



Idaho Medicaid Pharmacy and Therapeutics Committee

Department Guidelines for the Operation
of the Medicaid P&T Committee

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1 Organization and Operation

The following guidelines, subject to Department review and change as necessary, will generally apply:

Section A Name of the Organization

The name of the organization shall be the Idaho Medicaid Pharmacy and Therapeutics Committee (hereinafter referred to as the “P&T Committee” or “Committee”) serving the Idaho Medicaid Program administered by the Idaho Department of Health and Welfare (hereinafter referred to as the “Department”).

Section B Membership and Qualifications

1. The P&T Committee shall be composed of a minimum of eleven (11) members: eight (8) voting and three (3) non-voting.
 - a. The voting membership shall consist of practicing health care professionals with an unrestricted license to practice in the State of Idaho. Advanced Nurse Practitioners and Physicians Assistants must possess full prescribing authority for all scheduled and non-scheduled medications to be eligible for committee membership. The committee will have the following composition:
 - i. Four (4) physicians
 - ii. Three (3) pharmacists
 - iii. One (1) advanced nurse practitioner or physician’s assistant
 - b. The NON-voting members shall consist of :
 - i. One (1) representative of the State Board of Pharmacy
 - ii. One (1) representative of the Idaho Medicaid Pharmacy unit
 - iii. The Idaho Medicaid Medical Director
2. The majority of the voting members must be actively involved in the treatment of, or provision of healthcare services to, Idaho Medicaid clients.
3. A psychiatrist will be contracted to serve as a Clinical Consultant to the Committee anytime a Mental Health drug class is reviewed. This will include but is not limited to; Atypical Antipsychotics, Antidepressants, Antiepileptics and drugs used to treat ADHD. The P&T Committee may also consult with other health care professionals, as necessary.
4. The majority of the physician voting members shall be primary health care physicians. The Department defines primary health care physicians as – Family Practice, Internal Medicine, Pediatrics or OB/GYN practitioners. The Department defines primary health care pharmacists as those practicing in retail, ambulatory care, hospital acute care or long term care settings.
5. In developing drug use policies, the Committee should be attentive to the content of and changes to pertinent guidelines and policies of professional organizations and standards setting bodies such as the American Society of Health System Pharmacists, the American Hospital Association, medical and nursing associations, governmental organizations and others, as appropriate.

Section C Appointment and Term

1. Voting members of the Committee shall be appointed by the Director of the Department.
2. Non-voting members of the Committee membership shall be appointed by the Director of the Department or authorized designee.
3. The Committee Chairman shall be appointed from the voting members of the Committee by the Director of the Department.
4. Appointments of voting members will ordinarily be made for a term of two years. Non-voting members will serve terms determined by the Director or authorized designee.
5. Voting members may be appointed for additional terms.

Section D Resignation and Removal

1. A member of the P&T Committee may resign by written notice to the Committee Chair and the Department.
2. Any member of the Committee may be removed by the Department for good cause. Good cause shall include at least one of the following:
 - Nonattendance – Three (3) consecutive absences from scheduled meetings shall constitute a resignation.
 - Professional misconduct.
 - Conflict of Interest – Unresolved and/or undisclosed conflict of interest.
 - Failure to meets eligibility requirements for Committee appointment.

Section E Meeting Facilitation

The Chairman's designee from among the voting members will facilitate the Committee meeting in the absence of the Chair.

1. Department staff will prepare the agenda for the Committee meeting in consultation with the Committee Chair.
2. The Pharmacy Services Supervisor, under the direction of the chair, will be responsible to oversee the preparation of minutes in the permanent records of the Committee. The Department will provide administrative support for completion and distribution of the necessary records.
3. An agenda, supplementary materials (including minutes of the previous meeting) prepared by the supporting Department staff, and written comments or materials submitted by pharmaceutical manufacturers, Medicaid providers, and other commentators, shall be reviewed by the Committee Chair and submitted to Committee members before each meeting.

