



Medicaid Drug Utilization Review Board General Operating Procedures

I. Introduction

The name of this body is Medicaid Drug Utilization Review Board hereinafter referred to as DURB. The purpose and responsibilities of the DURB are established in Social Services Law Title 11-C section 369-BB and Public Health Law Title 1 sections 270, 272, 274 and 280.

II. Purpose

The purpose of the DURB is to provide clinical guidance to the Commissioner regarding the utilization of pharmaceuticals and the evaluation of drug expenditures within the Medicaid program. DURB activities include but are not limited to the following:

- establishment and implementation of medical standards and criteria for the prospective and retrospective DUR program,
- development, selection, application, and assessment of educational interventions for physicians, pharmacists and recipients that improve care
- administration of pharmacy programs including the Preferred Drug Program and the Clinical Drug Review Program.
- evaluation of drugs which may be responsible for exceeding the budgetary drug cap.

III. Composition

DURB members are appointed by the Commissioner and the board consists of twenty-three (23) members.

Fifteen of the members will be clinicians, preferably with experience in at least one of the following specialties: HIV/AIDS, geriatrics, pediatrics, mental health, or internal medicine. The DURB is comprised of the following:

- One (1) chairperson representing the Department of Health
- Six (6) licensed and actively practicing physicians
- Six (6) licensed and actively practicing pharmacists
- One (1) licensed and actively practicing nurse practitioner or midwife
- Two (2) drug utilization review experts, at least one of whom is a pharmacologist

- Three (3) 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
- Two (2) health care economists
- One (1) actuary
- One (1) representative from the NYS Department of Financial Services

IV. Terms

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

V. Resignation

Individual DURB members may voluntarily resign prior to the completion of their term by notifying the Commissioner or his/her designee 90 days prior to their resignation date.

VI. Vacancies

Vacancies resulting from a DURB member's resignation, non-renewal, or the completion of term will be filled, upon appointment by the Commissioner, with candidates that meet the requirements of the membership and preferably representing the same constituency as the former DURB member when applicable.

VII. Responsibilities of the DURB

The DURB is authorized to provide recommendations to the Commissioner of Health. Specific responsibilities are established in Social Services Law Title 11-C section 369-BB and Public Health Law Title 1 sections 270 – 274 and 280 in Section 271 et seq. in Article 2A of Chapter 58 of the Laws of 2005.

The DURB shall make its recommendations to the Commissioner or his/her designee. The Commissioner may, at his or her discretion, consider the DURB's recommendations and advice.

VIII. Staff Support and Cooperation of State Agencies

Department of Health program staff will 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.

IX. Conditions of DURB Membership

DURB members (other than consumer and financial/economic representatives) are required to be New York State licensed practitioners in good standing, with no Medicaid or Medicare sanctions against them.

DURB members will be required to sign on an annual basis, and adhere to, the Medicaid Drug Utilization Review Board Financial Disclosure/Confidentiality Statement that specifies report handling requirements and data confidentiality needs.

DURB members must report all legislative and or lobbying contacts and employment status changes to the Commissioner or his/her designee to avoid any actual conflicts of interest or the appearance of any conflicts of interest.

Any member who contacts, or is contacted by, private industry directly relating to DURB activities, must report these contacts to the Commissioner or his/her designee. Failure to do so may result in removal from the DURB.

X. Meetings

DURB meetings are conducted in Albany, New York.

DURB meetings require a quorum which shall consist of a majority of DURB membership.

DURB meetings will be held as often as necessary to carry out the responsibilities of the DURB.

With prior notice to the Department of Health 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 of Health at least one week in advance of a meeting to be added to the agenda. Individuals granted permission to address the DUR Board will be notified of their inclusion on the public comment list when the list is deemed complete.

The public comment period will 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, the individual may provide a brief written statement.

DURB meetings will convene for up to eight hours per meeting.

The Department shall post the agenda on its web site no later than thirty days prior to the date of a scheduled meeting.

Agenda and supporting documentation will be sent to DURB members at least ten days prior to a scheduled meeting for their review and preparation.

A meeting summary will be prepared by New York State Department of Health program staff.

A meeting summary, including the recommendations of the DURB, will be posted on the Department's website five days prior to any final determination made by the Commissioner.

