BYLAWS OF THE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE

LEGAL MANDATE

The Pharmaceutical and Therapeutics Committee ("P&T Committee" or the "Committee") for the Connecticut Medical Assistance Program is established pursuant to the authority of subsection (a) of section 17b-274d of the Connecticut General Statutes.

DEFINITIONS AND ABBREVIATIONS

CMS means the Centers for Medicare & Medicaid Services of the United States Department of Health and Human Services.

Connecticut Medical Assistance Program ("CMAP") means the Connecticut Medicaid program administered pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, and section 17b-261 of the Connecticut General Statutes.

Department or DSS means the State of Connecticut, Department of Social Services.

Member means a member of the Pharmaceutical and Therapeutics Committee.

P&T Contractor means the entity selected by the Department to administer the P&T Committee and the Preferred Drug List ("PDL"), pursuant to section 17b-274d of the Connecticut General Statutes.

A potential conflict of interest exists if the member, in the discharge of his or her duties on the Committee, would be asked to take an action that would affect the financial interest of the member or the member's spouse, parent, brother, sister, child or the spouse of a child or a business with which the member is associated, unless the interest is de minimis in nature (under $100.00) or the interest is indistinct from that of a substantial segment of the general public.

Preferred drug list ("PDL") means a list of medications, within the classes of medications reviewed by the Committee, that are available without prior authorization.

A substantial conflict of interest exists when a member has reason to believe or expect that an action taken would directly affect the member's financial interests (the member will derive a direct monetary gain or suffer a direct monetary loss) or those of the member's spouse, dependent child, or business with which the member is associated and would do so in a way that is distinctly different from its effect on other persons in the same profession, occupation or group.

PURPOSE OF P&T COMMITTEE

The purpose of the P&T Committee is to serve in an advisory capacity in order to assist the

Department in the development of PDL(s) and the selection of drugs to be included on the PDL(s). The Committee may also make recommendations to the Department regarding the prior authorization of any prescribed drug, and which prescribed drugs, if any, should be eligible for automatic refill.

COMPOSITION AND MEMBERSHIP

Members of the P&T Committee are appointed by the Governor. There are sixteen (16) Members as follows: Seven (7) members shall be physicians licensed pursuant to Chapter 370 of the Connecticut General Statutes, including one (1) general practitioner, one (1) pediatrician, one (1) geriatrician, one (1) psychiatrist, one (1) child psychiatrist, one (1) oncologist, and one (1) specialist in family planning; four (4) members shall be pharmacists licensed pursuant to Chapter 400j of the Connecticut General Statutes; two (2) members shall be visiting nurses, one (1) specializing in adult care and one (1) specializing in psychiatric care; one (1) member shall be a clinician designated by the Commissioner of Mental Health and Addiction Services; one (1) member shall be a representative of a pharmaceutical manufacturer; and one (1) member shall be a consumer representative.

Physicians and pharmacists who are Members of the Committee must have experience serving the Medicaid population. Physicians on the Committee, except for the representative of a pharmaceutical manufacturer and the clinician designated by the Commissioner of Mental Health and Addiction Services, if they are physicians, must be enrolled in CMAP. In addition, Committee Members, except for the consumer representative, must have recognized knowledge and expertise in prescribing, dispensing, and/or monitoring the use of prescription drugs used by individuals on an outpatient basis.

The Committee Member who is representative of a pharmaceutical manufacturer shall be a non-voting Member of the Committee.

TERMS OF MEMBERSHIP

Terms of membership will be two years from the date of appointment. Members may be appointed for additional terms.

RESIGNATION, REMOVAL AND REPLACEMENT

1. A Member of the P&T Committee may resign by providing written notice to the Committee Chairperson and the Department.

2. Any Member of the P&T Committee may be removed by the Chairperson for good cause. Good cause shall include at least one of the following:

    - Nonattendance – If a member has two consecutive, unexcused absences from meetings, the Chairperson may send the member a formal notice that his or her continuing participation on the P&T Committee is in jeopardy. If there is

a third consecutive, unexcused absence, the member may be removed from the Committee.

- A Member has been disciplined by his or her licensure board resulting in a suspension or restriction of his or her professional license since the date of appointment.

- A Member does not comply with the Conflict of Interest provisions in these Bylaws.

- Failure to meet eligibility requirements for Committee membership.

3. In the case of a vacancy created by death, resignation or removal of a Member due to good cause, the Chairperson of the P&T Committee shall notify DSS of such vacancy. DSS will inform the Governor's office of the vacancy and request the appointment of an individual representing the same profession as the person who will no longer be on the P&T Committee to serve the remainder of that particular term. Such individual shall be eligible to serve an additional two-year term, which would begin at the expiration of the term currently being served.

