Bylaws of the
Pharmacy and Therapeutics Committee
Nevada State Division of Health Care Financing & Policy

ARTICLE I

DEFINITIONS

A. "Administrator" shall mean the State's Administrator of the DHCFP.

B. "Advisory Committee" shall mean the committee established under the authority of Nevada Revised Statute 422.4025 (Assembly Bill No. 384) to advise the Pharmacy and Therapeutics Committee and the Drug Use Review Board.

C. "DHCFP" shall mean the Division of Health Care Financing and Policy, a division of DHR.

D. "DHCFP Coordinator" shall mean the DHCFP staff person assigned to coordinate the P&T Committee, act as Secretary, and provide staff assistance to the P&T Committee and its subcommittees.

E. "DHCFP's Pharmaceuticals Manager" shall mean the DHCFP contractor assigned responsibility for managing DHCFP's pharmaceuticals program and organizing P&T Committee activities.

F. "DHR" shall mean the Department of Human Resources of the State of Nevada.

G. "Director" shall mean the State's Director of DHR.

H. "Exhibit" shall mean a document to be presented to the P&T Committee whereby the P&T Committee is apprised of proposed changes in policy, regulation, or the State Plan. An Exhibit may require an action/vote by the Committee.

I. "Medicaid" shall mean the Medicaid program that is administered by DHCFP under Title XIX.

J. "Nevada Check-Up" shall mean the State Children's Health Insurance Program that is administered by the DHCFP under Title XXI.

K. "P&T Committee" is the Pharmacy and Therapeutics Committee.

L. "Presentation" shall mean public comments made orally at a meeting of the P&T Committee.

M. "Quorum" shall have the meaning stated in Nevada Revised Statutes § 241.015 (4) as a simple majority of the constituent membership of a public body or another proportion established by law.

ARTICLE II

FORMATION AND COMPOSITION

Section I. Creation

The P&T Committee is created within DHCFP by Nevada Revised Statutes §§ 422.4025 (Assembly Bill No. 384). The P&T Committee will operate in accordance with Nevada Medicaid Services Manual Chapter 1200 and Nevada Medicaid Operations Manual Chapter 200.

Section II. Number of members

The P&T Committee shall be comprised of at least nine (9) members and not more that eleven (11).

Section III. Appointment

The Governor shall appoint members to the P&T Committee based on recommendations from the Director. The DHCFP Chief of Program Services shall serve as the DHCFP Coordinator to the P&T Committee.

ARTICLE III

MEMBERSHIP, OFFICERS, AND ASSISTANCE

Section I. Qualifications for Membership in the P&T Committee

A. The P&T Committee membership shall meet the following criteria:

1. At least one-third of the members of the P&T Committee, and not more that 51 percent of the members of the P&T Committee, must be active physicians licensed to practice medicine in Nevada.

2. At least one member of the P&T Committee must be an active psychiatrist licensed to practice medicine in Nevada.

3. At least one-third of the members of the P&T Committee, and not more that 51 percent of the members of the P&T Committee, must be either active pharmacists registered in Nevada or persons in the state with doctoral degrees in pharmacy.

4. Members serving on the P&T Committee may not have a current affiliation, while serving the board/committee term, with a business or corporation that manufactures prescription drugs. This includes direct compensation through employment and contractual activities. This does not exclude members from participating in continuing educational units or conferences sponsored by the above entities.

5. P&T Committee members shall be health care professionals who have knowledge and expertise in one or more of the following:

   a. The clinically appropriate prescribing of outpatient prescription drugs that are covered by Medicaid;

   b. The clinically appropriate dispensing and monitoring of outpatient prescription drugs that are covered by Medicaid;

   c. The review of, evaluation of, and intervention in the use of prescription drugs; and

   d. Medical quality assurance.

Section II. <u>Term</u>

A. After the initial terms*, the term of each member of the P&T Committee is two years. (*The term for 5 of 9 or 10, or 6 of 11 of the initial P&T Committee members shall be one year and the remaining members two years.)

