Amended August 11, 2021 by the Drug Review Committee

DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL SERVICES

ARKANSAS MEDICAID DRUG REVIEW COMMITTEE BYLAWS

Legal Authority

The Arkansas Medicaid Drug Review Committee (DRC) for the Preferred Drug List (PDL) of the Arkansas Medicaid Pharmacy Program ("Committee"), Division of Medical Services (DMS) of the Arkansas Department of Human Services (DHS) is established under the authority of § 240.000 of the Pharmacy Provider Manual.

Vision Statement

The Arkansas Medicaid Pharmacy Program maintains a Preferred Drug List (PDL) based on comparative evidence-based data from Clinical Evidence Reports (CER). The Drug Review Committee is charged with reviewing the CER to determine the safety and efficacy of medicines. The DRC will provide recommendations to the State for preferred and non-preferred status for the identified medications. The Arkansas Medicaid program will use these recommendations in conjunction with the recommendations of the Drug Cost Committee (DCC) to establish and maintain the Preferred Drug List.

Mission Statement

The Drug Review Committee (DRC) is established to serve the Medicaid Pharmacy Program in an advisory capacity for the purpose of developing and making recommendations on the status of drugs on the Preferred Drug List (PDL). The purpose of the PDL is to provide appropriate, safe, and effective pharmaceutical care to Medicaid beneficiaries in a cost-effective manner.

I. DRC Structure

1.01 Name – This body shall be known as the Arkansas Medicaid Drug Review Committee, hereinafter referred to as the DRC.

1.02 Composition – The composition of the DRC shall include licensed professionals from a cross-section of healthcare practice who are recognized for their knowledge and expertise in the appropriate prescribing and dispensing of prescription drugs, including the review of comparative evidence-based data from Clinical Evidence Reports (CER).

The voting membership of the DRC shall be composed of at least one-third (1/3) but no more than fifty-one (51%) licensed and actively practicing* physicians and at least

one-third (1/3) shall be licensed and actively practicing* pharmacists. “Actively participating” is defined as maintaining an active license with the respective licensing board and may include advising, consulting, and providing information concerning appropriate utilization of drugs.

The Arkansas Medicaid DRC shall be composed of:

(1) Three (3) licensed and actively practicing physicians
(2) Four (4) licensed and actively practicing pharmacists, and
(3) One (1) non-voting member nominated by each Provider-Led Arkansas Shared Savings Entity (PASSE) subject to written approval by the Director of DHS. Each PASSE representative should serve as the Pharmacy or Medical Director of that PASSE.

1.03 Appointment – The Director of the Arkansas Department of Human Services, with input from Medicaid leadership, shall appoint DRC members, fill any vacancy on the DRC and shall designate staff assistance to the DRC and its Officers for the routine conduct of business. The members will be chosen by considering specialty, board certification, prior pharmacy and therapeutics experience, state residency, experience treating Medicaid Recipients, absence of conflicts of interest, ability to represent a broad base of constituents, and number of years in practice.

1.04 Term of Office – DHS will appoint DRC members for three (3) year terms. In its discretion, DHS may reappoint current DRC members for a consecutive term or terms. DHS in its discretion may also remove committee members. Any DRC member who is unable to fulfill his/her term on the DRC shall provide written notice to the Chairperson prior to resignation. In the event that any DRC member is removed from membership, resigns, or is unable to fulfill his/her term on the DRC, a new member will be appointed to a vacancy on the DRC for a three (3) year term. Appointments shall be staggered to minimize the loss of multiple members at the same time.

1.05 Attendance – Regular and meaningful participation in the meetings is important in fulfilling the purpose of the DRC.

Each voting and non-voting DRC member is expected to attend all Committee meetings, unless otherwise excused by the Chairperson. Members who have two (2) consecutive unexcused absences per fiscal year may be removed from the DRC, at the discretion of the Director of the Department of Human Services.

Each member of the DRC is required to be present in-person or virtually for the entire meeting. Members are required to be present at the start of the meeting for the required reading of the Disclosure of the Conflicts of Interest statements. Members entering the meeting 20 minutes after the commencement of the meeting or later, will be considered late for that meeting. A member who is late more than two (2) times in a state fiscal year may be removed from the DRC.

1.06 Ethics and Disclosure of Conflict of Interest— Pursuant to Ark. Code Ann. §§ 21-8-1001 and 21-8-301, members of a state board are required to disclose conflicts of interest. Specifically, no member of a state board shall participate in, vote on, influence, or attempt to influence an

official decision, if the member has a pecuniary interest in the matter under consideration by the board. Accordingly, each DRC member shall review the agenda at each meeting and determine if a conflict of interest exists based on the criteria outlined below. Regardless of whether a conflict of interest exists, each member shall complete, sign and submit a Disclosure of Conflict of Interest form to the Chairperson at the beginning of the meeting, wherein any conflict of interest or lack thereof shall be disclosed. It is the individual DRC member's responsibility to ensure that this form is completed and submitted at the beginning of the meeting. A DRC member shall not enter into discussion or vote on any agenda items until the signed disclosure of conflicts of interest has been submitted.

