

DATE: April 16, 2019
To: Holders of the AHCCCS Contractor Operations Manual
FROM: Division of Health Care Management Contracts and Policy Unit
SUBJECT: AHCCCS Contractor Operations Manual (ACOM)

This memo describes revisions and/or additions to the ACOM.

Please direct questions regarding policy updates to the Contracts and Policy Unit at 602-417-4295 or 602-417-4055 or email at DHCMContractsandPolicy@azahcccs.gov.

UPDATES AND REVISIONS TO THE AHCCCS CONTRACTOR OPERATIONS MANUAL (ACOM)

To view the policies and attachments, please access the following link:

AHCCCS CONTRACTOR OPERATIONS MANUAL (ACOM)

POLICY 111, AHCCCS PHARMACY THERAPEUTICS COMMITTEE

ACOM 111 is a new policy which operationalizes the responsibility of the AHCCCS Pharmacy and Therapeutics Committee (Committee) in regards to evaluating scientific evidence of the relative safety, efficacy, effectiveness, and clinical appropriateness of prescription drugs.

○ **CONFLICT OF INTEREST DISCLOSURE FORM**

Conflict of Interest Disclosure Form is new and is to be utilized in the Committee Member Appointment Process as specified in Policy section III., B., 2.,a.

○ **POST-PUBLIC COMMENT CHANGES:**

Policy Section II., Definitions, have been revised as follows:

Business Day

A business day means a Monday, Tuesday, Wednesday, Thursday, or Friday unless a legal holiday falls on Monday, Tuesday, Wednesday, Thursday, or Friday.

COMMITTEE

The AHCCCS Pharmacy and Therapeutics Committee, as appointed by the Chief Medical Officer (***CMO***) or ***designee***.

SIMPLE-MAJORITY

~~Greater than 50%. With respect to conducting Committee business, a simple majority of all Committee members, as specified in this Policy, is necessary to constitute a quorum in order for the Committee to hold a meeting and conduct Committee business. Minimum number that is greater than 50%. With respect to approving a motion, a simple majority of the quorum present at the Committee meeting must vote in favor of the motion in order for the motion to be approved.~~ ***Committee members who are AHCCCS staff do not have voting rights.***

Policy Section III., A., 2., has been revised as follows:

2. 10 health care providers with active Arizona licenses in good standing and registered with AHCCCS (as applicable ***to the type of licensure***) including one from each of the following disciplines and/or specialties:
 - a. Family practice,
 - b. Internal medicine,
 - c. Obstetrics and Gynecology,
 - d. Pain management,
 - e. Pediatrics,
 - f. Pharmacist,
 - g. Psychiatry, and
 - h. Registered nurse.

Policy Section III., B., has been revised as follows:**B. COMMITTEE MEMBER APPOINTMENT PROCESS AND CONFLICT OF INTEREST**

1. Committee members who are AHCCCS staff, ~~or their designees~~, serve continuously and are non-voting members. AHCCCS staff, ~~or their designees~~, are counted for ***the*** purposes of determining whether or not a Quorum has been met in order to proceed with the Committee meeting. The remaining Committee members shall be appointed by the AHCCCS CMO for a two-year term with the option of ~~one~~ ***an additional*** single term renewal, for a ***four year*** maximum ~~of four years of total participation on the Committee.~~

2. Recruitment and selection of Committee member vacancies:
 - a. The AHCCCS website <https://www.azahcccs.gov/PlansProviders/Pharmacy/> ~~details~~ **provides** instructions for completion of the AHCCCS P&T Committee Application for Appointment and the Conflict of Interest Disclosure Form to be submitted to AHCCCS for consideration, and
 - b. Factors considered in AHCCCS' selection of Committee members include but are not limited to: the position **for which** they are applying ~~for, experience in, Arizona Medicaid~~ **experience**, and the submitted Conflict of Interest Disclosure Form.
3. AHCCCS has the sole discretion to appoint Committee members and may terminate the appointment of any member at any time.
4. Committee members shall not:
 - a. Be employed by, subcontract with, or directly or indirectly represent a pharmaceutical manufacturer,
 - b. Be employed by, subcontract with, or directly or indirectly represent ~~a pharmacy benefits management~~ **Pharmacy Benefits Management** (PBM) company, or
 - c. Receive payments or compensation from the pharmaceutical industry in excess of the physician mean general payment amount for the most recent year as specified on openpaymentsdata.cms.gov.
5. Before a Committee member participates in his/her first Committee meeting, Committee members shall submit the completed Conflict of Interest Disclosure Form and ~~identify~~ **disclose** any potential conflicts of interest with respect to their participation in Committee business.
6. Committee members shall update their Conflict of Interest Disclosure Form no less than annually from the date of first completion, and ~~as specified below when information in the Conflict of Interest Disclosure Form is~~ **additionally** no longer accurate. ~~Committee members shall update and submit their Conflict of Interest Disclosure Form within~~ later than 30 calendar days from any change to **the** information in the existing Conflict of Interest Disclosure Form. The form shall be submitted to AHCCCS at AHCCCSPharmacyDept@azahcccs.gov.
7. Committee members shall recuse themselves from any discussion, recommendation, or voting with respect to an individual drug and/or entire drug class if they have any potential conflict of interest concerning the individual drug or drug class under review.
8. Committee members shall complete annual conflict of interest training conducted by AHCCCS.

