

## **P&T COMMITTEE PLAN OF OPERATIONS**

This Pharmacy & Therapeutics Committee, its officers, members and any committees or working groups acting on behalf of the Committee shall recognize, observe and be bound by the provisions of this Plan of Operation and Bylaws.

The Pharmacy and Therapeutics Committee shall perform its functions in accordance with the requirements of RCW 70.14.050 (as amended 2003, or as hereafter amended), the Social Security Act, Title 19 §1927, Chapter 41.05 RCW, this Plan of Operation and Bylaws (the Plan), as adopted or as may be hereafter amended. The Plan shall become effective upon approval in writing by the Appointing Authority.

### **A. NAME:**

This entity shall be known as the Washington State Pharmacy and Therapeutics Committee (P&T Committee or Committee).

### **B. AUTHORITY TO ACT:**

The P&T Committee is formed pursuant to RCW 70.14.050 (as amended, 2003 ) to evaluate available evidence regarding the relative safety, efficacy and effectiveness of prescription drugs in a class and to make recommendations to state agencies regarding the development of a preferred drug list.

The Committee is a "technical review committee" established by the Appointing Authority to aid in the development, acquisition, or implementation of state-purchased health care. Pursuant to RCW 42.17.310(1), information obtained by the Committee in pursuant of its duties may be exempt or withheld from public inspection and copying whether held by the HCA or the Committee.

### **C. DEFINITIONS:**

- 1) "Act" means SB 6088, Ch. 29 Laws 1st Special Session, 2003, as may be codified.
- 2) "Appointing Authority" means the agency heads of the Washington State Health Care Authority (HCA), Department of Social and Health Services (DSHS), and the Department of Labor and Industries (L&I), acting together. Any agency head may designate a representative to act on his or her behalf. Any such designation may include the authority to hear and determine any matter.
- 3) "Agreement" or "Contract" means the written agreement between HCA and the members of this Committee, including all exhibits, attachments, amendments and materials incorporated by reference.
- 4) "Centers for Medicare and Medicaid Services" or "CMS," means that division of the federal Department of Health and Human Services.
- 5) "CONTRACTOR" means the entity or person contracting with HCA to provide services pursuant to an Agreement as a member of the state of Washington Pharmacy and Therapeutics Committee.
- 6) "DUR" means the Drug Utilization Review Board established by the state of Washington Department of Social and Health Services, Medical Assistance Administration (DSHS/MAA), as set forth in WAC 388-530-1850 and the federal Social Security Act, Title 19 §1927.

7) "Efficacy" means the potential effects of treatment by the drug under optimal circumstances (for example, patients all taking their doses at the right times, physicians prescribing correct doses, side effects appropriately monitored, etc). Efficacy studies are typically the foundation of new drug submissions to the FDA.

8) "Effectiveness" means the actual effects of treatment by the drug under "real life" conditions (for example, patients not always remembering to take their doses, physicians often not prescribing the FDA recommended doses, side effects not all controlled, etc).

9) "Evidence-based" means a process of independent and objective decision making based on consideration of objective data.

10) "OHSU EPC" means the Oregon Health & Science University, Evidence-Based Practice Center located in Portland, Oregon.

11) "Personal Information" includes, but is not limited to, information identifiable to an individual that relates to a natural person's health, finances, education, business, use or receipt of governmental services, or other activities, names, addresses, telephone numbers, social security numbers, driver license numbers, financial profiles, credit card numbers, financial identifiers and other identifying numbers.

12) "Plan," means this Plan of Operation and Bylaws of the Committee.

13) "P&T Committee" or "Committee" means this independent Pharmacy and Therapeutics Committee established by the 2003 Legislature at Section 9, SB 6088, amending RCW 70.14.050(4). The P&T Committee also serves as the Drug Utilization Review Board (DUR) established by the state of Washington Department of Social and Health Services, Medical Assistance Administration (DSHS/MAA), as set forth in WAC 388-530-1850 and the federal Social Security Act, Title 19 §1927.

