



Amended July 21, 2021 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 (DUR) Board of the Arkansas Medicaid Pharmacy Program ("Board"), 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.

DUR Board Mission Statement

The Arkansas Medicaid Drug Utilization Review (DUR) 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 beneficiaries.

I. DUR Board Structure

- **1.01 Name**—This body shall be known as the Arkansas Medicaid Drug Utilization Review Board, hereinafter referred to as the DUR 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, and medical quality assurance. Additionally, the State Health Officer and DHS Medical Director may attend the meeting in an advisory capacity only. The State Health Officer and the DHS Medical Director may not send a designee as a substitution.





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 <u>and</u> 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:

- Five (5) licensed and actively practicing physicians, with preferably one psychiatrist, one oncologist, 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 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 DUR Board members, fill any vacancy on the DUR Board and shall designate staff assistance to the DUR 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 DUR Board, a new member will be appointed to a vacancy on the DUR 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 Director of the Department of Human Services.

Each member of the DUR 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 9:00 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 DUR Board.

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 DUR 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 Director of DHS, 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 DUR 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 DUR 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.

II. DUR Board Meetings

2.01 Regular Meetings – The DUR Board shall hold quarterly meetings in the City of Little Rock, generally on the third Wednesday of the month during the months of January, April, July, and October. Meetings may be held virtually as needed. 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 meeting 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.

DUR Board Regular Meeting agendas will be posted on the Arkansas Medicaid Pharmacy 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 thirteen (13) total members, a quorum shall consist of seven (7) 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 by-laws, 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 Director of DHS/DMS or his/her designee.

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 allowing 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) Other matters that may be specified by law and within the Board's jurisdiction.
- **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 above vision,





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

3.03 Prior Approval Drug Criteria—The DUR Board shall review 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.
- (5) 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 Use (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 Use 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 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 Use 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.
- **3.06 Application of Standards for Drug Use 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.
- **3.07 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.
- **3.08 Annual Report**—Pursuant to 42 U.S.C. § 1396r–8(g)(3)(D), the Chairperson of the DUR Board 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 use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, 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 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 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 DUR Board to act as Secretary for the routine conduct of its business.
- **4.02 Duties of Officers**—The Chairperson of the DUR Board 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, and perform other duties which may be delegated by the DUR Board and approved by the Director of DHS.

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 shall be open to public inspection. All files shall be maintained for five years.

6.02 Minutes and Provider Notification – The DUR Board meeting minutes and the provider memoranda, which is a joint report from the 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.

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. 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; and
- (5) An electronic copy of any presentation materials the speaker intends to use.

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 six (6) 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— 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 DUR Board meeting. These meetings may be held in-person or by conference call up to three 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.

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 was submitted in writing at the previous meeting of the DUR Board and is included in the notice of the meeting at which a vote is to be taken.

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 <u>21st</u> day of <u>July</u>, <u>2021</u>.

Approved:	
Cinnamon Pearson, Pharm.D Chairperson, Arkansas Medicaid DUR Board	I
Date:7/21/2021	





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 DUR 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 DUR Board 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 DUR Board agenda, then it is the responsibility of the member to disclose the conflict of interest.

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