B. All appointed members of the P&T Committee serve at the pleasure of the Governor.

C. At the end of an appointed member's term, the Governor may reappoint a P&T Committee member to a subsequent term.

D. If a vacancy occurs in the membership of the P&T Committee, the Governor shall fill the vacancy for the remainder of the unexpired term in the same manner as the original appointment.

E. A member of the P&T Committee may resign by written notice to the Chairperson and the DHCFP Coordinator.

Section III. Officers

A. The Governor shall appoint the Chairperson and Vice-Chairperson of the P&T Committee from among its members.

B. The Chairperson and Vice-Chairperson shall serve a term of one year, unless otherwise specified by the Governor.

C. The Chairperson shall preside over the P&T Committee and shall confer with the DHCFP Coordinator on agenda items in advance of each meeting.

D. The Chairperson shall be physically present to preside over a meeting.

E. The Vice-Chairperson shall assume the duties of the Chairperson in his/her absence.

F. If the Chairperson is unable to continue to serve, the Vice-Chairperson shall assume the responsibilities of the Chairperson until the Governor appoints a new Chairperson.

Section IV. Assistance

A. The DHCFP shall provide the P&T Committee with staff assistance and independent technical assistance as needed to enable it to accomplish its functions and duties.

B. The Advisory Committee shall review recommendations and plans developed by the P&T Committee, and shall provide a written response advising the P&T Committee members of any concerns related to prescription drugs used by seniors, persons who are mentally ill or persons with disabilities. In addition, one or more members of the Advisory Committee may be asked to attend meetings of the P&T Committee at the discretion of the Chairpersons.

C. DHCFP's Pharmaceuticals Manager shall provide the P&T Committee with relevant clinical information (see Appendix A) and with support that includes, but is not limited to, accepting and summarizing submissions by pharmaceutical manufacturers and special interests groups.

ARTICLE IV

MEETINGS AND PRE-MEETING ACTIVITES

Section I. Frequency, Location and Attendance

A. The P&T Committee shall meet at least once every three months.

B. The P&T Committee shall meet at such times and places as the Chairperson and the DHCFP Coordinator deem necessary to conduct its business and/or and carry out its duties.

C. A simple majority of the members of the P&T Committee constitutes a quorum for the transaction of business.

D. Members may attend meetings telephonically; however, attendance in person to the maximum extent possible is highly encouraged.

Section II. Agenda, Meeting Preparation and Meeting Structure

A. The P&T Committee shall conduct its meetings pursuant to the Nevada Open Meeting Law set forth in Nevada Revised Statues Chapter 241.

B. Drug classes to be reviewed shall be posted on the DHCFP website 45 days prior to the scheduled meeting. Manufacturers and special interest groups will be given a deadline for submission of information at the time of this posting. The deadline shall allow at least 15 days for submission from the posting date.

C. The Chairperson and the DHCFP Coordinator shall be responsible for developing a DRAFT agenda for each P&T Committee meeting and the DRAFT agenda, along with Exhibits of proposals from DHCFP or its Pharmaceuticals Manager shall be distributed to each member not later than 15 business days prior to each meeting. (To the greatest extent possible, Exhibits shall be provided in electronic form or as a link to a website.) Any member of the P&T Committee may request the removal of an item from the DRAFT agenda if they conclude additional time or information is required. A FINAL agenda must be posted in accordance with the Open Meeting Law.

