the proper discharge of his or her official duties on the DURB.
- f. A DURB member should not, by his or her conduct, give reasonable basis for the impression that any person can improperly influence him or her or unduly enjoy his or her favor in the performance of his or her official duties on the DURB, or that he or she is affected by the kinship, rank, position or influence of any party or person.
- g. A DURB member should abstain from making personal investments in enterprises which he or she has reason to believe may be directly involved in decisions to be made by him or her or which would otherwise create substantial conflict between his or her duty in the public interest and his or

her private interest.

- h. A DURB member should endeavor to pursue a course of conduct which will not raise suspicion among the public that he or she is likely to be engaged in acts that are in violation of his or her trust.
- i. No DURB member nor any firm or association of which such person is a member nor any corporation where a substantial portion of stock is owned or controlled directly or indirectly by such member, should sell goods or services to any person, firm, corporation or association which is licensed or whose rates are fixed by the state agency in which such DURB member serves or is employed.
- j. DURB members must report all legislative and or lobbying contacts regarding any issue or decision under the purview of the DURB, or from an agent or representative of an entity directly affected by DURB activity; and employment status changes to the Commissioner or his or her designee to avoid any actual conflicts of interest or the appearance of any conflicts of interest.
- k. DURB members may consult with medical/clinical peers for their professional expertise on an as needed basis, however, members must report to the Chairperson any contacts with private industry intended to influence the member in carrying out his or her duties on the DURB or intended to influence a decision of the DURB. Failure to do so may result in removal from the DURB.
- l. DURB members must complete the Department's Ethics Training for Members of Advisory Boards and Councils within three months of beginning DURB service, or within three months of the Ethics Training becoming available. Members should address questions regarding the Code of Ethics to Department staff, the Department's Ethics Officer, and the attorney for the DURB.

## 2. Financial Conflicts of Interest

During the period of DURB membership, no DURB member may have a financial interest in any entity that has a direct interest in matters before the Board. Such financial interests shall include, but not be limited to, the following:

- a. Owning stocks or other securities in a pharmaceutical corporation (other than through a diversified mutual fund or through a discretionary account, in which an authorized broker buys and sells securities without the approval of the client).
- b. Acting as a consultant for, or being under contract with, a pharmaceutical corporation, regardless of compensation;
- c. Receiving compensation for services from a pharmaceutical corporation (including but not limited to advisory Boards, speaker bureaus, publications);
- d. Holding an advisory position or position of authority with a pharmaceutical corporation, regardless of compensation.
- e. Speaking publicly on behalf of a pharmaceutical corporation, regardless

of compensation;

- f. Accepting a gift or gifts totaling more than \$15 in value from a pharmaceutical company or its representative. Gifts include but are not limited to money, services, loans, travel, lodging, meals, refreshments, and entertainment. Directing a gift to a third party is not permitted. DURB members may accept complimentary attendance, including food or beverage, at an event sponsored by a pharmaceutical company only if all of the following criteria are met:
  - i. the event is a professional development or educational program; and
  - ii. it is not reasonable to infer that the event is intended to influence the DURB member in carrying out his or her DURB duties; and
  - iii. it is not reasonable to infer that acceptance would influence the member in carrying out his or her DURB duties and
  - iv. complimentary attendance and food and beverage are offered to all attendees of the program;
  - v. the member may provide notice to the Chairperson of his or her intent to attend the program in advance of attendance; and
  - vi. the member provides information of all such events prior to each meeting, concurrent with the submission of the DURB Conflict of Interest Statement referenced in Section V(B)(3) of these Bylaws.
- g. The Chairperson reserves the right to prohibit attendance where he or she concludes that attendance would create a conflict of interest or the appearance of a conflict of interest.
- h. Working on a grant paid by a pharmaceutical corporation or participating in clinical trial(s) or grant(s) for which compensation is paid directly to the DURB member by the pharmaceutical corporation. DURB members shall notify the Chairperson of participation in pharmaceutical company-funded clinical trials or grants in which the DURB member is not paid directly by the pharmaceutical corporation.