MEMBERS' RESPONSIBILITIES

Members of the P&T Committee shall:

1. Attend all P&T Committee meetings, unless otherwise excused by the Chairperson or Vice-Chairperson.

2. Apply knowledge of current best clinical practice to the development and review of pharmaceutical and medical criteria, CMAP medication utilization trends, evidence-based medical standards, special medication or formulation availability needs for special populations (i.e. liquid formulations for young children), and educational intervention methods when making recommendations to the Department concerning (a) the establishment of one or more PDLs; (b) which prescribed drugs to include in the PDL or PDLs; and (c) prior authorization policies and procedures for prescribed drugs covered by CMAP.

3. Make recommendations to the Department, as necessary and appropriate, regarding prior authorization policies and procedures for any prescribed drug covered by CMAP.

4. Maintain confidentiality of information that is protected by law as confidential, including, but not limited to, any financial, cost, or market analyses that may be presented to the Committee and information disclosed by manufacturers or wholesalers in a form that discloses the identity of a specific manufacturer or prices charged for drugs by such manufacturer.

5. Comply with the following conflict of interest provisions:

- To ensure the Committee will operate in a manner that protects the objectivity and credibility of its recommendations, each Committee member shall, at the beginning of the Member's term and annually, sign an agreement that he or she will disclose to the Chairperson of the Committee and the Department all potential and substantial conflicts of interest as they may arise. (Attachment A). Each Committee member has an ongoing duty to disclose any potential or substantial conflicts of interest to the Chairperson and the Department.

- If a matter poses a substantial conflict of interest to a member, the Member shall recuse himself or herself and shall not participate in the matter. The Member shall leave the room and not participate in deliberations or debates and will not make recommendations, give advice or in any way assume responsibility for or participate in any aspect of decision-making, whether inside or outside of formal meetings, relating to the matter(s) that pose a substantial conflict of interest concerning matter(s) for which the Member is recused. (Attachment B).

- For matters that pose a potential conflict of interest, the Member may either recuse himself or herself or prepare a written statement describing the matter requiring action, the nature of the potential conflict, and explaining why, despite the potential conflict, he or she can vote and otherwise participate fairly, objectively, and in the public interest. The Committee Chairperson shall determine whether the Member may participate in the matter or must recuse himself or herself due to the potential conflict. (Attachment B).

6. Comply with all applicable state and federal statutes and regulations.

COMMITTEE OFFICERS AND ELECTIONS

There shall be a Chairperson and Vice Chairperson of the Committee. They are elected by the Members of the Committee on an annual basis.

Election of the Chairperson and Vice Chairperson

The P&T Committee Members shall, on an annual basis, elect a Chairperson and Vice-Chairperson from the Committee membership. The election will take place at the first P&T Committee meeting of each calendar year. If a quorum is not present at that meeting, the election will take place at the next meeting at which a quorum is present. The terms of office for these positions are one year, and members may serve a maximum of three (3) terms. The Chairperson and Vice Chairperson shall serve until replaced by election.

Election Procedures

Nominations will be accepted from the floor by the serving Chairperson. Voting for the Officers

will be done by written ballot or by a show of hands of the Members. If a Member is nominated by a majority of the Members, then that Member is elected to that office. If there are several nominees and no one Member is nominated by a majority of the Members, the nominee who received the lowest number of votes is dropped, and the Members vote from the remaining nominees. This procedure is repeated until a nominee receives a majority of the votes.

Responsibility of the Chairperson

The Chairperson shall:

1. Provide leadership for the Committee at Committee meetings.

2. Consider the views and opinions of all Members of the Committee, and strive to maintain an atmosphere at Committee meetings that encourages Members to express their views freely.

3. Confer with the P&T Contractor and the Department when planning and organizing P&T Committee activities, including but not limited to:

    a. Preparing the agenda for each P&T Committee meeting;

    b. Establishing meeting dates and calling meetings;

    c. Canceling and rescheduling meetings, as necessary; and

    d. Establishing ad hoc committees.

4. Appoint P&T Committee Members to serve on ad hoc committees.

5. In consultation with, and as agreed to by the Department, act as P&T Committee spokesperson and respond to inquiries from the public and the media concerning the activities of the P&T Committee.

6. Accept information and materials from interested individuals and manufacturers concerning the establishment of the PDL and which drugs, if any should be eligible for automatic refill and, as appropriate, disseminate such information and materials to P&T Committee Members.

Responsibilities of the Vice-Chairperson

The Vice-Chairperson shall perform the same functions as the Chairperson, at the request or in the absence of, the Chairperson.