The Department will post the Commissioner's final determination within ten days of the Commissioner's decision.

XI. Attendance

In accepting appointment to the DURB, members commit themselves to regular attendance at the scheduled meetings. Meeting dates will be scheduled sufficiently in advance to allow for requisite planning and scheduling for attendance by DURB members.

DURB members may consult with medical/clinical peers for their professional expertise on an as needed basis. Substitute members are not permitted.

Members unable to attend a meeting must notify the Commissioner or his/her designee prior to the meeting.

It is expected that a 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 a recommendation to the Commissioner that such member be removed from the DURB. New members will be appointed to fill any vacancies in accordance with the operating procedures.

XII. Rules of Conduct

The DURB meetings will be conducted in keeping with the general precepts of Robert's Rules of Order, recognizing the need for integrating all DURB members' opinions. Members will work cooperatively on mutually agreed upon goals.

The DURB will not present its recommendations as the policy of the State or release information that is made available to members as a result of their participation on the DURB.

XIII. Decision Making

Every DURB member has one vote.

Voting will take place while the meeting is convened.

DURB recommendations should be made by consensus, with recommendations made by simple majority when necessary.

XIV. Conflicts of Interest

DURB members shall not participate in discussions, deliberations or voting on matters where an actual conflict of interest or the appearance of a conflict of interest may exist. DURB members should assess conflict on a case-by-case basis, acknowledge such conflicts and withdraw from participation in matters where the conflict exists. Such instances shall include, but are not limited to, the following:

- When the member is a paid consultant for a manufacturer on a particular drug.
- When the member speaks on behalf of a pharmaceutical manufacturer's product.
- When the member is working on a grant paid by a pharmaceutical manufacturer.
- When the member sits on an advisory committee that renders advice and decisions on a particular drug.
- When the member participates in a drug's clinical trials.

When recusal from voting is warranted, DURB members must refrain from deliberations or debate, expressing opinions, volunteering advice, voting and participating in any way in the recommendation process.

Members should exercise their duties and responsibilities as DURB members in the public interest of the people of the State, regardless of their affiliation with, or relationship to, any facility, agency or program, category of provider, or interest group.

Members should report all conflicts of interest, directly relating to DURB activities, to the Commissioner or his/her designee. Failure to report conflict of interest may result in removal from the DURB.

Code of conduct includes the following:

- 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 duties in the public interest.
- No DURB member should accept employment which will impair his or her independence of judgment in the exercise of his or her official duties.

- No DURB members should accept employment or engage in any business or professional activity which will require him or her to disclose confidential information which he or she has gained because of his or her official duties.
- No DURB member should disclose confidential information acquired by him or her during his or her duties on the DURB nor use such information to further his or her personal interests.
- No DURB member should use or attempt to use his or her official position 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.
- 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.
- 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, or that he or she is affected by the kinship, rank, position or influence of any party or person.
- 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 will otherwise create substantial conflict between his or her duty in the public interest and his or her private interest.
- 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.
- No DURB member employed on a full-time basis 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.

Any member who shall knowingly and intentionally violate any conflict of interest provisions may be removed from the DURB at the discretion of the Commissioner of Health.

XV. Financial Disclosure

Members of the DURB will be required to disclose any financial interest or professional or personal affiliations with any entity that may have a direct interest in matters before the DURB. Members will be required to submit a financial disclosure form (Medicaid Drug Utilization Review Board Financial Disclosure/Confidentiality Statement) to the Department of Health at least annually. This form will be provided to the DURB membership on an annual basis by state staff.

XVI. Reimbursement

Members of the DURB will receive no compensation but will be entitled to reimbursement for any necessary travel expenses incurred in connection with the performance of their duties.

DURB members will be reimbursed by the Department of Health at levels in accordance with NYS approved amounts for travel expenses including transportation, meals and lodging costs required to attend DURB meetings.

XVII. Amendments to the DURB Operating Procedures

Amendments to the DURB operating procedures can be made when recommended by the DURB and approved by the Commissioner or his/her designee. The operating procedures will be reviewed at least annually.

XVIII. Technical Assistance

Technical assistance and staff support will be provided by the Department of Health Office of Health Insurance Programs.