#### **D. OPERATING PRINCIPLES OF THE P&T COMMITTEE:**

The Committee is an independent technical review committee appointed by the Appointing Authority.

The objectives of this Committee shall be to:

1) Establish procedures to evaluate evidence-based reviews of prescription drug classes to assist in the formation of recommendations to the Appointing Authority regarding the development of a preferred drug list.

2) Consider and recommend action on independent evidence-based reviews of drug classes. Reviews of such drug classes shall be based on the evidence of safety, efficacy, and effectiveness available at the time of the review. The OHSU EPC, or another similar entity, will be contracted by the HCA to conduct the evidence-based reviews and make its findings available for detailed consideration by the Committee. All analysis, evidence and references brought to the Committee for review shall be the result of a rigorous assessment of the scientific evidence.

3) Evaluate the then-available evidence regarding the safety, efficacy, and effectiveness of the drug or drugs in a class of drugs based on the report provided by OHSU EPC or other contracted entity. Recommendations by the Committee to the Appointing Authority will be solely based on available evidence, not on cost considerations. The cost analysis will be performed by the Appointing Authority.

4) Identify the most clinically effective drug or drugs from among the drugs in the reviewed class or determine that there is sufficient evidence of similar safety, efficacy, and effectiveness for the drugs in a class to allow therapeutic interchange of the drugs within that class and forward its recommendation to the Appointing Authority for final deliberation and inclusion in the state's preferred drug list.

5) Serve as the Drug Utilization Review Board (DUR) established by the Washington State Department of Social and Health Services, Medical Assistance Administration (DSHS/MAA), as set forth in WAC 388-530-1850 and the federal Social Security Act, Title 19 §1927.

#### **E. PURPOSE OF THE P&T COMMITTEE:**

The purpose of the P&T Committee is to evaluate available evidence regarding the relative safety, efficacy, and effectiveness of prescription drugs within a class or classes of prescription drugs and make recommendations to the Appointing Authority for its deliberation in the development of the state's preferred drug list established in Section 9, SB 6088 (as codified at RCW 70.14.050). In its evaluation, the P&T Committee may review and consider outcome studies of the long-term effects of drugs. The Committee shall also undertake DUR functions as required by DSHS/MAA.

#### **F. PURPOSE OF THE PLAN OF OPERATION AND BYLAWS:**

It is the purpose of the Plan:

1) To establish a framework for the work of the Committee:

- a) To provide for selection of a chair, vice chair and such other officers as the Committee may determine;
- b) To create subcommittees or working groups as may be necessary;
- c) To establish regular times and places for meetings of the Committee;
- d) To conduct periodic evaluations to assure the general accuracy of data submitted to the Committee; and
- e) To review, consider and act upon any matters deemed by it to be necessary and proper to the administration of the Committee.

2) Establish procedures for consideration of evidence presented by OHSU EPC, or other comparable entity, for consideration and deliberation;

3) Adopt policies and procedures to evaluate the available evidence of safety, efficacy, and effectiveness of prescription drugs within a class to guide the development of a preferred drug list as required by RCW 70.14.050, for approval by the Appointing Authority; and

4) Establish a protocol for deciding when additional information or evidence is necessary for the work of the Committee and procedures for collection of additional information.

#### **G. REVIEW STANDARDS:**

The P&T Committee will evaluate evidenced-based reviews of classes of prescription drugs provided by OHSU EPC or other contracted entity. The evidence-based reviews shall be based on well-designed, well-conducted studies that:

1) Consider the overall quality of the evidence available at the time of review, including a consideration of whether the study compares the safety, efficacy or effectiveness of similar drugs, rather than just compared to placebo;

- 2) Select and refine questions that assist the Committee in evaluating provider and patient perspectives;
- 3) Make use of an independent, systematic review of evidence of the relative safety, efficacy, and effectiveness of prescription drugs in a class;
- 4) Produce explicit, defensible recommendations based on careful evaluation of the available evidence at the time of the review;
- 5) Evaluate each class of drugs in a manner free of bias emphasizing the best evidence as reported by OHSU or other entity;
- 6) Review direct evidence, if available at the time of review, that addresses health outcomes rather than intermediate outcomes, including the spectrum of patients to whom a drug will be prescribed (not just highly selected patients in research studies); and
- 7) Consider the potential harms as well as the benefits of the intervention being considered.

