Amended July 17, 2024 by the Drug Utilization Review Board

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES
OUTPATIENT PRESCRIPTION DRUG PROGRAM
DRUG UTILIZATION REVIEW (DUR) BOARD BYLAWS

Legal Authority

The Drug Utilization Review Board of the Arkansas Medicaid Pharmacy Program, Division of Medical Services (DMS) Department of Human Services (DHS) is established under the authority of 42 U.S.C. §1396r–8(g)(3) and 42 CFR § 456.716. State DUR Board Requirements are listed in the Code of Federal Regulations (CFR) at 42 CFR §456.716, which outlines member qualifications, Board composition, Board activities, and funding for the Board.

DUR Board Vision Statement

Arkansas Medicaid beneficiaries receiving prescription drug benefits under Title XIX of the Social Security Act shall receive therapeutically and medically appropriate pharmacy care utilizing screening and edits to prevent potential drug therapy problems, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. The Preferred Drug List (PDL) is maintained by the Arkansas Medicaid Pharmacy Program. This Board will review Clinical Evidence Reports (CER) to determine the safety and efficacy of medications under review, and the Board will make recommendations to the State for preferred and nonpreferred status.

DUR Board Mission Statement

The Arkansas Medicaid Drug Utilization Review Board shall strive to improve the quality of care of Arkansas Medicaid beneficiaries receiving prescription drug benefits under Title XIX of the Social Security Act and shall strive to conserve program funds while ensuring therapeutically and medically appropriate pharmacy care for our beneficiaries. The Board shall serve the Medicaid Pharmacy Program in an advisory capacity for the recommendations on the PDL. The purpose of the PDL is to provide appropriate, safe, and effective pharmaceutical care to Medicaid beneficiaries in a cost-effective manner.

I. DUR Board Structure

1.01 Name—This body is the combination of the Arkansas Medicaid Drug Utilization Review Board and Drug Review Committee, hereinafter referred to as the Drug Utilization Review Board, or DUR Board or the “Board”.

1.02 Composition—Pursuant to 42 CFR §456.716(b), the composition of the DUR Board shall include licensed professionals from a cross-section of healthcare practice who are recognized for their knowledge and expertise in the appropriate prescribing, dispensing, and/or monitoring of Medicaid-covered outpatient prescription drugs, including drug use review, evaluation, intervention, comparative evidence-based data, and medical quality assurance. Additionally, the State Health Officer and the DHS Medical Director may attend the meeting in an advisory capacity only. The State Health Officer and the DHS Medical Director may send a designee as a substitution with approval from the State.

The voting membership of the DUR Board shall be composed of at least one-third (1/3) but no more than fifty-one percent (51%) licensed and actively practicing physicians and at least 1/ 3 of the Board members shall be licensed and actively practicing pharmacists. "Actively practicing" 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 DUR Board shall be composed of:

(1) Five (5) licensed and actively practicing physicians, with preferably one psychiatrist, one gerontologist and one pediatrician on the Board depending on availability; and
(2) Two (2) licensed and actively practicing physicians or advanced practice registered nurses currently treating rare diseases or conditions; and
(3) Seven or eight (7 or 8) licensed and actively practicing pharmacists; and
(4) One (1) non-voting member nominated by each Provider-Led Arkansas Shared Savings Entity (PASSE) subject to written approval by the Arkansas Medicaid Director. Each PASSE representative should serve as the Pharmacy or Medical Director of that PASSE.

1.03 Appointment ---The Arkansas Medicaid Director, with input from Medicaid leadership, shall appoint DUR Board members, fill any vacancy on the Board and shall designate staff assistance to the Board and its Officers for the routine conduct of its business.

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

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

Each voting and non-voting member of the DUR Board is required to attend a minimum of three (3) out of four (4) meetings per state fiscal year from July 1 – June 30. Members who miss more than one (1) meeting per fiscal year may be removed from the DUR Board, at the discretion of the Arkansas Medicaid Director.

Each member of the Board 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 at 9:00am 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 Board.

1.06 Ethics and Disclosure of Conflict of Interest—Members of the Arkansas Medicaid DUR Board are required to disclose conflicts of interest. Specifically, no member of the DUR 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 DUR Board 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 DUR Board member's responsibility to ensure that this form is completed and submitted at the beginning of the meeting. A DUR Board 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 DUR Board meetings. Members who have disclosed a conflict of interest shall not participate in the discussion or vote on the matter at hand. The Arkansas Medicaid Director, in his/her discretion, may remove from the Board any member who recuses from discussion or deliberation of three (3) or more drug classes during a state fiscal year.

