IDAHO DEPARTMENT OF HEALTH & WELFARE

DIVISION OF MEDICAID

Idaho Medicaid Pharmacy and Therapeutics Committee

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

TABLE OF CONTENTS

I. 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.

II. 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 therapeutic 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.

III. 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. 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.
6. 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.
7. 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.
8. Public testimony fits generally into two categories, clinical experience from a health care provider or a Medicaid participant or scientific information provided by pharmaceutical manufacturers or their representatives.

Clinical experience, either from a provider or a Medicaid participant

a. Clinical experience information is available to the Committee through letters received by the Committee and/or by oral testimony given during the public comment period of the P&T meeting. Providers and participants will not be restricted from relating clinical experience, other than the time constraints needed to accommodate speakers during the 60-minute public comment period.

b. Written submissions should be submitted to a designated Medicaid representative (currently Tami Eide):

Idaho Medicaid
Pharmacy & Therapeutics Committee
Attention: Tami Eide, Pharm.D.
3232 Elder Street
Boise, Idaho 83705

eidet@dhw.idaho.gov

c. 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 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.

Scientific information provided by pharmaceutical manufacturers or their representatives

a. Pharmaceutical manufacturer scientists or representatives must submit in writing any proposed testimony to be considered for review by the P&T Committee Membership.

b. Pharmaceutical manufacturer representatives who wish to submit scientific information should review the information already available to Committee members. This information is publicly available on the Idaho Medicaid P&T website www.medicaidpharmacy.idaho.gov. Pharmaceutical representatives may submit scientific information not already available to Committee members through Provider Synergies, the Drug Effectiveness Review Project (DERP) and/or other standard drug information sources. Submitted information is most useful if reviewed in conjunction with drug class reviews that Committee members are already studying. Submission of scientific information, therefore, is required to be submitted to the Idaho Medicaid Pharmacy Unit in writing at least 15 business days prior to the meeting so that if approved, it can be carefully considered by Committee members prior to the meeting.

c. There may be times when scientific information may become available less than 15 business days prior to the meeting. In such cases, special requests may be made to the Medicaid Pharmacy Unit for submission to the P&T Chairman for approval or rejection.

d. All scientific information submitted will be restricted to new information only. New information is considered to be: (1) New study results published since the last review that meet good evidence requirements of randomized double-blind active control studies. Placebo controlled, observational, open-label and non-randomized studies are not accepted for consideration. Studies must have been published or accepted for publication in a peer-review journal. Online publications and poster presentations will not be considered. (2) New product or new indication information not included in the Provider Synergies' Therapeutics Class Reviews or the DERP Reviews posted on the P&T Website.

e. All scientific information submitted must include a one page cover sheet of 250 words or less that summarizes the key points and directs the Committee members to the key areas of the submitted information for consideration. Page number, paragraphs and line numbers should be cited.

f. Material submitted for review shall be limited to only new information meeting the requirements above. Product monographs and dossiers, P&T Committee briefs, extensive bibliographies, or similar inclusions will not be considered.

g. Written submissions should be submitted to the Chairman of the P&T Committee through a designated Medicaid representative (currently Tami Eide). Written submissions may either be mailed or e-mailed.

Idaho Medicaid
Pharmacy & Therapeutics Committee
Attention: Tami Eide, Pharm.D.
3232 Elder Street
Boise, Idaho 83705

e-mail: eidet@dhw.idaho.gov

h. The P&T Committee chairman or his designee will review the submitted information to determine if it meets the new information guidelines noted above. The Department will then advise submitters of acceptance or rejection of the information at least 10 days prior to the meeting. If submitted information is rejected, the P&T Committee Chairman or his designee shall provide a written summary to the submitter detailing the reasons for rejection. The Department will disseminate accepted materials to P&T Committee members for review.

i. All submitted written testimony and scientific information provided by a pharmaceutical manufacturer shall be posted to the P&T Committee website. Testimony accepted for P&T Committee review will be designated as such.

j. A company who has submitted information accepted for review has the option of having a designated representative available at the P&T meeting to present the accepted testimony. Such testimony shall not exceed five (5) minutes including questions. Such time limitation may be extended at the discretion of the chairman.

k. If a company has reason to believe that during the P&T meeting that submitted information was misrepresented to or by committee members or that facts were mis-stated, they may submit an appeal in writing detailing their concerns by 5:00 PM of the next business day following the P&T Committee meeting. The concerns shall be presented concisely in less than 250 words and delivered to the Medicaid Pharmacy Unit (contact information above) for delivery to the Idaho Medicaid P&T Committee Chair. This written appeal and supporting information considered by the committee members and shall be posted on the P&T website. This process is limited to inaccuracies, mis-statements, or misrepresentations concerning submitted information. Any perceived inaccuracies of DERP or Provider Synergies drug class reviews should be routed through their established processes.

l. 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.

m. 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.

9. 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.

IV. 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.