The P&T Committee may consider such other evidence and reviews as the Committee appropriate to a well-informed review.

#### **H. REQUIREMENTS FOR MEMBERSHIP IN THE P&T COMMITTEE:**

- 1) The Committee shall consist of no fewer than ten members appointed by the Appointing Authority. Each member serves at the pleasure of the Appointing Authority.
- 2) Members shall enter into an Agreement with the HCA at the time of their appointment to the Committee and shall act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.
- 3) The membership composition at all times shall be consistent with applicable federal requirements under the federal Social Security Act, Title 19 §1927 and the requirements of DSHS/MAA for its DUR. Therefore, pharmacists and physicians each shall represent at least 31%, but no more than 51% of Committee membership respectively.
- 4) All members shall be actively practicing in their clinical area of expertise throughout the entire term of their appointments.
- 5) Members must have knowledge and expertise in one or more of the following:
  - a) Clinically appropriate prescribing of covered outpatient drugs;
  - b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;
  - c) Drug use review;
  - d) Medical quality assurance;
  - e) Disease state management; or
  - f) Evidence-based medicine.
- 6) Members of the Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term and for eighteen months prior to their appointment.
- 7) No member may have a substantial financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies. Members

shall update their Conflict of Interest disclosure statements any time their circumstances change in order to ensure their information is current.

8) Any person appointed as a member of the Committee or any subcommittee, working group or advisory group established by the Committee, must disclose to the Appointing Authority any potential conflict of interest, including receipt of any remuneration, grants, or other compensation from a pharmaceutical manufacturer or pharmaceutical benefits management company prior to such appointment.

9) At each meeting any member of the Committee must recuse himself or herself from discussion and decision making of an entire drug class if he or she has a material conflict with any drug in that class. If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an effected drug class or other action of the Committee, that person shall be subject to immediate dismissal.

10) Committee members shall not use the name of the Committee in any publication, meeting, negotiation, or promotion without prior approval of the Appointing Authority.

#### **I. APPOINTMENT PERIOD:**

1) Members shall be appointed to a term of three years and until a successor is duly appointed.

2) A member may be re-appointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

3) Committee members shall serve staggered three-year terms. Of the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for 24 or fewer months, that period of time shall not be counted toward the limitation of years of appointment described above.

4) Vacancies occurring on the Committee shall be filled by appointment of the Appointing Authority. If a vacancy occurs due to termination of a member during the term of his or her appointment, the initial appointment shall be for the remainder of the term of the vacant position. If the appointment is for 24 or fewer months, that period of time shall not be counted towards the limitation of years of appointment described above.

#### **J. COMPENSATION**

Members of the Committee will be compensated for participation in the work of the Committee in accordance with a personal services contract to be executed after appointment and prior to commencement of activities related to the work of the Committee.

#### **K. QUALIFICATIONS FOR APPOINTMENT:**

1) The Appointing Authority has the sole right to appoint Committee members and may terminate appointment of any member at any time during the term.

2) Appointment to the Committee shall be made by the Appointing Authority from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the Appointing Authority. Members of the public may at any time recommend or nominate candidates for membership in the Committee.

3) As part of the application process, prospective Committee members shall complete a Conflict of Interest disclosure form, provided by the Appointing Authority, and after appointment, annually by July 1st of each year. Members must keep the disclosure statement current and provide updated information whenever circumstances change.

4) Members of the Committee may not participate in discussions or deliberations of any class of drugs or any agenda item for which a material conflict of interest is identified and may not vote on any such matter.

5) If a conflict of interest is so great as to make it difficult for a Committee member to participate meaningfully in the work of the P&T Committee, that person may be asked to resign. For example, resignation from the Committee may be requested if a member must recuse himself or herself from participation in more than one drug class review in a year.