DUR Board members are expected to address matters before the Board in an unbiased and professional manner, while maintaining the highest ethical standards. A conflict of interest exists when a DUR Board member possesses personal, financial, or professional interests that compete, conflict or otherwise interfere with the DUR Board 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 DUR Board. A nominee for appointment to the Board or a DUR Board 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 DUR Board or matters which may be under consideration by the DUR Board.

To avoid the appearance of, or actual, conflicts of interest, DUR Board 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 DUR Board.

1.07 Stipend – DUR Board members are eligible to receive a $100 reimbursement for his/her services for each meeting attended. Board members must complete a hiring packet to receive the stipend.

II. DUR Board Meetings

2.01 Regular Meetings – The DUR Board shall hold quarterly meetings, generally on the third Wednesday of the month during the months of January, April, July, and October. Meetings are open to the public and may be held in-person in Little Rock and/or virtually. Meeting information whether in-person or virtual will be provided on the posted agenda prior to each meeting. Depending upon the availability of members and the agenda, the meeting time shall generally be from 8:30am to 11:30am and may be extended to 12:30pm as needed. Notice of the date and time of regular quarterly meetings shall be given in accordance with these bylaws.

2.02 Special Meetings – If the DUR Board is unable to work through the entire agenda during the regular quarterly meeting, any remaining decisions on prior authorization criteria or review of Prospective/Retrospective Drug Utilization Review topics will require a supplemental special meeting or reconsideration during the next quarterly meeting, depending on time sensitivity of the outstanding reviews as determined by the Chairperson and a majority of the DUR Board. The DUR Board may meet at such other times and places as the Chairperson determines to be necessary and appropriate. The Chairperson must notify each DUR Board member of the meeting at least forty-eight (48) hours prior to the time of the special meeting.

2.03 Meeting Notice – Each DUR Board member shall file and update their contact information with the Chairperson of the DUR Board 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 board member, six (6) weeks prior to the meeting. Notice of special meetings shall be sent to the DUR Board 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 provide public notice with one year advanced notice of scheduled quarterly meetings. DUR Board regular meeting agendas will be posted on the Arkansas Medicaid Pharmacy website and as public notice on the DHS website six (6) weeks prior to the DUR Board meeting. Special meeting agendas will be posted as soon as practicable.

2.04 Quorum – Quorum shall depend upon the number of active voting members who are present at a DUR meeting. If the DUR Board has fifteen (15) active voting members, a quorum shall consist of eight (8) voting members.

2.05 Conduct of Business – The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the DUR Board 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 DUR Board may adopt. The DUR Board shall be assisted in carrying out its administrative duties, including the maintenance of minutes and records, by staff designated by the Division of Medical Services (DMS) Director.

III. DUR Board Purpose and Authority

3.01 Purpose

The purpose of the Board is to advise the State Medicaid Agency on matters as outlined and described below:

(1) Federally required Medicaid Drug Utilization Review Program duties under 42 CFR § 456.703;
(2) Prospective drug utilization review (ProDUR) in compliance with 42 CFR § 456.716(d)(2) of use of restrictions or clinical prior authorization criteria on covered prescription drugs using recommended predetermined standards to monitor potential drug therapy problems;
(3) Retrospective DUR (RDUR) in compliance with 42 CFR § 456.716(d)(3) to identify standard care provided by healthcare professions with prescribing authority while permitting sufficient professional prerogatives to allow for individualized drug therapy;
(4) Educational interventions for Medicaid providers to improve prescribing and dispensing practices and effectively improve the quality of drug therapy in compliance with 42 CFR § 456.716(d)(5) and 456.716(d)(6);
(5) PDL review of the preferred and nonpreferred status while reviewing manufacturer's drug information, drug evaluations, therapeutic class review (TCR), Clinical Evidence Reports (CER), and evidence-based comparative reports.
(6) Other matters that may be specified by law and within the Board's jurisdiction.

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3.02 Powers and Duties –The DUR Board shall make recommendations to the Arkansas Medicaid Pharmacy Program regarding the following activities in order to fulfill the vision, mission, and purpose of the DUR Board. The Drug Cost Committee (DCC) is an internal DHS committee that reviews confidential and proprietary information, such as State supplemental rebate contract offers, CMS rebate amount, and final net cost to the state on PDL classes. The DCC shall make recommendations to the Arkansas Medicaid Pharmacy Program regarding cost effective options.

