**AHCCCS Pharmacy and Therapeutics Committee Draft Operational Policy**

**October 20, 2015**

**PURPOSE**

The Committee serves in an advisory capacity to AHCCCS and is responsible for evaluating scientific evidence of the relative safety, efficacy, effectiveness and clinical appropriateness of prescription drugs. The Committee shall make recommendations to AHCCCS on the development and maintenance of a statewide preferred drug list. Committee members shall evaluate individual drugs and/or therapeutic classes of drugs in a manner free of bias emphasizing the best clinical evidence.

**DEFINITIONS**

1. “Committee” means the AHCCCS Pharmacy and Therapeutics Committee, as appointed by the Chief Medical Officer.
2. "Efficacy" means the ability of a treatment to achieve the desired results under ideal study conditions.
3. "Effectiveness" means the actual effects of a drug treatment under real life conditions.
4. "Evidence-based medicine" means the integration of the best research scientific evidence with clinical expertise and patient values when making decisions about the care of individual patients.
5. “Preferred Drug List” means a list of medications and related products supported by current evidence-based medicine, health care clinicians and other experts. The primary purpose of the preferred drug list is to encourage the use of the safe, effective, clinically appropriate and most cost-effective medication.

**COMPOSITION**

The Committee shall be composed of:

1. AHCCCS representatives:
	1. Chief Medical Officer or designee
	2. Pharmacy Administrator or designee
	3. AHCCCS Medical Management Administrator or designee
2. Health care providers with a direct interest in the AHCCCS program:
	1. A pediatrician
	2. A primary care provider
	3. An obstetrician gynecologist
	4. A child and adolescent psychiatrist
	5. A retail pharmacist
	6. A hospital pharmacist
	7. A registered nurse
3. Members of the public:
	1. Medicaid member
	2. Member advocate
	3. Representative from the tribal community
4. AHCCCS Managed Care Organizations (MCOs) and Regional Behavioral Health Authority (RBHA) representatives:
	1. Three MCO Acute Plan Medical Directors or Pharmacy Directors or designees
	2. One MCO ALTCS Medical Director or Pharmacy Director or designee
	3. One RBHA Medical Director or Pharmacy Director or designee

**MEMBER APPOINTMENT PROCESS AND LENGTH OF TERM**

1. The AHCCCS Chief Medical Officer, Pharmacy Administrator, and the Medical Management Administrator or their designees are ex‐officio. The remaining fifteen committee members shall be appointed by the AHCCCS Chief Medical Officer for two year terms with the option of term renewal, for a maximum of four years.
2. The committee may submit to the AHCCCS Chief Medical Officer a list of nominees with expiring terms. The AHCCCS Chief Medical Officer may solicit or receive nominations from other sources.
3. AHCCCS has the sole discretion to appoint Committee members and may terminate the appointment of any member at any time during the term.

**MEETINGS**

1. The AHCCCS Chief Medical Officer or a designee is the committee's chairperson is responsible for setting meeting agendas. The chairperson can call special meetings. The chairperson shall preside at all meetings, and shall facilitate discussion by the members.
2. The Committee shall meet at least quarterly and may meet at other times at the discretion of the Chair or AHCCCS. Advance notice shall be provided to Committee Members of all meetings, both regular and special.
3. If a committee member is unable to attend a meeting, the member is requested to notify the Chair of their absence prior to the date of the meeting. Members are encouraged to send a delegate to meetings they are unable to attend. Members are required to notify the Chair with the name of the individual who will be attending on their behalf.
4. Pharmaceutical representatives may present clinical information in accordance with the Pharmaceutical Representative’s Comment Protocol when individual drugs and/or drug classes are scheduled for review at the Committee meeting in order to establish preferred agents on the AHCCCS Preferred Drug List to obtain supplemental rebates.
5. The AHCCCS supplemental rebate contractor may be present to assist the chairperson during meetings when supplemental rebate is a topic on the agenda.
6. The Committee is open to the public. However, executive sessions in which confidential information is discussed shall not be open to the public. Executive sessions are composed of only Committee members. The Chairperson shall adjourn to executive session when discussing this information.
7. Recorded minutes shall be the only formal recording of the activities of the Committee meetings. Telephonic attendance by members is permitted in accordance with these by-laws. Members participating by teleconference must be audible to all present so that their participation may be appropriately recorded in the minutes.
8. Minutes of the Committee's deliberations will be distributed prior to the next meeting and a formal approval process will be used to accept the minutes at the beginning of each meeting.
9. Committee meetings may be held by teleconference 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.

