Pharmacy and Therapeutics Committee
General Operating Procedures

I. Introduction

The name of this body is The New York State Department of Health Pharmacy and Therapeutics Committee hereinafter referred to as P&T Committee. The purpose and responsibilities of the P&T are established in Chapter 58, Article 2A, Section 271 et seq. of the Laws of 2005.

II. Purpose

The purpose of the P&T Committee is to make clinical recommendations to the Commissioner of Health on pharmacy issues including but not limited to, the Medicaid Preferred Drug Program and the Clinical Drug Review Program.

III. Composition

Committee members are appointed by the Commissioner and consist of eighteen (18) members.

Fourteen 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 and will be 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
- One (1) pharmacologist or Pharm. D. with an expertise in drug utilization review
- Three (3) members will be 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 EPIC recipients.

IV. Terms

Each Committee member shall serve for a three year term except for the initial appointments, five (5) members shall serve one year terms, seven (7) shall serve two year terms, and five (5) shall serve three year terms.

Committee members may be reappointed upon the completion of their terms.

V. Resignation

Individual Committee 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 the acceptance of resignation, non-renewal or the completion of term of a non-clinical Committee member, will be filled, upon appointment by the Commissioner, with candidates preferably representing the same constituency as the former Committee member.

VII. Responsibilities of the Committee

The Committee is authorized to provide recommendations to the Commissioner of Health including, but not limited to, the adoption of a preferred drug program and clinical drug review program. Specific program responsibilities are established in Section 271 et seq. in Article 2A of Chapter 58 of the Laws of 2005.

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

VIII. Staff Support and Cooperation of State Agencies

Department of Health program staff will be available to assist Committee members. In addition, other specialty physicians, pharmacists, and nurses, as requested by the Committee, may be consulted for their professional expertise on an as needed basis.

IX. Conditions of Committee Membership

Committee members are required to be New York State licensed practitioners in good standing, with no Medicaid or Medicare sanctions against them.

Committee members will be required to sign on an annual basis, and adhere to, a confidentiality agreement specifying report handling requirements and data confidentiality needs.

Committee 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 Committee activities, must report these contacts to the Commissioner or his/her designee. Failure to do so may result in removal from the Committee.

X. Meetings

Committee meetings will be held in Albany.

Committee meetings will require a quorum which shall consist of a majority of the Committee members.

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

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 Committee during a public comment segment of the meeting on any item under consideration by the Committee.

Individuals interested in providing public comments to the Committee must notify the Department of Health at least 1 week in advance of a meeting to be added to the agenda.

The public comment period will be at the beginning of the meeting. Up to ninety minutes will be devoted to public comments on issues to be considered by the Committee. 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.

Committee meetings will convene for up to six 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 Committee members at least ten days prior to a scheduled meeting for their review and preparation.

A meeting summary will be prepared by State staff.

A meeting summary, including the recommendations of the Committee, 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 Committee, 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 Committee members.

Committee 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.

Should a member of the Committee fail to attend three quarters of scheduled Committee meetings within the calendar year, the Committee shall recommend to the Commissioner that such member be removed from the Committee. A new member will be appointed to fill the vacancy in accordance with these operating procedures.

XII. Rules of Conduct

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

The Committee 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 Committee.

XIII. Decision Making

Every Committee member has one vote.

Voting will take place while the meeting is convened.

Committee decisions should be made by consensus, with decisions made by simple majority when necessary.

XIV. Conflicts of Interest

Committee 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. Committee 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, Committee members must refrain from deliberations or debate, making recommendations, volunteering advice, voting and participating in any way in the decision making process.

Members should exercise their duties and responsibilities as Committee 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 Committee activities, to the Commissioner or his/her designee. Failure to report conflict of interest may result in removal from the Committee.

Code of conduct includes the following:

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

- No Committee 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 by reason of his or her official duties.

- No Committee member should disclose confidential information acquired by him or her in the course of his or her duties on the Committee nor use such information to further his or her personal interests.

- No Committee 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 Committee 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 Committee 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 Committee 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 Committee 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 Committee member employed on a full-time basis nor any firm or association of which such person is a member nor corporation a substantial portion of the stock of which 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 Committee member serves or is employed.

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

XV. Financial Disclosure

Members of the Committee 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 Committee. Members will be required to submit a Financial Disclosure Form (PDF, 82KB, 2pg) to the Department of Health at least annually.

XVI. Reimbursement

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

Committee 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 Committee meetings.

XVII. Amendments to the Committee Operating Procedures

Amendments to the Committee operating procedures can be made when recommended by the Committee and approved by the Commissioner or his/her designee. These 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.