RESPONSIBILITIES OF THE P&T CONTRACTOR

The P&T Contractor will provide support for, and coordinate the activities of, the P&T

Committee. More specifically, the P&T Contractor shall:

1. Establish and maintain effective working relationships with P&T Committee Members;

2. Consider the views, opinions and needs of the Committee membership;

3. Coordinate activities of the ad hoc committees and the P&T Committee, as necessary and appropriate;

4. Act as a liaison between Members of the P&T Committee and the Department;

5. Confer with the P&T Committee Chairperson and the Department in planning, organizing and conducting P&T Committee business, including, but not limited to, as follows:

    a. Prepare a yearly schedule for regular meetings and post the meeting schedule on the Department's Internet website. The Department will file the schedule with the Secretary of the State;

    b. Prepare agenda and support materials for each P&T Committee meeting;

    c. File a copy of the agenda, including notice of the time and place of the Committee meeting in Department's regular office or place of business not less than twenty-four (24) hours before the meeting. The Department will file the agenda with the Secretary of the State;

    d. Post the notices of special meetings (meetings other than regular meetings on the yearly schedule), including time and place, on the Department's Internet website not less than that twenty-four (24) hours prior to the meeting. The Department will file notices with the Secretary of the State;

    e. Prepare and distribute information and materials for use by the P&T Committee Members at meetings;

    d. Maintain P&T Committee records;

    e. Arrange meetings and meeting sites for P&T Committee meetings;

    f. Record the votes of each Committee member and make the writing available to the public for inspection within forty-eight (48) hours and record the votes in the meeting minutes.

    g. Prepare minutes following every P&T Committee meeting. The minutes of the meeting shall be available for public inspection and posted on the Department's Internet website not later than seven (7) days after the meeting date to which the

minutes refer. The meeting minutes shall include a record of all votes taken at the meeting.

h. Send copies of minutes to Members of the P&T Committee, the Department, and other interested individuals who have expressed an interest in receiving copies of the minutes;

i. Maintain tracking report of recommendations made, actions taken and issues raised by the Committee;

j. As requested, inform the Committee of the status of recommendations made by the Committee.

AD HOC COMMITTEES

The Chairperson may designate members to serve on Ad Hoc Committees for the purpose of addressing a particular issue or concern. Appointments to such Ad Hoc Committees shall be subject to review and approval by the Department. Ad Hoc Committees shall be disbanded upon their completion.

NON-MEMBERS

Staff of the Department's Pharmacy Unit and the Department's Medical Director, although not members of the P&T Committee may participate in discussions of the P&T Committee. Other non-members of the Committee in attendance at P&T Committee meetings may not participate in discussions of the P & T Committee, except as otherwise permitted in advance or as permitted by the Chairperson.

FREQUENCY OF MEETINGS

The P&T Committee shall meet at least biannually, and may meet at other times at the discretion of the Chairperson and the Committee members. Unless otherwise scheduled in advance, the date of the next meeting of the Committee will be decided at the end of the meeting prior to it.

OPERATIONAL PROCEDURES

Meetings will be conducted in accordance with Robert's Rules of Order.

There must be a quorum of the P&T Committee present in order for the Committee to conduct business. If less than a quorum of the P&T Committee is present, there shall be no meeting. For purposes of the P&T Committee, a quorum is met if a majority of the current voting members are present at the meeting.

As long as there is a quorum, a majority vote of the voting members present shall be the act of the P&T Committee. For purposes of acting on a particular matter requiring a vote, if a Member of the Committee recuses himself or herself from participation in and voting on a

matter due to a conflict of interest, that Member is not counted when determining whether a quorum exists.

PUBLIC PARTICIPATION

At P&T Committee meetings, the Committee will provide an opportunity for pharmaceutical manufacturers agreeing to provide supplemental rebates pursuant to 42 U.S.C. § 1396r-8(c) to present evidence supporting inclusion of a product on the CMAP PDL. Members of the public also have the opportunity to address the P&T Committee on matters relevant to its agenda items.

The following guidelines will apply to all public testimony:

1. Speakers must submit a written document to the Committee at least two weeks prior to the meeting at which they wish to speak, outlining the subject matter they wish to cover. The document may not be more than ten (10) pages and the font must not be smaller than twelve (12) point.

2. The Chairperson or Vice-Chairperson will decide which speakers may present at the next meeting. The chosen speakers will be notified at least one (1) week prior to the Committee meeting at which they will present. Speakers will be strongly encouraged to present information only if it adds to or amplifies the written materials already submitted to committee members, rather than simply summarizing or repeating the materials.

3. Public comment will occur by class of drug and before the Committee votes on drugs to be included on the PDL.

4. At the discretion of the Chairperson or Vice-Chairperson, speakers' presentations are limited to a maximum of **two (2)** minutes. Questioning by Committee members after speakers' presentations shall be permitted or limited at the discretion of the Chairperson.

5. Speakers will state their names and identify the company, group or organization they represent, and only one speaker per company, group or organization will be permitted.

AMENDMENT OF BYLAWS

Proposed amendments to the P&T Committee's Bylaws will be adopted upon a majority vote. At the discretion of the Chairperson, proposed amendments to the Bylaws may be presented at one meeting and voted upon at the next meeting.