Policy Sections III., C., 4., 5., 6., and 7. a – c., have been revised as follows:

4. ***A teleconference line will be available for the public portion of the meeting.***
5. ***Committee members shall physically attend all meetings in-person. Telephonic attendance by Committee members is not permitted.***
6. Closed Sessions shall be held for the purpose of reviewing clinical information and proprietary financial information that pertain to preferred and non-preferred drug recommendations. Closed Sessions are confidential and are not open to the public. In addition, the Committee Chairperson ~~or designee~~ is responsible for calling the Closed Session ~~and the session~~ ***which*** shall be limited to Committee members and the AHCCCS supplemental rebate vendor staff. Closed Sessions are not controlled by A.R.S. §38-431.03.
- ~~5. A teleconference line will be available for the public portion of the meeting.~~
- ~~6. Committee members shall physically attend all meetings in person.~~
7. The Committee shall:
 - a. Review the AHCCCS Drug List, at a minimum, ~~annually~~ ***biennially***, or on an as needed basis,
 - b. Review new drugs and biosimilars on or about 180 days from the date the drug is commercially available. If the new drug is a new entry to a supplemental rebate class with preferred drug(s) listed on the AHCCCS Drug List:
 - i. The drug will be reviewed as a single agent if the supplemental rebate class' next review is scheduled for greater than 180 days from the date the new drug became commercially available, and
 - ii. The drug will be reviewed at the next scheduled supplemental rebate class' review if the supplemental rebate class' next review is less than 180 days from the date the new drug became commercially available.
 - c. ~~New~~ ***Review new*** drugs that are from a therapeutic class that is not currently listed as a supplemental rebate class with preferred drugs on the AHCCCS Drug List ~~shall be reviewed~~ in accordance with the following schedule:

NEW DRUGS COMMERCIALY AVAILABLE IN:	EXPECTED COMMITTEE MEETING FOR REVIEW:
January, February, March or April	May
May, June, July or August	October
September, October, November or December	January

Policy Sections III., C., 9., 10., 11., and 14, have been revised as follows:

9. On or about 30 days prior to the Committee meeting, the Committee members may obtain clinical information for therapeutic class reviews from the **website of the AHCCCS supplemental rebate vendor, Provider Synergies' website with a Synergies**, at <http://www.providersynergies.com/services/medicaid/default.asp?content=Arizona>. A secure username and password **is required**.
10. On or about seven days prior to the Committee meeting:
 - a. The Committee members will be provided an agenda and meeting materials, and
 - b. AHCCCS shall post **on the AHCCCS website**, the agenda with the list of approved speakers ~~on the AHCCCS website~~.
11. If a Committee member is unable to attend a meeting, the member is required to send email notification of the absence **as soon as possible prior to the meeting** to AHCCCSPharmacyDept@azahcccs.gov.
14. ~~To eliminate undue influence and potential conflicts of interest, individuals~~ **Individuals** described in Section **III., G** are prohibited from contacting AHCCCS P&T Committee members to discuss the individual drugs or therapeutic classes ~~that will to~~ be reviewed ~~by the~~ **at AHCCCS P&T Committee meetings**. However, those individuals are permitted to submit written testimony as described in Section **III., G**.

Policy Sections III., E., 1., and 3., have been revised as follows:

1. A Quorum is necessary for the Committee to hold a meeting and transact business. A minimum of 12 **of the 23** Committee members shall be present to constitute a Quorum to conduct Committee business.
3. Voting Committee members, ~~excluding,~~ shall have one vote on each matter submitted to vote to the Committee. **AHCCCS staff on the Committee are non-voting members.**

Policy Section III., F., has been revised as follows:

- F. Public Testimony **Provided To The Committee** By Individuals ~~Other Than Those Not~~ Described In **Section III., G**
 1. Individuals who are not Committee members and who are not ~~otherwise~~ described in Section III., (G) are permitted to present testimony to the Committee as representatives of the public **as set forth below**. In order to present testimony, whether written or verbal, the representative of the public shall not:
~~Be employed by, subcontract with, or be~~ directly or indirectly represent a **employed by, contracted with, or speaking on behalf of** pharmaceutical manufacturers, **PBMs**,