**SUBCOMMITTEES**

1. The Chairperson or AHCCCS may designate and appoint one or more subcommittees.
2. A minimum of two Committee members shall serve on each such subcommittee.
3. Other persons may participate as designated by the Chair.
4. No subcommittee shall have authority to amend, alter, or repeal this Policy, adopt any action contrary to the Committee, remove any member or take any action on behalf of the Committee or AHCCCS.
5. Any member of any subcommittee may be removed by the Chair or AHCCCS whenever the best interests of the Committee or the state will be best served by such removal.

**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 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 to the Committee.
3. A simple majority of voting members 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.
4. When a member must recuse him/herself from acting on any matter, that person shall not be counted for the purposes of determining a quorum.
5. Members must be present to vote on each matter submitted for a vote to the members. A member will be considered to be present if he or she attends in person or by teleconference or any similar communication method.
6. Members must regularly attend Committee meetings. Failure of a member to regularly attend Committee meetings or send a delegate shall be grounds for consideration of Committee membership termination.

**PUBLIC ATTENDANCE AND TESTIMONY**

1. Members of the public wishing to testify must register at the beginning of the meeting.
2. Registration to testify will include the name of the person wishing to testify, address and organization represented.
3. Testimony is time-limited to three minutes per person testifying.
4. In order to accommodate testimony from a variety of organizations and individuals, testimony is limited to one individual per organization or company on each agenda item.
5. Handouts may be distributed to the Committee, but audiovisual equipment is not allowed. Materials submitted for clinical review must be submitted to the AHCCCS pharmacy department, and promotional or marketing materials will be excluded. Written comments not to exceed two pages may also be submitted to AHCCCS pharmacy department.

**CONFLICT OF INTEREST**

1. Members must complete a Conflict of Interest disclosure form, provided by AHCCCS prior to attending their first Committee meeting and annually by July 1st of each year.
2. Members must update their Conflict of Interest disclosure statements any time their circumstances change in order to ensure their information is current.
3. Members cannot be employed by a pharmaceutical manufacturer or a pharmacy benefits management company.
4. Members cannot have a financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies.
5. Members must disclose to AHCCCS 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 becoming a member or participating on a work group.
6. A member must recuse him/herself from any discussion and decision making of an individual and/or entire drug class if he or she has a material conflict with the individual drug or drug in the class under review.

**CONTRACTS**

The Committee shall not enter into contracts, but may recommend that AHCCCS enter into such contracts as are necessary or proper to carry out the provisions and purposes of the work of the Committee. Such contract(s) may include engagements of independent legal, actuarial, clinical, research or other consultants.

**CHANGES TO COMMITEE OPERATIONAL PROCEDURES**

Amendment(s) of by-laws may be made at any meeting of the Committee by vote of a two-thirds majority of the members present, provided that written notice of the proposed amendment(s) is sent to AHCCCS at least ten business days prior to the meeting. AHCCCS will distribute this notice to the Committee members.

**EFFECTIVE DATE**

This AHCCCS P&T Committee Operational Policy was duly adopted at the meeting of the P&T Committee on the \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_.

This AHCCCS Committee Operational Policy was approved by the AHCCCS Policy Committee on the \_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_ at the AHCCCS Policy Committee meeting.

References:

Academy of Managed Care: Managed Care Terms 2016 at [www.AMCP.org/ManagedCareTerms/](http://www.AMCP.org/ManagedCareTerms/)