D. The DHCFP Coordinator shall ensure that:

1. Thirty (30) minutes prior to the beginning of the meeting, a sign-in sheet is available at the door where individuals, organizations, or agencies may sign up to make public comments during the meeting;

2. Public comment is limited to five minutes per individual, organization, or agency (but may be extended at Chair's discretion), and

3. Sequence of speakers is assigned based on the order of sign-up within each drug class to be discussed.

E. Speakers shall be required to participate according to the following guidelines.

1. Anyone presenting documents for consideration shall provide sufficient copies for each member of the P&T Committee and the official record (if possible, provide documents in electronic form for record retention purposes). In addition:

    a. Copies for public comment shall be made available at the time of sign-up and shall be distributed at the time of the meeting;

    b. DHCFP or its Pharmaceuticals Manager shall not distribute public comment information prior to the public meeting, and

    c. Exhibits, proposals and handouts must meet the standards set forth in Article IV, Section III of these Bylaws.

2. Each presentation must include:

    a. The speaker's name;

    b. Affiliation/representation;

    c. Any funding, grants, affiliations and/or compensation received from special interest groups (e.g., pharmaceutical manufacturers including, but not limited to, speakers bureau memberships, advisory committee appointments or financial interests/holdings), and

    d. The source of funding for all studies cited.

3. Products jointly represented by more than one company may be represented during the public comment period by only one individual.

Section III. <u>Exhibits, Proposals and Handouts</u>

A. Exhibits, proposals and handouts will include the following items, as applicable:

1. Statement of need/purpose;

2. History;

3. Present policy or regulation, to include coverage and cost in other states and by Medicare and private insurance, if available;

4. Reason for change/justification;

5. Proposed policy or regulation change or adoption; and

6. Effect of change, to include potential cost and/or savings.

B. Exhibits, proposals and handouts may be submitted to the Board for consideration, in accordance with the following guidelines:

1. Electronic submissions are preferred;

2. Summaries must be broad and not exceed two pages, 8½ x 11, one side;

3. Whenever possible, summaries should include a web site URL as an option for obtaining additional details.

C. Documentation of a purely marketing or soliciting nature is discouraged.

Section IV. Briefings

DHCFP staff will be available to conduct oral presentations on pending issues of significance to DHCFP. The P&T Committee may request written briefings. Copies of any pertinent laws or regulations shall be mailed to each member fifteen (15) days in advance of each scheduled presentation or briefings.

Section V. Submission of Clinical Information

A. Pharmaceutical manufacturers and special interests groups wishing to provide the P&T Committee with clinical information, questions or comments about the preferred drug list must make submissions directly to DHCFP's Pharmaceuticals Manager. (See submission details in Appendix B.)

B. Manufacturers must make submissions through their product manager using the approved form (see Appendix C). This form constitutes a request for information pertaining to peer-reviewed literature, including off-label studies or unpublished data.

C. Written comments are encouraged; electronic transmittal is preferred.

D. As noted in Article V, Section II, Part B of these Bylaws, drug classes to be reviewed shall be posted on the DHCFP website no later than 45 days prior to the scheduled meeting. Clinical information that manufacturers or special interest groups wish to have considered in the review process should be submitted to DHCFP's Pharmaceuticals Manager no later than 30 days prior to the meeting. The deadline for submission shall be posted on the website when the drug classes to be reviewed are posted.

E. Information provided to DHCFP's Pharmaceuticals Manager shall be summarized at a high level for review by members of the P&T Committee. Upon request of any of the Committee members, additional details shall be provided.

F. Manufacturers or special interest groups wishing to provide their information directly to the Committee members shall be required to provide a website for member access.

Section VI. Voting

A. Each of the members constituting a quorum of the P&T Committee shall vote to approve or disapprove each action item on the agenda.

B. An affirmative vote of a majority of **ALL** members of the P&T Committee is required to take action.

Section VII. Minutes

A. Records/minutes of the P&T Committee meeting will be kept and made available in accordance with the Open Meeting Law.

1. The minutes may be a summary of discussions, but they must reflect the substance of matters proposed, discussed, or decided.

2. The substance of public comment will be included if the member of the general public requests their comments to be included for the record.

B. Minutes and other relevant materials shall be accessible via the DHCFP website. Individuals who do not have access to the Internet may request hard copies by calling the DHCFP Hearings and Policy office, (775) 684-3605.