All conflicts of interest disclosures shall be read into the record and documented in the minutes at the DRC meetings. Members who have disclosed a conflict of interest shall not participate in the discussion or vote on the matter at hand. The Director of DHS, in his/her discretion, may remove from the Committee any member who recuses from discussion or deliberation of three (3) or more drug classes during a state fiscal year.

DRC members are expected to address matters before the DRC in an unbiased and professional manner, while maintaining the highest ethical standards. A conflict of interest exists when a DRC member possesses personal, financial, or professional interests that compete, conflict or otherwise interfere with the DRC member's actual or perceived ability to act in the best interests of DHS or such member's ability to address in a fair and impartial manner any matter under consideration by the DRC. A nominee for appointment to the DRC or a DRC member must disclose any personal or professional relationships (and those of any immediate family members, including parents, spouse, siblings, and children) which may give rise to the appearance of and/or create an actual conflict of interest based on the nominee's membership on the DRC or matters which may be under consideration by the DRC.

To avoid the appearance of, or actual, conflicts of interest, DRC members shall not meet with pharmaceutical manufacturers, distributors or retailers or their representative with respect to any matters which are known to be under review by the DRC.

1.07 Stipend – DRC Members are eligible to receive a $300 reimbursement for his/her services for each meeting attended. Committee members must complete and return a hiring packet to receive the stipend.

II. DRC Meetings

2.01 Regular Meetings – The DRC shall hold quarterly meetings in the City of Little Rock, generally on the second Wednesday of the month during the months of February, May, August, and November. Meetings may be held virtually as needed. Depending upon the availability of members and the agenda, the meeting time shall generally be from 9:00 am to 12:00pm and may be extended to 1:00pm as needed. Notice of the date and time of regular quarterly meeting shall be given in accordance with these bylaws. The date and time of Committee meetings may be changed, so long as proper notice is given pursuant to these bylaws. Additional meetings may be held on an *ad hoc* basis, at the discretion of the Chairperson.

2.02 Meeting Notice – Each DRC member shall file and update their contact information with the Chairperson of the Committee including the address, telephone number(s), fax number(s), and email to which meeting notices are to be sent. Written notice of all regular meetings shall be sent via email to each committee members, at least six (6) weeks prior to the meeting. Notice of *ad hoc* meetings shall be sent to the DRC members at least forty-eight (48) hours prior to the time of the special meeting and shall include the time and place of the meeting.

The Medicaid Pharmacy Program shall give reasonable advance public notice of the time and place of each meeting. The public notice shall consist of the DRC meeting agenda posted on the Medicaid Pharmacy Program website https://arkansas.magellanrx.com/provider/documents/. DRC meeting agendas will be posted on the Arkansas Medicaid Pharmacy website six (6) weeks prior to the Committee meetings. Special Meeting agendas will be posted as soon as practicable.

2.03 Quorum – Quorum shall depend upon the number of active voting members who are present at a DRC Meeting. If the DRC has seven (7) total members, a quorum shall consist of four (4) voting members.

2.04 Conduct of Business – The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the DRC in all cases in which they are applicable, to the extent that they are not inconsistent with the laws of Arkansas, these bylaws, or any special rule which the DRC may adopt. The DRC shall be assisted in carrying out its administrative duties, including the maintenance of minutes and records, by staff designated by the Director of DHS/DMS or his/her designee.

III. DRC Purpose

3.01 Purpose – The Committee serves in an advisory role to the Medicaid Pharmacy Program. The Committee shall review manufacturer's drug information, drug evaluations, Therapeutic Class Reviews (TCR), Clinical Evidence Reports (CER), evidence-based comparative reports and any other relevant information to make unbiased clinical recommendations as to whether selected drugs should have "preferred status" or "non-preferred status" in the PDL and recommend any associated criteria. The Committee shall consider efficacy, comparative effectiveness, safety, and other relevant clinical information in making recommendations. The DRC shall also recommend drug classes to be considered in the future, for placement on the PDL.

3.02 Interaction with the Drug Cost Committee (DCC) of the Medicaid Pharmacy Program – The DCC is an internal committee within the Arkansas Department of Human Services. DCC meetings are closed meetings and not open to the public. The DCC shall meet following the DRC meeting. Confidential and proprietary information, such as State supplemental rebate contract offers, CMS rebate amount, and the final net cost to the state, shall be reviewed in closed sessions. The DCC shall make a recommendation to the Medicaid Pharmacy Program Director for the most cost-effective selections for preferred status on the PDL. If any additional prior approval criteria or other edits on PDL drugs are needed, these will be made by the DUR Board.

