Pharmacy & Therapeutics Committee By-Laws

PENNSYLVANIA Department of Human Services
Pharmacy & Therapeutics Committee
By-Laws

Article I - POLICY

Section 1

The Pennsylvania Department of Human Services (DHS) Pharmacy & Therapeutics (P&T) Committee will monitor the pharmacy management system on behalf of the enrolled health care providers and recipients of the Medical Assistance (MA) Program. The working document of the pharmacy management system is the Preferred Drug List (PDL), inclusive of any applicable utilization protocols.

Article II - PURPOSE

Section I - Duties

The P&T Committee will act as an advisory board to DHS for pharmacy management issues. 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 pharmacy management 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 all activities and recommendations to the Department. It is an advisory committee for DHS, 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 will establish recommendations regarding PDL status of brand and generic products for coverage under the prescription drug benefit. The Committee will also establish recommendations on the appropriate utilization protocols for individual medications or for therapeutic categories. These protocols include, but are not limited to prior authorization, automated prior authorization, system edits and guidelines, generic substitution programs, quantity limits and other utilization management tools.

Article III - MEMBERSHIP

Section I - Appointment

The P&T Committee will consist of a minimum of 15 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 the following:

A. External members

- One Family Physician
- One Certified Registered Nurse Practitioner
- One Internist
- One Pediatrician
- One Psychiatrist
- One Retail Pharmacist
- One Hospital or Academic Pharmacist
- One Physician or Pharmacist from each of the three managed care zones
- One Physician or Pharmacist, and/or one Consumer nominated by and representing Office of Medical Assistance Programs (OMAP) Consumers
- One Physician or Pharmacist, and/or one Consumer or Family Member nominated by and representing Office of Mental Health and Substance Abuse Services (OMHSAS) Consumers

B. Internal DHS members

- The Office of Medical Assistance Programs Chief Medical Officer
- The Office of Mental Health Substance Abuse Services Chief Medical Officer
- The OMAP Pharmacy Director (Chairperson with tie breaking vote only)

When the P&T Committee addresses certain therapies or drug classes, other ad hoc medical specialists or consultants may be added. The Department shall disclose any ad hoc medical specialists 10 days prior to the P&T Committee meeting.

All professional members shall be licensed under Pennsylvania law in their respective fields. The members will be chosen by specialty, board certification, prior P&T experience, state residency, experience treating Medical Assistance 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 Public Welfare for a two-year term after which each member will come up for review and new members may be considered. Members may serve an unlimited number of terms.

Section III - Officers

The Chairperson will be the OMAP Pharmacy Director.

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

Section IV - Responsibilities

Each P&T Committee member is expected to attend all Committee meetings, unless otherwise excused by the Chairperson. If a P&T Committee member is unable to attend a Committee meeting in person, the member will be permitted to participate via teleconference at the discretion of the Chairperson.

P&T Committee members are expected to volunteer and apply their knowledge of current clinical practice during discussion. Matters discussed during executive sessions must remain confidential.

P & T Committee members must complete a Disclosure of Interest Forms and provide updated information prior to each meeting.

Section V – Termination and Resignation

The Chairperson will be the Director of the Division of Pharmacy for the Department of Human Services.

A Vice-Chairperson will be nominated and elected by the Committee at the first meeting of the P&T Committee. The Vice-Chairperson will take the place of the Chairperson upon their absence or request.

Section V - Termination and Resignation

The Secretary may dismiss a P&T Committee member. Termination may result due to not disclosing a conflict of interest, participating in wrongdoing or misconduct 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 semi-annually. Additional meetings may be called by the Chairperson or Committee at any time.

Section II - Procedure

Semi-annual P&T Committee meetings will be subject to the provisions of the Pennsylvania Sunshine Act 65 Pa.C.S.A.§ 701 et.seq.

Public notice of the meeting will be published approximately 60 days prior to the date 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 P&T Committee members will be given a copy of the final agenda and meeting materials at least 10 days prior to the meeting.

The Department shall post on the Web site the final agenda and list of approved speakers at least 10 days 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 pubic view within 30 days of the date of the meeting at which the minutes are approved. Minutes will include vote totals.

Article V - QUORUM

The presence of 50 percent or more of P&T Committee members will be considered a quorum. 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. The registration for testimony must be received at least 14 days before the meeting. The registration form is interactive and when submitted will go directly to the Committee Chairperson.
2. Registration will occur on a first-come, first-serve basis.
3. The registered speaker must identify the drug that will be the subject of the testimony as part of registration.
4. Registrants who prefer to provide testimony in writing only may do so and will be instructed to bring hard copies of the written testimony to the meeting for distribution to all P&T Committee members.
5. Manufacturers that produce products in multiple drug classes may register to testify on each class of drugs.
6. Only one manufacturer representative can testify (orally or in writing) per product. If more than one manufacturer representative registers for testimony on the same

product, the first registered will be allowed to testify or present written testimony and the other(s) will be declined.

Section II - Public Testimony Guidelines

1. Each testimony will be a maximum of two minutes long.
2. Each speaker must share their name, title, organization, city of business and disclose if a drug manufacturer requested them to appear and testify in a paid or unpaid capacity. Written testimony must also include this information.
3. Each speaker must provide a hard copy of the testimony at meeting sign-in and may distribute copies to the P&T Committee members at the time of testimony. Copies of written testimony should also be provided at meeting sign-in.
4. Materials will be restricted to one (1), 8 ½ X 11 inch, single-sided page of bulleted information.
5. No audiovisual equipment can be used.
6. There will be no question and answer period.
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 III - Public Testimony Procedures

1. At meeting sign-in, registered speakers will be informed of the recommended designation of the drug that they are interested in and given the opportunity to defer testimony when the recommendation is "preferred."
2. Reviews will be completed on a class by class basis.
3. After an overview of the drug monograph for a specific class of drugs, registered speakers who did not defer their testimony will testify.
4. If the final vote of the P&T Committee is different from the original recommendation and the final recommendation is "non-preferred," registered speakers who deferred testimony will be given the opportunity to provide their testimony.

Section IV - Public Resources

The DHS Web site will exhibit information for public view. The Web site will include the P&T Committee member list, the meeting minutes, the meeting agendas, and the working PDL. Testimony registration information will also be available on the Web site. The Web site also includes all policies and regulations that govern pharmacy services in the Medical Assistance Program, Medical Assistance Bulletins and provider handbooks, including the Prior Authorization of Pharmacy Services Handbook.

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

Amendments to the By-Laws of the P&T Committee may be decided by majority vote at any P&T Committee meeting. Any proposed amendments must be submitted prior to the meeting and included in the agenda of the meeting during which the vote will be taken.

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