ARTICLE V

FUNCTIONS AND DUTIES

Section I. Functions

A. The P&T Committee shall identify the preferred prescription drugs, which should be included on the Preferred Drugs List (hereinafter referred to as the "PDL") developed by the DHCFP.

B. The P&T Committee shall identify the preferred prescription drugs included on the PDL, which are or should be excluded from any restrictions for inclusion on the PDL Exclusion List being developed by the DHCFP. These drugs include, but are not limited to:

1. ~~Atypical and typical antipsychotic medications that are prescribed for the treatment of a mental illness of a patient who is receiving services pursuant to Medicaid;~~

2. Prescription drugs that are prescribed for the treatment of the human immunodeficiency virus or acquired immunodeficiency syndrome, including, without limitation, protease inhibitors and antiretroviral medications;

3. ~~Anticonvulsant medications;~~

4. Antirejection medications for organ transplants;

5. ~~Antidiabetic medications;~~

6. Antihemophilic medications; and

7. Any prescription drug that the P&T Committee identifies as appropriate for exclusion from any restrictions that are imposed on drugs that are on the list of the PDL.

C. The P&T Committee shall make the final determination of:

1. Whether a class of therapeutic prescription drugs is included on the PDL and is excluded from any restrictions that are imposed on other drugs that are on the PDL;

2. Which therapeutically equivalent prescription drugs shall be reviewed for inclusion on the PDL and for exclusion from any restrictions that are imposed on other drugs that are on the PDL; and

3. Which prescription drugs should be excluded from any restrictions that are imposed on other drugs that are on the PDL based on continuity of care concerning a specific diagnosis, condition, class of therapeutic prescription drugs or medical specialty.

D. In executing its duties, the P&T Committee shall:

1. Base its decisions on evidence of clinical efficacy and safety without consideration of the cost of the prescription drugs being considered;

2. Review new pharmaceutical products in as expeditious a manner as possible; and

3. Consider new clinical evidence supporting the inclusion of an existing pharmaceutical product on the PDL and new clinical evidence supporting the exclusion of an existing pharmaceutical product from any restrictions that are imposed on drugs that are on the PDL in as expeditious a manner as possible.

E. If the P&T Committee determines that there are no significant differences between drugs within a specific category based on clinical efficacy and safety, DHCFP may consider cost in determining which drugs are selected for inclusion on the PDL.

F. In executing its duties, the P&T Committee is authorized to:

1. Exercise clinical judgment and analyze peer review articles, published studies, and other medical and scientific information; and

2. Establish subcommittees to analyze specific issues that arise as the P&T Committee carries out its duties.

G. At least annually, the P&T Committee shall review all classes of therapeutic prescription drugs on the PDL.

ARTICLE VI

COMPENSATION

Section I. Compensation

A. Members of the P&T Committee serve without compensation.

B. Each member of the P&T Committee who is an officer or employee of the State of Nevada or a local government must be relieved from his/her duties without loss of his regular compensation so that he/she may prepare for and attend meetings of the Committee and perform any work necessary to carry out the duties of the Committee in the most timely manner practicable. A state agency or local governmental entity shall not require an officer or employee who is a member of the P&T Committee to make up the time that he/she is absent from work to carry out his/her duties as a member of the Committee or to use annual vacation or compensatory time for the absence.

Section II. Per Diem and Other Expenses

A member of the P&T Committee is entitled, while engaged in the business of the Committee, to receive travel expenses provided for state officers and employees generally, including per diem, transportation, lodging, and associated miscellaneous expenses.

ARTICLE VII

ADOPTION AND AMENDMENTS TO THE BYLAWS

Proposed amendments to these Bylaws must be submitted, in writing, to the P&T Committee members and the Director fifteen (15) days in advance of a scheduled meeting in order to be acted upon. An affirmative vote of a majority of **all** members of the P&T Committee shall be required to adopt a proposed amendment, and such amendments must be approved by the Director to become effective.