The State Medicaid Agency retains the authority to accept, reject, or amend the recommendations of the DUR Board and/or DCC.

3.03 Prior Approval Drug Criteria—The DUR Board shall **r**eview proposals for prior approval criteria algorithms for drugs covered by Arkansas Medicaid Pharmacy Program ("Program") and provide recommendations for approval to the program regarding the algorithms. The DUR Board shall consider the following factors in prior approval drug criteria:

(1) Differing but acceptable modes of treatment,
(2) Methods of delivering care within the range of appropriate diagnosis,
(3) Treatment of the patient's health condition consistent with professionally recognized and evidence-based patterns of care, and
(4) Consideration of Medicaid's obligation to pay only for care that is in fact medically necessary and delivered efficiently and economically.

Any new FDA approved medication or new label expansion released prior to placement on the DUR Board agenda will be reviewed with a prior authorization request using the manufacturer's package insert and treatment guidelines for guidance.

3.04 Role of Retrospective Drug Utilization Review (RDUR) Contractor—The RDUR Contractor shall provide for an ongoing periodic examination as outlined in the contract of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under Title XIX, or associated with specific drugs or groups of drugs. Pursuant to 42 U.S.C. **§**1396r–8(g)(3)(C)(iii), the RDUR Contractor shall provide ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of Retrospective Drug Utilization Review by the RDUR Committee. Intervention programs shall include, in appropriate instances, at least the four methods of communication outlined in 42 U.S.C. **§**1396r–8(g)(3)(C)(iii). The DUR Board shall re-evaluate RDUR contractor criteria interventions, claim edits, and clinical edits after an appropriate period of time to determine if the intervention or edit improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

3.05 Role of the DUR Board in Retrospective Drug Utilization Review (RDUR) —Pursuant to 42 U.S.C. **§**1396r–8(g)(2)(C), the DUR Board shall review data presented on drug use using explicit predetermined standards including but not limited to therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse. Following review, the DUR Board shall recommend claim edits or clinical criteria edits in order to improve the quality of care of the individuals that are receiving benefits under this title and to conserve program funds.

When developing prior authorization criteria or edits, the DUR Board shall take into consideration CMS Release #141 Compendia Clarification and 42 U.S.C. **§**1396r–8(k)(6), which defines 'medically accepted indication' to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia described in subsection (g)(1)(B)(i) – the American Hospital Formulary Service Drug Information, United States Pharmacopoeia-Drug Information (or its successor publications), and the DRUGDEX Information System. The Social Security Act requires coverage of off-label uses of FDA-approved drugs for indications that are

supported (as opposed to listed) in the compendia specified in 42 U.S.C. **§** 1396r–8(g)(1)(B)(i). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia.

3.06 Prospective Drug Utilization Review—Pursuant to 42 CFR § 456.716(d)(2), the DUR Board shall review and approve edits used in screening drug claims at the point-of-sale or point of distribution for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

3.07 Application of Standards for Drug Utilization Review Program— The DUR Board shall use predetermined standards consistent with the compendia and literature referred to in 42 U.S.C. **§** 1396r–8(g)(1)(B)(i): American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), the DRUGDEX Information System, or peer-reviewed medical literature. For application of standards regarding prior authorization criteria, see section 3.03.

3.08 Educational program— The DUR Board shall review, approve, or make recommendations on common drug therapy problems identified through utilization for intervention criteria for specific drugs or groups of drugs to the RDUR contractor. The RDUR contractor shall follow-up by providing educational efforts to providers when the RDUR contractor has identified a pattern regarding potential abuse, gross overuse, or inappropriate or medically unnecessary care for individuals receiving benefits under this title. The DUR Board shall approve intervention criteria for the RDUR contractor for active and ongoing educational outreach programs to educate practitioners, with the aim of improving prescribing or dispensing practices.

3.09 Annual Report—Pursuant to 42 U.S.C. **§** 1396r–8(g)(3)(D), the Chairperson of the DUR Board or designee shall prepare a report on an annual basis consisting of a description of the activities of the DUR Board, including the nature and scope of the prospective and retrospective drug utilization review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, an update on PDL, and an estimate of the cost savings generated as a result of the DUR Board. Each PASSE will also prepare an annual report and provide it to the DUR Board. The State shall submit all reports on an annual basis to the Federal Secretary.