6) Each Committee member must comply with all applicable local, state and federal licensing, certification, accreditation and registration standards and requirements necessary for the performance of this Agreement. He or she must remain in good standing with any applicable agencies, boards, professional licensing boards or commissions throughout the term of the Agreement.

#### **L. DUTIES OF P&T COMMITTEE MEMBERS:**

The duties of the Committee members include:

1) To establish procedures under which evidence-based reviews of classes of drugs are evaluated and considered.

2) To recommend to the Appointing Authority selected drugs from each class of drugs reviewed for the purpose of establishing a statewide preferred drug list.

3) To regularly attend meetings of the Committee. Failure of a member to regularly attend Committee meetings without adequate excuse shall be grounds for referral to the Appointing Authority for consideration of termination of membership in the Committee.

#### **M. OFFICERS:**

1) A Chair and a Vice Chair, selected by the members, shall manage the Committee and such other officers as are deemed necessary to administer the affairs of the Committee.

2) The term of office shall be for two years beginning on January 1st of the year following selection. Each officer shall hold office until a successor is duly elected.

3) The officers of the Committee shall fulfill the following functions:

a) Chair: The chair shall be the principal executive officer of the Committee and shall generally supervise and control all of the business and affairs of the Committee. The Chair will be selected in even numbered years. The Chair may appoint such other officers, subcommittees, working groups or advisory groups, as he or she deems appropriate. The Chair shall:

i) Preside at all meetings of the Committee;

ii) Assist with the development and implementation of a program to publicize the existence of the Committee, qualifications for appointment and procedures for maintaining public awareness of the Committee;

- iii) Complete an annual report of the activities of the Committee by May 1st of each year and forward it to the Appointing Authority; and
- iv) Shall serve as an ex-officio member of all subcommittees, working groups or advisory groups.

b) Vice Chair: The Vice Chair shall perform all duties of the Chair in the absence of the Chair or when the Chair is unable to act or refuses to act. When so acting, the Vice Chair shall have all of the powers and be subject to all of the restrictions of the Chair. The Vice Chair will be selected in odd numbered years. In addition, the Vice Chair shall:

- i) Perform such other duties as may be assigned by the chair or the Appointing Authority.
- ii) Act as the designee of the chair as ex-officio member of all Committees, working groups or advisory groups of the Committee.

4) Any officer selected or appointed by the Committee may be removed by a majority vote of the full Committee whenever in its judgment the best interests of the Committee would be served thereby.

5) The Chair and the Vice Chair should not be employed by the same entity. The Committee should strive to select officers from different regions of the state whenever possible.

6) For the 2003-4 year, the Chair shall be selected for a two-year term and the Vice Chair selected for a one-year term.

7) In the absence of both the Chair and the Vice Chair, an acting vice chair shall be appointed by a majority of the Committee present at that meeting and shall preside at that meeting of the Committee.

8) If a vacancy occurs in the office of Chair due to his or her death, resignation, removal, disqualification or other act of the Committee or the Appointing Authority, the Vice Chair shall automatically fill such vacancy until a successor is elected at the next regularly prescribed time. If a vacancy occurs in the office of Vice Chair, he or she shall be replaced by a majority vote of the members for the remainder of the term.

9) If contested, all elections of officers shall be conducted by secret ballot.

#### **N. VOTING AND QUORUM:**

1) All business of the Committee shall be transacted by motion or resolution, which may be made by any member in attendance, including the Chair or other person presiding at that meeting, 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.

2) Each member of the Committee shall have one vote on each matter submitted to a vote of the Committee. The Chair shall be a voting member of the Committee.

3) The presence of six members (or one-half plus one if the membership is more than ten at the time of voting) shall constitute a quorum for the transaction of business.

4) A simple majority of those voting shall be required for all matters. A majority of the quorum must vote in favor for a motion in order for the motion to be adopted.