2 Scope of Responsibilities

Section A Responsibilities

The P&T Committee has the following responsibilities:

1. To serve in an evaluation, education and advisory capacity to the Idaho Medicaid Program specific to the prior authorization of drugs with therapeutically interchangeable alternatives.
2. To receive evidence-based clinical data and recommend to the Department the agents to be considered for prior authorization in selected classes of drugs in which there are therapeutically interchangeable alternatives and provide for regular review of the Department's decisions. The recommendation of the committee of agents to be considered for exemption from prior authorization shall be based primarily on objective evaluations of their relative safety, effectiveness, and clinical outcomes of the agents in comparison with other therapeutically interchangeable alternative agents in the same class of drugs and secondarily on relative cost. The Committee will only consider relative cost as part of its evaluation of selected classes of drugs if there are drugs within a class that have proven to be clinically superior for a specific disease or condition.
3. To recommend to the Department the classes of medications to be reviewed through evidence-based evaluation.
4. To review drug utilization outcome studies and intervention reports from the Drug Utilization Review Board as part of the process of reviewing and developing recommendations to the Department.

Section B Scope

Recommendations of the Committee will be presented to the Department for adoption, modification or referral back to the Committee for further action or review.

3 Meeting Guidelines

Section A Conduct of Meetings

1. The P&T Committee is subject to the Idaho Open Meeting Law – Idaho Code §§ 67-2340 through 67-2347.
2. The Committee will meet at least four times per year, or more often as deemed necessary by the Department in consultation with the Committee Chair.
3. All Committee members are expected to be physically present at quarterly Committee meetings, unless excused by the Chair.
4. Tape recorded and subsequent minutes will be the only formal record of the activities of the Committee meetings.
5. A simple majority of the voting membership of the P&T Committee will constitute a quorum.
6. Actions of the P&T Committee may be taken by a simple majority of voting members present provided there is a quorum.
7. All business of the Committee, including recommendations to the Department, shall be transacted by motion or resolution in open meeting, which may be made by any voting member in attendance, including the Chairman, and shall require a second. Voting on all

motions and resolutions shall be by voice vote unless a member asks that the roll be called and that the vote of each member be recorded.

8. The acts of the majority of the voting Committee members present at a meeting at which a quorum is present shall be the acts of the Committee.
9. The Committee shall take action with reference to each drug class under consideration by the Committee following the presentation of clinical and evidence based data and public comment relating thereto, unless an Executive Session relating thereto is held with reference to such drug class as provided herein. In the event matters are considered in Executive Session with reference to a drug class, the Committee shall make its recommendation in open meeting, immediately following such Executive Session, unless the matter is postponed to a time certain, which time shall be publicly announced. The P&T Committee may adjourn to executive session as permitted by Idaho Code § 67-2345.

Section B Public Participation

1. Meetings will be open to the public, and shall comply with the Idaho Open Meetings Law. Public notice of meetings will be published on the Department website, at least 10 days prior to each meeting.
2. A sign in sheet will be placed at the entrance of the meeting room. It will be available for any member of the public wishing to address the Committee to sign up 30 minutes prior to the meeting to 30 minutes after the start of the meeting. Anyone wishing to provide public comment must sign in during the 60 minute sign in period.
3. If a speaker plans to discuss more than one drug, he/she must sign in separately for each drug they wish to discuss.
4. Public comment will be limited to clinical and social comments. Testimony regarding pricing is not permitted.
5. Data presented during public testimony fits generally into two categories:
 - Clinical experience, either from provider or Medicaid participant
 - Clinical experience data is available to the Committee only through letters received by the Committee and/or by the testimony given during the public comment period of the P&T meeting. Providers and participants will not be restricted from giving clinical experience, other than time constraints needed to accommodate speakers during the 60-minute public comment period.
 - Scientific data provided by pharmaceutical scientists or their representatives
 - Material submitted for review needs to be limited to only what will be presented. Submissions containing more than this will be returned to submitters. Sending product monographs and dossiers, P&T Committee briefs, extensive bibliographies, or similar inclusions will cause submissions to be rejected and returned.
 - Those who wish to present scientific data should review the data already available to Committee members. This is publicly available on the P&T website. Persons may present scientific data not already available to Committee members through Provider Synergies, OHSU's DERP and/or other standard drug information sources. This information is most useful if reviewed in conjunction with drug class reviews that Committee members are already studying. Persons presenting scientific data, therefore, will be required to present their data to the Idaho Medicaid Pharmacy Unit in

writing at least 30 days prior to the meeting so it can be carefully considered by Committee members prior to the meeting.

