

Bylaws of the Drug Use Review Board

Nevada State Division of Health Care Financing & Policy

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ARTICLE I- PURPOSE & DEFINITIONS

Section 1: Nevada Medicaid Drug Use Review Board Purpose

The Drug Use Review Board (DUR) is a requirement of the Social Security Act, Section 1927 and operates in accordance with Nevada Medicaid Services Manual, Chapter 1200 – Prescribed Drugs and Nevada Medicaid Operations Manual Chapter 200.

The mission of the Nevada DUR Board is to work with the agency to improve medication utilization in patients insured by Medicaid. The primary goal of drug utilization review is to enhance and improve the quality of pharmaceutical care and patient outcomes by encouraging optimal drug use.

Section 2- Definitions

- A. "Actively Practicing Practitioner" shall be the continuous medical practice defined by NRS 639.0125.
- B. "Actively Practicing Pharmacist" shall be the continuous pharmacy related services defined by NRS 639.0124.
- C. "Administrator" shall mean the State's Administrator of the Division of Health Care Financing and Policy.
- D. "DHCFP" shall mean the Division of Health Care Financing and Policy, a Division of the Department of Health and Human Services (DHHS).
- E. "DHCFP Coordinator" shall mean the DHCFP staff person assigned to coordinate the DUR Board meetings and provide assistance to the DUR Board members.
- F. "DHCFP's Pharmacy Benefit Manager (BPM)" shall mean the DHCFP's contractor who's responsible for management of the Pharmacy Benefit Program.
- G. "DHCFP Website" shall mean: <u>https://dhcfp.nv.gov/index.htm</u>.
- H. "DHHS" shall mean the Department of Health and Human Services of the State of Nevada.
- I. "Director" shall mean the State's Director of DHHS.
- J. "DUR Board" shall mean the Drug Use Review Board established in accordance with 42 § CFR 456.716 and the Social Security Act (SSA) § 1927(g)(3) [42 USC § 1396r-8].
- K. "Exhibit" shall mean a document to be presented to the DUR Board whereby the DUR Board is apprised of proposed changes in policy, regulation, or the State Plan. An Exhibit may require an action/vote by the Board. Exhibits are displayed information that may not be provided in the DUR binder.
- L. "Medicaid" shall mean the Medicaid program that is administered by the DHCFP under Title XIX.
- M. "Nevada Check-Up" shall mean the State Children's Health Insurance Program that is administered by the DHCFP under Title XXI.
- N. "Per Diem" shall be defined in the State Administrative Manual (SAM) found at http://budget.nv.gov/uploadedFiles/budgetnvgov/content/Governance/SAM.pdf.
- O. "Pharmacy and Therapeutics Committee (P&T)" shall mean the committee created within the DHCFP by Nevada Revised Statutes (NRS) 422.4035.
- P. "Presentation" shall mean public comments made orally at a meeting of the DUR Board.
- Q. "Quorum" shall have the meaning stated in NRS § 241.015 (4) as a simple majority of the constituent membership of a public body or another proportion established by law.

ARTICLE II- FORMATION AND COMPOSITION

Section I. Legal Authority

The Drug Use Review Board is established in accordance with 42 § CFR 456.716 and SSA § 1927(g)(3) [42 USC § 1396r-8]. The DUR Board will operate in accordance with Nevada Medicaid Services Manual Chapter 1200 and Nevada Medicaid Operations Manual Chapter 200. 42 CFR § 456.716 states that the Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

Section II. Composition

The DUR Board shall consist of no less than five members and no more than 10 members.

Section III. Appointment

The Director is the appointing authority and shall make all appointments to the DUR Board based on recommendations provided by DHCFP. The DHHS Senior Advisor on Pharmacy shall serve as the DUR Board Coordinator.

ARTICLE III- MEMBERSHIP

Section I. Qualifications for Membership in the DUR Board

- A. The DUR Board membership shall meet the following criteria:
 - 1. At least one-third, but no more than 51%, of the membership of the DUR Board shall be comprised of physicians who are both currently licensed and actively practicing medicine in Nevada.
 - 2. At least one-third of the membership of the DUR Board shall be comprised of pharmacists who are both currently licensed and actively practicing pharmacy in Nevada.
 - 3. Membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in the following:
 - a. The clinically appropriate prescribing of covered outpatient drugs;
 - b. The clinically appropriate dispensing and monitoring of covered outpatient drugs;
 - c. Drug use review, evaluation and intervention; and
 - d. Medical quality assurance.

Section II. Managed Care Organizations

The Director shall appoint one member recommended by each Managed Care Organization (MCO) contracted with the DHCFP. This member shall not be an employee or contractor of any MCO.

Section III. Conflict of Interest

Members serving on the DUR Board may not have a current affiliation with a business or corporation that manufactures prescription drugs. This includes direct compensation through employment and contractual activities. This does not exclude members from participating in continuing educational units or conferences sponsored by the above entities.