IV. DRC Officers

4.01 Officers – The DRC shall have a Chairperson. The Director of DHS or his/her designee shall appoint a Pharmacist from the Medicaid Pharmacy Program to serve as Chairperson. The Director of DHS or his/her designee shall also designate staff assistance to the DRC to act as Secretary for the routine conduct of its business.

4.02 Duties of Officers— The Chairperson shall facilitate meetings to ensure that the Committee proceeds fairly and professionally to implement its responsibilities for the PDL process. The Chairperson shall confer with the Medicaid Pharmacy Program vendor representative responsible for the PDL or his/her designee on agenda items in advance of each meeting and perform other duties which may be delegated by the DRC and approved by the Director of DHS.

V. DRC Documents

5.01 Official Papers – All official records of the DRC shall be kept on file at DHS and shall be open to public inspection. All files shall be maintained for five years.

5.02 Minutes and Provider Notification – The DRC meeting minutes and the provider memoranda, which is a joint report from the Drug Utilization Review (DUR) Board and the Drug Review Committee (DRC), will be posted on the Arkansas Medicaid Pharmacy website, within two (2) weeks of the conclusion of the DRC Meeting.

VI. Public Participation

6.01 Public Participation – Citizens may attend all DRC meetings. The DRC may make and enforce reasonable rules regarding the conduct of persons attending its meeting.

6.02 Outside Speakers -- Outside speakers with clinical or scientific credentials or patient experience pertinent to a product or topic that is posted on the upcoming DRC meeting agenda may request to speak on that product or topic. Requests to speak at the DRC meeting must be made in writing to the Chairperson at least two (2) weeks before the DRC meeting date, and must specify:

(1) The speaker's name, title, and organization;
(2) Contact information for the speaker including address, telephone number, and email;
(3) The agenda item(s) which the speaker intends to address;
(4) Prepared comments not to include any manufacturer's package insert; and
(5) An electronic copy of any presentation materials the speaker intends to use, if any.

This information shall be included in information sent to Committee members two (2) weeks prior to the Committee meeting. Presentations or public comments given at the DRC meeting are limited to a total of two (2) minutes per drug, which may be shared by multiple speakers. This time limit does not include responses to any questions raised by DRC members during the course of the meeting.

6.03 Pre-Committee Meeting Input to DHS – Interested parties for products or topics listed on the quarterly meeting agenda may reach out to the Arkansas Medicaid Pharmacy Program after the agenda is posted to request a meeting with staff prior to the DRC meeting. These meetings may be held in-person or by conference call up to three (3) weeks prior to the DRC meeting and shall be no longer than 30 minutes in duration. These meetings will be disclosed to the DRC, along with any written materials provided in the meetings, as part of the information provided to members two (2) weeks prior to the quarterly meeting.

6.04 Industry Communication – Pharmaceutical representatives shall not contact DRC members directly in an attempt to influence voting on an agenda item when a drug class has been announced for review.

VII. Revision and Compliance

7.01 Amendments – The bylaws of the DRC may be amended, unless the amendment is inconsistent with State or Federal law, at any regular meeting of the DRC by a majority vote, provided that the proposed amendment was submitted in writing at the previous meeting of the DRC and is included in the notice of the meeting at which a vote is to be taken.

7.02 Review – The bylaws shall be reviewed in total at least every two (2) years, with a limited annual review for compliance with Section 4401, 1927(g) of the Omnibus Reconciliation Act of 1990. The Chairperson shall make copies available as necessary, after incorporation of any approval revisions. The bylaws shall be signed and dated to indicate the time of last review.

7.03 Effective Date – The foregoing bylaws shall go into effect on the ___11th___ day of August__, 2021____.

Approved:

Cinnamon Pearson, Pharm.D._____
Chairperson, Arkansas Medicaid Drug Review Committee

Date: _____8/11/2021_____

ARKANSAS DEPARTMENT OF HUMAN SERVICES

DISCLOSURE OF CONFLICT OF INTEREST

Arkansas Code Annotated § 21-8-1001 and §21-8-301, require members of a state board to disclose conflicts of interest. Specifically, no member of a state board shall participate in, vote on, influence, or attempt to influence an official decision if the member has a pecuniary interest in the matter under consideration by the board. Therefore, it is a requirement of each Drug Review Committee member to review the agenda at each meeting and determine if a conflict of interest exists. If so, a Disclosure of Conflict of Interest form must be completed.

If a **Drug Review Committee** member reasonably suspects to either sustain a financial loss or obtain a financial gain as a result of his/her involvement of an item on the DRC agenda, then it is the responsibility of the member to disclose the conflict of interest.

I,_____, on _____, 20_____, have reason to
[Print name] [Date] [Year]

suspect that a conflict of interest exists due to agenda item

_____

_____

_____

(insert a description of the item on the agenda.) Therefore, I shall not participate in, vote on, influence, or attempt to influence an official decision for the item(s).

I,_____, on _____, 20_____, have **NO**
[Print name] [Date] [Year]

reason to suspect that a conflict of interest exists for any agenda items.

Signed: _____ Date: _____