IV. DUR Board Officers

4.01 Officers – The DUR Board shall have a Chairperson. The Arkansas Medicaid Director or his/her designee shall appoint a pharmacist from the Medicaid Pharmacy Program to serve as Chairperson. The DMS Director or his/her designee shall designate staff assistance to the DUR Board to act as Secretary for the routine conduct of its business.

4.02 Duties of Officers—The Chairperson of the DUR Board or designee shall preside at all meetings of the DUR Board, prepare recommendations for review by the DUR Board including clinical and quantity edits on new medications or drug classes, confer with the Medicaid Pharmacy Provider vendor representative responsible for the PDL in advance of the meeting, and perform other duties which may be delegated by the DUR Board and approved by the Arkansas Medicaid Director.

V. Committees

Section 5.01 Committees – Committees may be designated at any time by action of the Chairperson and a majority of the voting Board members. Such committees shall be formed when necessary for the efficient functioning of the DUR Board. The Chairperson shall appoint members to a committee and a committee chairperson from among membership of the DUR Board. In creating such committees, the Chairperson shall specify the time within which the committee is to make its report(s) to the DUR Board.

VI. DUR Board Documents

6.01 Official Papers – All official records of the DUR Board shall be kept on file at DHS and are subject to FOIA. All files shall be maintained for five years.

6.02 Minutes and Provider Notification – The DUR Board drafted meeting minutes and the provider memoranda will be posted on the Arkansas Medicaid Pharmacy website, no later than 30 days after the conclusion of the DUR Board Meeting.

VII. Public Participation

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

7.02 Outside Speakers -- Outside speakers with clinical or scientific credentials or patient experience pertinent to a product or topic that is posted on the upcoming DUR Board meeting agenda may request to speak on that product or topic. Public comments will not be permitted for topics not included on the agenda. Requests to speak at the DUR Board meeting must be made in writing to the DUR Chairperson at least two (2) weeks before the DUR Board meeting date, and should include:

(1) The speaker's name, title, relevant credentials, 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 which are not a reiteration of the FDA approved package insert; and
(5) Any educational materials for Board members in advance of the meeting.

This information shall be included in information sent to Board members two (2) weeks prior to the Board meeting. Presentations or public comments given at the DUR Board meeting are limited to a total of three (3) minutes per drug, which may be shared by multiple speakers. This time limit does not include responses to any questions raised by DUR Board members during the course of the meeting.

A copy of the proposed criteria for the specific agenda item on which an individual requests to speak may be requested from the Chairperson three (3) weeks prior to the DUR Board meeting. The information will be in draft form and may be changed by the DUR Board prior to being finalized. As such, the draft criteria should not be shared with clinicians or patients.

7.03 Pre-Board 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 via the DUR Board Chairperson after the agenda is posted to request a meeting with staff prior to the DUR Board meeting. These meetings may be held in-person or by conference call up to three

(3) weeks prior to the DUR meeting and shall be no longer than 30 minutes in duration. These meetings will be disclosed to the DUR Board, 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.

7.04 Industry communication – DUR Board members should refrain from discussing agenda topics with pharmaceutical representatives to prevent any potential bias in voting on agenda issues.

VIII. Revision and Compliance

8.01 Amendments – The bylaws of the DUR Board may be amended, unless the amendment is inconsistent with State or Federal law, at any regular meeting of the DUR Board by a majority vote, provided that the proposed amendment is submitted to Board members for review at least 30 days prior to the meeting at which a vote will be taken. The intent to review bylaws will be posted on the meeting agenda.

8.02 Review – The bylaws shall be reviewed in total at least every two 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.

8.03 Effective Date – The foregoing bylaws shall go into effect on the 17th day of July, 2024.

Approved:

Cinnamon Pearson, Pharm.D.
Chairperson, Arkansas Medicaid DUR Board

Date: 7/17/2024

ARKANSAS MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD
DISCLOSURE OF CONFLICT OF INTEREST FORM

Members of the Arkansas Medicaid DUR Board must submit a signed Disclosure of Conflict of Interest form prior to each meeting, regardless of the presence or absence of any conflicts. No member of the DUR 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 DUR Board member to review the agenda at each meeting and determine if a conflict of interest exists.

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

☐ Conflict of interest exists.

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).

☐ Conflict of interest does not exist.

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

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

Signed: _____ Date: _____