Each Board member shall read and sign the Drug Utilization Review Board Disclosure Agreement upon appointment and every reappointment of their term.

Section IV. Terms

Members of the DUR Board shall be appointed to terms as follows:

- A. All appointed members of the DUR Board serve at the pleasure of the Director.
- B. Members of the DUR Board shall serve two-year term and no more than three consecutive terms or six years (whichever comes first).
- C. At the end of an appointed member's term, the Director may reappoint a DUR Board member at the Director's discretion for up to no more than three consecutive terms, or six years (whichever comes first).
- D. If a vacancy occurs in the membership of the DUR Board, the Director shall fill the vacancy for the remainder of the unexpired term in the same manner as the original appointment.
- E. A member of the DUR Board may resign by written notice to the Chairperson and the DHCFP Coordinator.

Section V. DUR Board Member Removal

A violation of any of the DUR Board member responsibilities are grounds for dismissal and may result in removal of appointment from the board.

- A. If a member votes or deliberates on an issue that would provide monetary or other gain that presents a conflict of interest to the member or an entity with which a member is closely affiliated.
- B. If a member refuses to sign or violates the Drug Utilization Review Board Disclosure Agreement, any documents required in the Bylaws or any other Nondisclosure Agreement.
- C. If a member loses his or her license or is no longer actively practicing in their field as a provider (physician or pharmacist).

- D. If a member changes status that alters the category of membership that the member was filling.
- E. If a member does not maintain high level of integrity that warrants public trust, including complying with all applicable ethics guidance provided by DHHS and all aspects of Nevada Open Meeting Law.
- F. If a member discloses confidential or draft information acquired through his or her participation on the Board not in accordance with the Bylaws.
- G. A member, in a 12-month period, misses three or more meetings with or without notice to the DHCFP Coordinator.
- H. The Director may remove any member of the board at his or her discretion.

Section VII. Assistance

- A. The DHCFP Coordinator and the PBM shall provide the DUR Board with staff assistance and independent technical assistance as needed to enable it to accomplish its functions and duties.
- B. The DHCFP's PBM and MCOs shall provide the DUR Board with relevant clinical information and with support that includes, but is not limited to, accepting and summarizing submissions by MCO's, pharmaceutical manufacturers and special interest groups.

ARTICLE IV- FUNCTIONS AND DUTIES

Section I. Functions

The Drug Use Review Board (DUR) is a requirement of the Social Security Act, Section 1927 and operates in accordance with Nevada Medicaid Services Manual, Chapter 1200 – Prescribed Drugs and Nevada Medicaid Operations Manual Chapter 200.

Section II. DUR Board Activities

The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

- A. Application of Standards
 - 1. Review and make recommendations on predetermined standards submitted to it by the Medicaid or the agency's contractor.
 - 2. Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make

recommendations to the Medicaid agency or the agency's contractor concerning medication or elimination of existing predetermined standards or the addition of new ones.

- 3. Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.
- B. Prospective Drug Utilization Review (Prospective DUR)
 - 1. The DUR Board shall review and make recommendations on prospective drug therapy edits submitted to it by the DHCFP or the DHCFP's PBPM. These prospective drug therapy edits shall be used by the DHCFP or the DHCFP's PBPM to screen for potential drug therapy problems due to therapeutic duplication, drugdisease contraindications, drug-drug interactions (including non-prescription drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse prior to the dispensing of a prescription. The prospective drug therapy edits are based upon the compendia and literature referred to under §1927 (g)(B) of the Social Security Act as predetermined standards.
- C. Retrospective Drug Utilization Review (Retrospective DUR)
 - 1. Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.
 - 2. Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of predetermined standards or the addition of new ones.
- D. Education Program
 - 1. Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.
 - 2. Make recommendations as to which mix of the interventions set forth in §456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR Board recommendations must be based upon in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the education program with the drug therapy problems identified.
 - 3. Periodically re-evaluate and, if necessary, modify the interventions.

Section II. Board Officers

The Director elects a Chairperson and Vice-Chairperson. The Chairperson and Vice-Chairperson shall serve a term of one year, unless otherwise specified by the Director.

A. Responsibilities of the Chairperson:

- 1. The Chairperson shall preside over the DUR Board and provide democratic leadership to the board;
- 2. Promote, maintain, and encourage a participatory environment;
- 3. Confer with the DHCFP Coordinator in:
 - i. Preparation of a suitable agenda
 - ii. Planning DUR Board activities
 - iii. Establishing subcommittees and ad hoc committees
 - iv. Appointing DUR Board members to serve on subcommittees
- 4. Coordinate the annual report with the DHCFP Coordinator, agency contractor, and MCO's.
- B. Responsibility of the Vice-Chairperson:
 - 1. Perform the same functions as the Chairperson in his or her absence.
 - 2. If the Chairperson is unable to continue to serve, the Vice-Chairperson shall assume the responsibilities of the Chairperson until the Director appoints a new Chairperson.

