# PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
# Office of Medical Assistance Programs
# Pharmacy & Therapeutics Committee By-Laws

## Article I - POLICY

The Pennsylvania Department of Human Services ("department") Pharmacy and Therapeutics (P&T) Committee advises the department on behalf of the enrolled health care providers and beneficiaries of the Medical Assistance (MA) Program. The working document is the Preferred Drug List (PDL), inclusive of any applicable utilization protocols.

## Article II - PURPOSE

Section I - Duties

The P&T Committee will act in an advisory role to the department. The P&T Committee will recommend a PDL that promotes the use of safe and effective Food and Drug Administration (FDA) approved medications and certain non-drug products. The P&T Committee will ensure that PDL management is based on sound clinical evidence and 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 designed to ensure unbiased clinical perspective in areas such as product 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 statuses. The P&T Committee will make recommendations regarding preferred and non-preferred statuses for brand and generic products included in the PDL. The P&T Committee will also make recommendations on the appropriate utilization protocols for individual medications or for therapeutic classes. These protocols include but are not limited to 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 fifteen (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

1. One (1) family physician
2. One (1) certified registered nurse practitioner
3. One (1) internist
4. One (1) pediatrician
5. One (1) psychiatrist

6. One (1) retail pharmacist
7. One (1) hospital or academic pharmacist
8. One (1) physician or pharmacist from each MA managed care organization
9. One (1) physician or pharmacist and/or one (1) consumer nominated by and representing physical health managed care consumers
10. One (1) physician or pharmacist and/or one (1) consumer or family member nominated by and representing behavioral health managed care consumers

B. Internal Department Members

11. The Chief Medical Officer
12. The Chief Psychiatric Officer
13. The 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.

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 MA beneficiaries, 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 department's secretary for a two (2)-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 department's pharmacy director.

The vice-chairperson will be nominated and elected by the P&T Committee. The vice-chairperson will take the place of the chairperson upon their absence or request.

Section IV - Responsibilities

Each P&T Committee member is expected to attend all P&T Committee meetings unless otherwise excused by 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 form and confidentiality statement prior to each meeting.

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 or participating in wrongdoing or misconduct while a member of the P&T 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 annually. Additional meetings may be called by the chairperson or P&T Committee at any time.

Section II - Procedure

The P&T Committee meetings will be subject to the provisions of the Pennsylvania Sunshine Act, 65 Pa.C.S. §§ 701-716.

Representatives from the public are invited to attend. Seating for in-person meetings 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 ten (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 on the department's website for public view within 30 days of the date of the meeting at which the minutes are approved.

**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 will go directly to the department when submitted. Instructions for registering for public testimony are available on the department's website.
2. Registration will occur on a first-come, first-serve basis.
3. The registrant must identify the product, or therapeutic class that will be the subject of the testimony as part of registration.
4. Registrants may provide testimony for multiple products.
5. Only one manufacturer representative may testify per product. If more than one manufacturer representative registers for testimony on the same product, the first registered manufacturer representative will be allowed to testify or submit written testimony, and the other(s) will be declined.

Section II – Public Testimony Guidelines

1. Each spoken testimony will be a maximum of two (2) minutes long.
2. Each speaker must share their name, title, organization, and city of business and disclose if a manufacturer requested them to appear and testify in a paid or unpaid capacity. Written testimony must also include this information.
3. Written materials will be restricted to one (1), 8 ½ X 11 inch, single-sided page of bulleted information.
4. There will be no question-and-answer period.

Section III – Public Testimony Procedures

1. Registered speakers will be informed of the recommended PDL status of the product that they are representing 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 each therapeutic class, registered speakers who did not defer their testimony may testify.
4. If the final vote of the P&T Committee is for a PDL status that 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 spoken testimony.

Section IV - Public Resources

The department's website will exhibit information pertaining to the P&T Committee for public view. The website will include the P&T Committee member list, meeting minutes, meeting agendas, and PDL. Testimony registration information will also be available on the website. The website also includes all policies and regulations that govern pharmacy services in the MA Program, MA Bulletins, and prior authorization clinical guidelines.

**Article VII - DISCLOSURE OF INTEREST**

Members of the P&T Committee will be required to submit a disclosure of interest form 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 themself from the voting process for the therapeutic 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 product or therapeutic class.

**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.