### 3. Financial Disclosures and Recusal Requirements

Prior to appointment to the DURB, and annually thereafter, members are required to disclose any interest, financial or otherwise, held by the member, his or her spouse/partner and minor children, in any entity that may have a direct interest in matters before the DURB.

At least ten days prior to each meeting, members are required to complete and sign the Medicaid Drug Utilization Review Board Conflicts of Interest Statement, to report any financial or other interests in any drug or the manufacturer of any drug being considered during the meeting, or to certify that he or she has no such interests, and to report any attendance to any events sponsored by a pharmaceutical company in which the member received complementary attendance since the last meeting.

If a conflict of interest or appearance of a conflict of interest arises that is not due to a financial interest held by a DURB member, the member must recuse him or herself from participating in the relevant presentation, discussion and the vote.

The Chairperson has final authority to determine whether and when recusal is required, or whether the conflict of interest can be avoided only by divestiture or resignation from the Board.

A conflict of interest caused by a financial interest held by a DURB member may not be remedied by recusal. The member must either divest himself or herself of the conflicting financial interest within a reasonable time set by the Chairperson or resign from the Board. If a member intends to divest himself or herself of such interest but has not done so before the next DURB meeting, the member may be permitted to recuse himself or herself entirely from one meeting. In no event shall a member be permitted to recuse himself or herself from more than one meeting due to non-divestiture.

If a conflicting financial interest not reported by a member has been reported by a third party, the member may provide information or evidence to the Chairperson, who will determine, consistent with these Bylaws, whether recusal, divestiture or resignation is required.

#### 4. Failure to Disclose

The failure of a member to accurately report a conflicting financial interest, and/or, to recuse himself or herself from a discussion, vote, or meeting when a conflict of interest exists, may result in removal from the DURB.

The Chairperson shall determine whether the member's failure to report a conflicting interest necessitates recusal or removal from the DURB.

A member's failure to resign or divest himself or herself of such interest if so, directed by the Chairperson shall result in removal from the DURB.

The Chairperson shall have ultimate authority to determine, consistent with these Bylaws, whether an interest disclosed by a member gives rise to a conflict of interest and, if so, whether it necessitates recusal, divestiture, or removal from the Board.

### VI. Administration of the Board

#### A. Terms

Each DURB member shall serve for a three-year term. DURB members may be reappointed upon the completion of their terms.

#### B. Resignation

Individual DURB members may voluntarily resign prior to the completion of their term by notifying the Commissioner or his or her designee 90 days prior to their resignation date. If a situation exists in which a member has a financial conflict of

interest in a drug or the manufacturer of any drug being considered during a meeting scheduled less than 90 days from the date on which the conflict is discovered, the resignation of the member may be effectuated before the upcoming meeting.

#### C. Removal from the Board

A member may be removed from the DURB for a knowing and intentional violation of any provision of these Bylaws, or for any other reason at the discretion of the Commissioner.

#### D. Vacancies

Vacancies resulting from a DURB member's resignation, non-renewal, or the completion of term shall be filled, upon appointment by the Commissioner, with candidates who meet the requirements of the membership.

#### E. Staff Support and Cooperation of State Agencies

Department program staff shall be available to assist DURB members. In addition, other clinical and financial specialists as requested by the DURB may be consulted for their professional expertise on an as needed basis. Technical assistance and staff support shall be provided by the Department.

#### F. Reimbursement

Members of the DURB shall receive no compensation but shall be entitled to reimbursement for any necessary travel expenses incurred in connection with the performance of their duties, at levels in accordance with NYS approved amounts for travel expenses including transportation, meals and lodging costs required to attend DURB meetings.

#### G. Amendments to these DURB Bylaws

The Department may propose amendments to these Bylaws to the DURB. Amendments to the Bylaws shall be made when recommended by the DURB and approved by the Commissioner or his or her designee. The Bylaws shall be reviewed at least annually.