5) When a member must recuse himself or herself from acting on any matter, that person will not be counted for purposes of determining a quorum. Thus, if six members are present at a meeting where a vote is scheduled to occur and one member cannot participate, a quorum is not present and voting

on the matter must be postponed or tabled or the matter fails for lack of a quorum, at the discretion of the Chair.

6) The acts of the majority of the Committee members present at a meeting at which a quorum is present shall be the acts of the Committee.

7) Members must be present to vote on each matter submitted to a vote of the members. A member will be considered to be present if he or she attends in person or by telephone conference call or any similar communication method.

#### **O. MEETINGS OF THE P&T COMMITTEE:**

1) The P&T Committee shall meet at least quarterly and may meet at other times at the discretion of the Chair or the Appointing Authority.

2) Committee meetings shall in all respects comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and shall be subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

3) The Committee shall constitute a technical review committee created to facilitate the development, acquisition, or implementation of state purchased health care under RCW 41.05.026, and as such may hold an Executive Session in accordance with Chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 (1) through (5).

4) Meetings shall be held at such time and place as the Chair or the Appointing Authority shall determine in order to conduct all business deemed necessary for the administration of the Committee.

5) At each meeting, the Committee shall review the status of all business before the Committee, review and act upon outstanding issues.

6) Advance notice of all meetings, both regular and special, of the Committee will be published in the Washington State Register and will be provided to interested parties. Persons interested in receiving information about meetings shall be encouraged to provide electronic addresses or information regarding such other means of receiving notice as may be determined to be appropriate by the Appointing Authority or the Chair.

7) Notice of the time and manner of any meeting may be given orally, or by telephone to the office, residence or normal place of business of each Committee member at least two days prior to the time of such meeting and such notice shall be sufficient for all purposes.

8) A recording of each meeting shall be made. The HCA staff person assigned to provide assistance to the Committee shall retain the original copy. Minutes of the Committee's deliberations may be, but need not be, kept and published. Minutes of the DUR will be kept and published by DSHS/MAA staff.

9) A member of the Committee or a member of the public may request a transcription of the recording of a meeting. If a member of the public requests a transcription, the requesting party may be required by the Appointing Authority to pay for its production. After completion, any transcription so made shall be made available to any person upon request.

10) Meetings of the Committee may be held by means of a conference telephone or similar communication equipment, by which all persons participating in the meeting can hear each other at

the same time, and participation by such means shall constitute the presence of a person at a meeting.

**P. CONFLICTS OF INTEREST:**

- 1) Applicants may not have been employed by a Pharmaceutical Manufacturer or Pharmacy Benefit Manager at the time of application or within the most recent eighteen months.
- 2) The Initial Appointees shall complete a Conflict of Interest (COI) disclosure form shall be completed as part of the appointment process.
- 3) At any meeting of the Committee, members of the Committee must recuse themselves from discussion and decision making of an entire drug class if the member believes that a material conflict exists as to any drug in that class.
- 4) If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an affected drug class or other action of the Committee, that person shall be subject to immediate dismissal.
- 5) If the conflicts of interest of any member are so great as to make participation in the work of the Committee ineffective, the member will be expected to resign or will be asked to resign.
- 6) Future applicants must submit a completed COI disclosure form with their application before the Appointing Authority considers their appointments. All disclosed conflicts will be considered before an offer of appointment is made.

**Q. STAFF ASSISTANCE:**

- 1) Staff assistance to the Committee will be provided by HCA employees, independent contractors employed by the HCA for this purpose, or such other supporting staff as the Appointing Authority may deem appropriate or necessary to assure that the mission of the Committee is carried out.
- 2) Staff assistants shall cause all votes of all proceedings to be recorded and shall cause a recording of the meeting to be made and transcribe the recordings, upon request.
- 3) Staff shall:
  - a) Give or cause to be given, notice of all meetings, including publication in the Washington State Register, to all members of the Committee and such parties who have advised staff of their interest in the activities and meetings of the Committee;
  - b) Act as custodian of the records of the Committee;
  - c) Keep a register of the address of each member, maintain a record of the names of members entitled to vote, and provide public access to all such records;
  - d) Assist Committee members to complete reports of expenses, as may be required for reimbursement by the state and keep accurate accounts of such reports; and
  - e) Perform such other duties as may be prescribed by the Committee, the Appointing Authority, or the HCA Administrator.