- ~~lobbyists for these entities, or subcontractors of these entities. Be employed by, subcontract with, or directly or indirectly represent a PBM company, or Receive~~
2. ***Any physician who receives*** payments or compensation ~~from the pharmaceutical industry~~ in excess of the physician national mean ~~general payment amount~~ ***for their specialty as reported*** for the most recent ***available*** year as specified, on ***the CMS Open Payments Database*** at openpaymentsdata.cms.gov ~~As of 02/13/19, the 2017 data was the most recent information available and the physician national mean amount is \$3,307.06.~~ ***limited to providing written testimony. Oral testimony is not permitted.***

~~In-person verbal testimony~~

3. ~~The~~ ***Individuals, who receive payment(s) or compensation from pharmaceutical manufacturers, PBMs, or lobbyists for these entities or subcontractors of these entities, are limited to providing written testimony. Oral testimony is not permitted.***
4. ***In-person oral testimony by representatives of the public may present testimony as set forth below.***
- In order to present oral testimony the*** individual ~~requesting to provide in-person verbal testimony~~ ***shall be physically present at the committee meeting,***
 - The representative*** shall complete the Public Testimony Registration Form and the Conflict of Interest Form on the AHCCCS website at:
<https://www.azahcccs.gov/PlansProviders/Pharmacy/> no later than 14 business days prior to the meeting,
 - Registration is available on a first-come, first-serve basis and ~~is limited to 15 total presenters per meeting,~~ ***shall be no more than 20 total presenters per meeting. At the discretion of the Committee Chairperson, the total number of individuals who are permitted to provide oral testimony may be adjusted based on the Committee meeting agenda and time constraints,***
 - Testimony is limited to one individual per organization per drug,
 - Individuals who present ***testimony*** shall sign in at least 10 minutes prior to the start of the meeting ~~otherwise.~~ ***Failure to do so may result in the individual may not be being*** permitted to present comments,
 - The Committee Chairperson will recognize the speakers in alphabetical order of the drugs listed in the therapeutic class being reviewed,
 - Speakers may provide comments ~~verbally~~ ***orally*** and through written handouts provided to Committee members at the meeting,
 - Speakers are limited to comments that do not exceed three minutes in length per drug,
 - Questions or comments from the Committee will not be entertained unless the Committee Chairperson grants approval for questions or comments from the Committee members, and

- j. The Committee Chairperson may suspend or elect to not offer the comment process for reasons including, but not limited to, speaker noncompliance with the comment process, time constraints, and/or quality of the information presented.
5. Written testimony
 - a. The individual requesting to provide written testimony shall complete **and submit** the Public Testimony Registration Form and the Conflict of Interest Form on the AHCCCS website at <https://www.azahcccs.gov/PlansProviders/Pharmacy/> no later than 14 business days prior to the meeting, and
 - b. Written testimony is limited to one individual per organization on each agenda item and shall not exceed ~~one page~~ **two pages**.

Policy Sections III., G., 1., 2., 3., and 4., have been revised as follows:

- G. ***Testimony Provided to the Committee by Representatives of Pharmaceutical Manufacturers, PBMs, Lobbyists And Other Related Companies Including Subcontractors' Testimony Related Entities***
1. Testimony ***provided to the Committee*** by a ~~representative, who may be directly or indirectly employed by or contracted with a~~ ***representatives of*** pharmaceutical manufacturer, PBM, lobbyist, or other related companies including Subcontractors, ***manufacturers, PBMs, and related entities*** is limited to written testimony. ~~In person verbal~~ ***Oral testimony by these representatives*** is not permitted. ~~Representatives as described in~~ ***For purposes of Section III., G. 1., representatives are individuals who are directly or indirectly employed by, or contracted with, or speaking on behalf of pharmaceutical manufacturers, PBMs, lobbyists for these entities, or subcontractors of these entities.***
 2. ***Representatives of pharmaceutical manufacturers, PBMs, and related entities*** who wish to submit written testimony to the Committee shall submit information to the AHCCCS Supplemental Rebate Vendor at: pswebmail@magellanhealth.com no later than 30 business days prior to the meeting.
 3. All clinical information submitted shall include a one-page cover sheet 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 shall be cited.
 4. Written content submitted by a ***representative of*** pharmaceutical ~~manufacturer or PBM~~ ***manufacturers, PBMs, and related entities*** is limited to drugs relevant to the drug classes specified in the meeting agenda.

APPROVED NOT YET EFFECTIVE

To view the policies and attachments, please access the following link:

ACOM APPROVED NOT YET EFFECTIVE

None at this time.