# Executive Office of Health & Human Services

## Pharmacy & Therapeutics Committee By-Laws

Rhode Island Fee for Service Medicaid Program

Pharmacy & Therapeutics Committee

By-Laws

*November 2006*
*December 2007*
*June 2015*

**Article I - POLICY**

Section 1

The Rhode Island Medicaid Fee for Service (FFS) Program Pharmacy & Therapeutics (P&T) Committee was created pursuant to RIGL 40-21-1 to develop and review the Preferred Drug List (PDL) and associated utilization protocols. Determinations of drugs included on the PDL will be made by the State Department of Human Services, and a listing of such drugs shall be maintained on a public website. In making these determinations, the Department shall consider the recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, whose membership shall include practicing pharmacists and physicians, faculty members of the University of Rhode Island's College of Pharmacy, and consumers or consumer representatives. Drugs except from the PDL shall include: (1) anti-retrovirals; and (2) organ transplant medications. Physicians will be informed about prior authorization procedures for medications not on the PDL, and seventy-two (72) hour emergency supplies may be dispensed if authorizations cannot be obtained.

**Article II - PURPOSE**

Section I - Duties

The P&T Committee will act as an advisory committee to the Medicaid Program for the PDL. The Committee will recommend a Preferred Drug List (PDL) that promotes the use of safe and effective Food and Drug Administration (FDA) - approved medications. The Committee will ensure that the PDL is based on sound clinical evidence that is both safe and cost-effective.

Section II - Process

The P&T Committee is a standing committee that will report its' activities and recommendations to the Department. It is an advisory committee for the Rhode Island Medicaid Program, designed to ensure unbiased clinical perspective in areas such as drug evaluations and utilization protocols.

The P&T Committee will review new and existing therapies using criteria established for efficacy, safety, and quality. Following this evaluation, cost factors will be included in the final determination regarding PDL recommended status. The Committee may also establish recommendations on the appropriate utilization protocols for individual medications or for therapeutic categories. These protocols may include, but are not limited to prior authorization, automated prior authorization and guidelines, quantity limits and other utilization management tools.

## Article III - MEMBERSHIP

Section I - Appointment

The P&T Committee will consist of a minimum of eight and not more than fifteen voting members and the Chairperson who will be a non-voting member, except in the event of a tie vote. The voting and non-voting members will include practicing pharmacists and physicians, faculty members of the University of Rhode Island College of Pharmacy and consumers or consumer representatives

When the P&T Committee addresses certain therapies or drug classes, other ad hoc medical specialists or consultants may be invited to provide subject matter expertise. Ad hoc medical specialists are not voting members of the Committee.

All professional members shall hold an active license under Rhode Island law in their respective fields. The members will be chosen by specialty, board certification, prior P&T experience, state residency, experience treating Medicaid Recipients, absence of conflicts of interest, ability to represent a broad base of constituents, and number of years in practice.

Section II - Term

Each P&T Committee member is appointed by the Secretary of the Executive Office of Health and Human Services for a three-year term and may be reappointed to successive three-year terms. Appointments shall be staggered.

Section III - Officers

The Chairperson and Vice Chairperson will be nominated and elected by the Committee annually. The Vice-Chairperson will take the place of the Chairperson upon his or her absence or request or recusal.

Section IV - Responsibilities

Each P&T Committee member is expected to attend all Committee meetings, unless otherwise excused by the Chairperson.

P & T Committee members must complete a Disclosure of Interest Form annually and provide updated information as necessary. No member shall meet or discuss with manufacturer representatives any drug or drug-related information to be presented at P&T deliberations. If any member has had prior discussions with a manufacturer's representative related to a company's product, the member shall recuse him/herself from deliberating or voting on that manufacturer's product.

Section V - Termination and Resignation

The Secretary may dismiss a P&T Committee member for cause. Termination may result due to non-disclosure of a conflict of interest, participating in wrongdoing, misconduct or non-excused attendance while a member of the Committee.

A P&T Committee member may resign by submitting a written notice to the Chairperson. The Chairperson may resign by submitting a written notice to the Secretary.

