

**Colorado
Pharmacy and Therapeutics (P&T)
Committee
Policies and Procedures**



CO L O R A D O

**Department of Health Care
Policy & Financing**

Our mission is to improve health care access and outcomes for the people we serve while demonstrating sound stewardship of financial resources.

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Colorado Medicaid Pharmacy and Therapeutics Committee Policies and Procedures

Mission

To serve as an advisory board to the Colorado Health Care Policy and Financing (Department) Medical Assistance Program, perform reviews and make recommendations which facilitate the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.

Administration

Administrative coordination of the Pharmacy and Therapeutics (P&T) Committee is performed by a PDL support vendor, as designated by the Department or by the Department itself.

Duties

The P&T Committee shall, among other things:

1. Review drugs or drug classes selected by the Department.
2. Consider drug safety and efficacy and other review criteria requested by the Department.
3. Make clinical recommendations on drugs or drug classes.
4. Perform any other act requested by the Department necessary for the development and maintenance of the Preferred Drug List as described in 10 C.C.R. 2505-10, Section 8.800.
5. Meet at least quarterly at the discretion of the Department or the P&T Committee.

Membership

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- A. The P&T Committee shall consist of a minimum of nine Committee members, but no more than thirteen members, appointed by the Executive Director of the Department. The P&T Committee membership shall include:
 - 1. Four pharmacists;
 - 2. Two Medicaid member representatives;
 - 3. One physician who specializes in the practice of psychiatry;
 - 4. One physician who specializes in the practice of pediatrics;
 - 5. One physician who specializes in the treatment of clients with disabilities;
 - 6. Four physicians from any other medical specialty.
- B. Physicians and pharmacists must be licensed and actively practicing in the State of Colorado while a member of the P&T Committee.
- C. The Department shall solicit recommendations for P&T Committee members from professional associations, client advocacy groups and other Medical Assistance Program stakeholders.
- D. The P&T Committee may meet and conduct business when at least any nine members are appointed to the P&T Committee. A majority of the appointed P&T Committee members constitute a quorum for the transaction of business at any P&T Committee meeting.
- E. P&T Committee members must disclose, at the beginning of any P&T Committee meeting, any conflicts of interest that would make it difficult to fulfill P&T Committee duties in an objective manner.

Committee Appointments and Terms

- 1. P&T Committee members shall serve two-year terms and may be reappointed to additional terms at the discretion of the Executive Director.
- 2. The terms shall be staggered so that in each year at least two pharmacists, one Medicaid member representative and any three physicians are reappointed.
- 3. The Executive Director may appoint initial P&T Committee members to serve less than two years to provide for staggered terms.



4. The Executive Director may terminate the appointment of any P&T Committee member for Good Cause.
5. The Executive Director shall fill a vacancy occurring in the membership of the P&T Committee for the remainder of the unexpired term. Such replacement shall meet all applicable requirements as set forth in P&T Committee Policies and Procedures 10 C.C.R. 2505-10, 8.800.

Meetings

- A. Meetings are held at least quarterly at a time and place agreed upon by the P&T Committee, in collaboration with the PDL support vendor, if any, and the Department.
- B. Unless otherwise notified, meetings will be held in Denver, CO.
- C. An agenda will be prepared and posted at least thirty days prior to meetings. The clinical data used for drug class review will be prepared and distributed to the P&T Committee members and Department staff at least one week in advance of meetings to allow sufficient review time.
- D. The P&T Committee meetings shall be open to the public. If a P&T Committee meeting is required to be held in executive session pursuant to state or federal law, the executive session shall be convened prior to the open meeting.
- E. The P&T Committee shall discuss and vote on each drug class presented unless a two-thirds vote of appointed members agrees to table the matter. Tabled drug discussions will be brought before the P&T Committee at the next P&T meeting.

Stakeholder Comment and Oral Presentation

Stakeholders have the opportunity to present comments to the P&T Committee through written comments directed to the Pharmacy Benefits Section or delegated representative.

- A. Comment period is for a period of 14 calendar days prior to the P&T Committee meeting.
- B. Stakeholder comments will be restricted to products that are being reviewed for PDL status.
- C. All stakeholder comments received and approved by the deadline will be accessible to P&T Committee members. Manufacturers submitting comments shall also include a one page summation of their drug product that will be



included in the review packet provided to the P&T Committee members. The summary must be limited to clinical information only.

- D. Stakeholder comments are to:
 - 1. Be limited to clinical information only;
 - 2. Exclude any reference to cost;
 - 3. Exclude anecdotal content;
 - 4. Exclude general drug or disease specific economic information.
- E. Stakeholder comments should be clearly labeled as such and should indicate the product and drug class the comments represent.
- F. Oral presentations will be restricted to products that are being reviewed for PDL status. Presentations will be limited to a maximum of three minutes per stakeholder per drug product. Only one presentation per product will be permitted.
- G. Stakeholders will be called to present in the order in which they signed in by drug class. Stakeholders must sign up with the Department at least 24 hours prior to the meeting.
- H. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the one page summary that was submitted to the Department.
- I. Factual Inaccuracy:
 - a. During a Committee meeting, if a stakeholder believes that a factual inaccuracy has been stated by a Committee member, the stakeholder may hand a note to the Department representative or Committee Chair or Vice Chair. The stakeholder must provide the factual inaccuracy or a summary of the inaccuracy on the note. The Department representative will forward any comment to the Chair or Vice Chair. The Committee Chair/Vice Chair will then determine if there is need to publicly hear the inaccuracy prior to moving forward with motions and discussion. The Chair/Vice Chair will state the purported factual inaccuracy and will ask the Committee if they want to hear testimony regarding the factual inaccuracy. When providing testimony, the stakeholder must provide evidence to support the claim of inaccuracy and cannot provide opinions on the drug class being considered.

Responsibilities of the Chair, Vice-Chair and Secretary

- 1. The Chair and Vice Chair shall be elected by the P&T Committee on an annual basis. The Chair presides over the meetings of the P&T Committee.
- 2. The Committee shall elect a Chair and Vice-Chair who must have served on the P&T Committee for at least one year.



- C. The responsibilities of the Vice-Chair are to preside over meetings of the P&T Committee in the Chair's absence.
- D. The Secretary shall be a representative from the PDL support vendor or appointed by the Department.

Public Communication

1. The Department is responsible for public notification of P&T Committee meetings. The proposed agenda shall be posted publicly at least thirty days before the meeting.
2. If requests for information are made, the Department shall review and determine if the request shall be granted. If there is a PDL support vendor and it receives the request, the PDL support vendor shall forward the request to the Department for review and determination. If the request is approved, the Department will send the material, or give the PDL support vendor permission to provide the material.