**R. EXPENSES OF COMMITTEE MEMBERS:**

The expenses for which members of the Committee will be reimbursed are in accordance with the personal services contracts that shall be executed prior to the member's first meeting.

## **S. CONTRACTS:**

- 1) The Committee has no power to enter into contracts, but may recommend that the HCA enter into such contracts as are necessary or proper to carry out the provisions and purposes of the Act or the work of the Committee. Such contract may include engagements of independent legal, actuarial, clinical, research or other consultants.
- 2) The Committee may suggest necessary or desirable corrections, improvements or additions to any such contract.

## **T. SUBCOMMITTEES, WORKING GROUPS AND ADVISORY GROUPS:**

- 1) The Chair or the Appointing Authority may designate and appoint one or more subcommittees, working groups or advisory groups (collectively hereinafter "group").
- 2) Two or more Committee members shall serve on each such group.
- 3) Such other persons as may be designated by the Chair or the Appointing Authority may serve on any group.
- 4) No group shall have authority to amend, alter, or repeal this Plan, adopt any action contrary to the Committee, or remove any member or take any action on behalf of the Committee or the state of Washington.
- 5) The designation and appointment of any group and the delegation thereto of any authority of the Committee, shall not operate to relieve the Committee, or officers of the Committee, or any member of the Committee of any responsibility imposed upon him or her by law, rule or this Plan.
- 6) Any member of any group may be removed by the Chair or the Appointing Authority whenever the best interests of the Committee or the state will be best served by such removal.

## **U. COUNSEL TO THE COMMITTEE:**

The Assistant Attorney General providing general legal advice to the HCA will provide general legal assistance to the Committee.

## **V. INDEMNIFICATION:**

A Committee member may request defense and indemnification from the state for claims or actions arising out of performing, or in good faith purporting to perform, official duties of the Committee. Defense and indemnification will be provided to the extent permitted by applicable laws, including but not limited to RCW 4.92.060, .070 and .075.

## **W. REPORTING:**

The Chair shall cause an annual report to be completed and presented to the Appointing Authority no later than May 1st of each year. The annual report shall include an account of the prior year's activities.

## **X. AMENDMENTS:**

- 1) This Plan may be altered, amended or repealed in whole or in part at any meeting of the Committee. Alterations, amendments or motions to repeal shall not be voted on at the meeting during which they are proposed.
- 2) At least ten days prior notice of the intent to alter, amend or repeal any portion of the Plan shall be given to the members for their consideration.
- 3) Alterations, amendments or motions to repeal any provision of the Plan shall require approval by a simple majority vote of a quorum of the Committee.
- 4) All alterations, amendments, or motions to repeal all or a part of this Plan are subject to review and approval by the Appointing Authority before becoming effective.
- 5) Any amendments or alterations to this Plan must comply with the Act and other applicable State and federal laws.

**Y. TERMINATION:**

The Committee shall continue in existence subject to termination in accordance with requirements of laws of the state of Washington or action of the Appointing Authority. In case of termination, to the extent consistent with such laws or consistent with the action of the Appointing Authority, the Committee shall continue operating only to the extent necessary to orderly complete the work of the Committee.

**Z. EFFECTIVE DATE:**

This Plan shall be effective the date of adoption by the Committee and approval by the Appointing Authority, and shall terminate at termination of the Committee.

This Plan of Operation and Bylaws of the P&T Committee was duly adopted at the meeting of the P&T Committee on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

Signed:

Dan Lessler /S/ 12-17-2003  
Chair

This Plan of Operation and Bylaws of the P&T Committee was approved by the Appointing Authority on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

By:

Pete Cutler /S/ 01-13-2004  
Pete Cutler, Acting Administrator HCA, on behalf of the Appointing Authority

saved:  
PT Plan of Operation - final