## Article IV - MEETINGS

Section I - Frequency

The P&T Committee will meet four (4) times a year. Additional meetings may be called by the Chairperson or Committee at any time.

Section II - Procedure

Quarterly P&T Committee meetings will be subject to the provisions of the Open Meetings Law, RIGL 42-46-1 et al.

Registration shall occur on the day of the meeting. At the entrance to the meeting room a sign-in sheet will be provided and any representatives from the public are invited to attend. Seating is not reserved and will be on an as-available basis.

The Department shall post on the RI Secretary of State and EOHHS Web site the final agenda at least 48 hours prior to the meeting. In the case of a supplemental meeting, the agenda will be posted at least 48 hours prior to the meeting.

Public and written testimony shall be considered part of the public record and made available upon request.

The minutes from each meeting will be posted for public view in accordance with the Open Meeting Laws. Minutes will include vote totals.

## Article V - QUORUM

The presence of 51 percent or more of P&T Committee members will be considered a quorum. The quorum must be maintained throughout the meeting. A simple majority will determine the P&T Committee's recommendation, and any ties will be broken by the Chairperson.

## Article VI - PUBLIC PARTICIPATION

Section I - Public Testimony Registration

1. Registration will occur the day of the meeting
2. It will be on a first-come, first-serve basis on the day of the meeting. The speaker must be present to register.
3. The registered speaker must identify the drug or topic that will be the subject of their testimony as part of the registration.
4. Public testimony is limited to the agenda items.
5. Registrants who prefer to provide testimony in writing only may do so and will be instructed to bring hard copies of the written testimony (specifications in the next section) to the meeting for distribution to all P&T Committee members.
6. Once the meeting has started, registration will be closed to additional speakers.

Section II - Public Testimony Guidelines

1. Each company, pharmaceutical manufacturer, organization or group will have one (1) opportunity to speak.
2. Each testimony will be a maximum of four (4) minutes long. Multiple speakers representing a company, pharmaceutical manufacturer or organization will be permitted; however the total time shall not exceed four (4) minutes.
3. Each speaker must share their name, title, organization, city of business and disclose if a drug manufacturer requested them to appear and testify and state whether in a paid or unpaid capacity, or if the speaker was in any way funded, including but not limited to direct compensation, consultation fees, personal or work related grant recipient to provide testimony. Written testimony must also include this information.

4. Materials will be restricted to one (1), 8 ½ X 11 inch, single-sided page of bulleted information, New times roman font size 12 and double spaced Materials which do not comply to this format or testimony to drugs not on the agenda, will not be distributed to the committee.
5. No audiovisual equipment can be used.
6. Only committee members may ask questions of speakers.
7. No clinical submissions by manufacturers, companies, or organizations such as, but not limited to, package inserts, will be accepted in advance of the meeting for inclusion in the P&T Committee members' information packets or distributed during the meeting.

Section IV - Public Resources

The EOHHS Web site will exhibit information for public view. The pharmacy section of the EOHHS website will include the following P&T related items: P&T Committee member list, the meeting agendas and minutes, P&T bylaws and the working PDL.

**Article VII - DISCLOSURE OF INTEREST**

Members of the Committee will be required to submit Disclosure of Interest Forms and will have an ongoing duty to disclose any interests that develop after completion of the form.

If a member has an interest that may affect or be perceived to affect the member's independence of judgment, the member must recuse himself/herself from the voting process for the drug class concerned. This recusal includes but is not limited to refraining from deliberation or debate, making recommendations, volunteering advice and/or participating in the decision-making process in any way.

The Chairperson will review the criteria that P & T members should use to determine whether to recuse themselves from the voting process at the beginning of each meeting and ask whether any members need to recuse themselves from consideration of a particular drug or class of drugs.

**Article VIII - AMENDMENT OF BY-LAWS**

Recommendation of amendment(s) to the by-laws may be made at any meeting of the Committee by a vote of simple majority of the members present after establishment of a quorum has been established, provided that written notice of the proposed amendment(s) is made available to EOHHS and the members at least 10 (ten) business days prior to the meeting. These recommendations will then be submitted to EOHHS for final approval.