- There may be times when scientific data may become available less than one month prior to the meeting. In such cases, special requests may be made to make oral presentations at the P&T meeting.
 - Oral presentations will be restricted to new information only. New information is considered to be: **(1) new product in the drug class, (2) new indication since the last review, or (3) new studies released since the last review, excluding placebo studies only.**
 - The P&T Committee chairman or his designee will review information to see if it meets the new information guidelines noted above. The Department will then advise potential speakers if they will be able to present at least 5 days prior to the meeting.
6. Public comments shall be reserved for a sixty (60) minute period during the P&T Committee meeting. Public comments will occur at the beginning (within first hour) of the meeting. Idaho Medicaid providers will be given the opportunity to comment first. The Committee Chair may modify the comment periods as necessary to facilitate the work of the Committee and shall announce the modifications at the beginning of the meeting. If such modifications are known prior to the meeting, the changes shall be published as part of the public notice, at least 10 days prior to each meeting.
 7. Comments will be no longer than five (5) minutes per person per topic. The Committee Chair may modify the time for comment as necessary to facilitate the work of the Committee.
 8. Only one representative of a company, group or association may be included on a meeting agenda to address the Committee for each drug class in review.
 9. Presenters giving oral testimony must provide written comments to the secretary to assure accurate transcription of the presenter's comments into the minutes. Handouts may not be given to the P&T members during the public comment session.
 10. All presenters are required to disclose who they represent, including any financial relationships and conflict of interest. This is to be done on the Public Comment Sign-in Sheet as well as when addressing the P&T Committee.
 11. Written comments can be received at any time but must be received 7 days prior to the meeting if they are to be presented to the P&T members for review prior to the meeting. Written comment by an individual or group must disclose the commentator's employment, and, if not an employee of a drug manufacturer or group, must also disclose whether or not the commentator or group receives compensation, gratuities or grants from or has an affiliation with any drug manufacturer or related group. Individuals writing on their own behalf should designate their correspondence as such. Written comment can be sent to the Committee, in care of the Department at:

**Pharmacy & Therapeutics Committee
Attention: Robert Faller
3232 Elder Street
Boise, Idaho 83705**

12. Dossiers should be sent to Provider Synergies LLC, or Evidence Based Practice Center at Oregon Health Sciences University, depending on which entity is reviewing the drug class.

4 Disclosure of Conflict of Interest and Confidentiality Requirements

The Chair of the Committee is authorized and directed to see that the following policies are implemented:

Section A Disclosure of Conflict of Interest

1. The Committee will operate in a manner that ensures the objectivity and credibility of its recommendations. To that end, each Committee member will be required to execute an agreement to disclose conflicts of interest and will have an ongoing duty to disclose any conflicts of interest to the Committee Chair and the Department.
2. No Committee member, or his/her immediate family member:
 - a. Shall be actively employed by or in a contractual relationship with any drug manufacturer, pharmaceutical company, or pharmacy benefits management company; or
 - b. Participate as a committee member or director of any drug manufacturer, pharmaceutical company, or pharmacy benefits management company; or
 - c. Hold, as an individual shareholder, greater than a one (1) percent interest of any drug manufacturer, pharmaceutical company, or pharmacy benefits management company.

Committee members failing to report any conflict of interest in this area will be subject to immediate dismissal from the Committee.

3. Any Committee member having a conflict of interest on any matter, or having an immediate family member with a conflict of interest on any matter, may not vote or use his/her personal influence on the matter, and he/she may not be counted in determining the quorum for the meeting. The minutes of the meeting shall reflect the disclosure was made, the abstention from voting, and quorum situation.
4. In the event a Committee member, or immediate family member, is involved in activities or organizations which the majority of the Committee members consider either a significant real or apparent conflict of interest relative to his/her services as a member of the Committee, he/she shall take prompt action to resolve the conflict by either (a) terminating the conflicting activity; or (b) by resigning from the Committee. The Committee member will be given the opportunity to state his/her position on the matter and answer questions of other Committee members. If the Committee member fails to take the action required in this section 5, the Committee may dismiss the member by majority vote.
5. Each Committee member must comply with all HIPPA requirements regarding disclosure of patient information.

Section B Confidentiality

1. The following statement will be read at the beginning of meetings of the Pharmacy and Therapeutics Committee:

The Committee will keep confidential all information which is disclosed to them as members of the P&T Committee in accordance with the Department's confidentiality policy and to the extent allowed by Idaho law relating to exemptions from disclosure of public records. See I.C. §9-340D. No Committee member shall at any time disclose to others or use for that individual's benefit or the benefit of others any information owned, possessed or used by Idaho Medicaid or its contractors, except as authorized by the Idaho Medicaid Program and for its benefit. This does not include information that is publicly available.