ARTICLE V- MEMBER EXPECTATIONS

Section I. Frequency, Location and Attendance

- A. The DUR Board shall meet at least quarterly. Meeting times will be set by the DHCFP Coordinator.
- B. Interim or emergency meetings may be called by the Chairperson or by the DHCFP Coordinator.
- C. A simple majority of the members of the DUR Board constitutes a quorum for the transaction of business.
- D. Members may attend meetings telephonically; however, attendance in person to the maximum extent possible is highly encouraged.
- E. Members are expected to attend/participate in at least 50% or two out of four quarterly meetings.

Section II. Operational Procedures and Facilitation by DUR Contractor

- A. The DUR Board shall conduct its meetings pursuant to the Nevada Open Meeting Law set forth in NRS Chapter 241.
- B. Clinical materials on drug therapies to be reviewed shall be posted on the DHCFP website 45 days prior to the scheduled meeting.
- C. Information from MCOs, manufacturers and special interest groups will be given a deadline for submission of information at the time of the clinical material posting. The deadline will be 15 days after the clinical material is posted.
- D. The DHCFP Coordinator along with the PBM shall be responsible for developing an agenda for each DUR Board meeting. The agenda, along with the DUR binder from the DHCFP or its PBM shall be distributed to each member not later than 15 business days prior to each meeting. (These shall be provided in electronic form or as a link to a website.) A FINAL agenda must be posted in accordance with the Open Meeting Law.
- E. The PBM shall ensure that:
 - 1. Thirty minutes prior to the beginning of the meeting, a sign-in sheet is available at the door where individuals, organizations or agencies may sign up to make public comments during the meeting;
 - 2. Public comment is limited to five minutes per individual, organization or agency, but may be extended or limited at Chairperson's discretion.

Section III. DUR Binder (Exhibits, Proposals, and Handouts)

- A. Exhibits, proposals and handouts will include the following items, as applicable:
 - 1. Statement of need/purpose;
 - 2. History;
 - 3. Present policy or regulation, to include coverage by Medicare and private insurance, if available;
 - 4. Reason for change/justification;
 - 5. Proposed policy change or adoption; and
 - 6. Effect of change to include potential cost and/or savings.
- B. Exhibits, proposals and handouts may be submitted to the Board for consideration, in accordance with the following guidelines:
 - 1. An electronic submission must be provided.
- C. Documentation of a purely marketing or soliciting nature will not be accepted.

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Section IV. Briefings

The DHCFP Coordinator or elected staff will be available to provide a DHCFP update and report on pending issues of significance to the DHCFP. The DUR Board may request briefings on specific topics.

Section V. Submission of Clinical Information

- A. Pharmaceutical manufacturers and special interest's groups wishing to provide the DUR Board with clinical information, questions or comments about drug therapies must make submissions directly to the DHCFP Coordinator or PBM.
- B. Comments must be provided in electronic format and the pharmacy manufacturer or special interest groups are responsible for providing enough copies for all DUR Board members.
- C. As noted in Article IV, Section II, Part B of these Bylaws, drug therapies to be reviewed shall be posted on the DHCFP website no later than 45 days prior to the scheduled meeting. Clinical information that manufacturers or special interest groups wish to have considered in the review process should be submitted to the DHCFP's PBM no later than 15 days after this posting.
- D. Information provided to the DHCFP's PBM shall be summarized at a high level for review by members of the DUR Board within what is referred to as DUR binder. Upon request of any of the Board members, additional details shall be provided including but not limited to ad hoc utilization reports.

Section VI. Public Comment

- A. Anyone presenting documents for consideration shall provide sufficient copies for each member of the DUR Board and the official record (if possible, provide documents in electronic form for record retention purposes). In addition:
 - 1. Copies for public comment shall be made available at the time of sign-up and shall be distributed at the time of the meeting;
 - 2. The DHCFP or its PBPM shall not distribute public comment information prior to the public meeting; and
 - 3. Exhibits, proposals and handouts must meet the standards set forth in Article IV, Section III of these Bylaws.
- B. Each presentation must include:
 - 1. The speaker's name;
 - 2. Affiliation/representation;
 - 3. Any funding, grants, affiliations and/or compensation received from special interest groups (e.g., pharmaceutical manufacturers including, but not limited to, speaker's

bureau memberships, advisory committee appointments or financial interests/holdings); and

- 4. The source of funding for all studies cited.
- C. Products jointly represented by more than one company may be represented during the public comment period by only one individual.

Section VII. Voting

- A. Each of the members constituting a quorum of the DUR Board shall vote to approve or disapprove recommendation(s) on each action item on the agenda.
- B. An affirmative vote of a majority of members present of the DUR Board is required to take action.

Section VIII. Minutes

- A. A record of minutes of the DUR Board meeting will be kept and made available in accordance with the Open Meeting Law.
 - 1. The minutes may be a summary of discussions, but they must reflect the substance of matters proposed, discussed, or decided.
 - 2. The substance of public comment will be included if the member of the general public requests their comments to be included for the record.
- B. Minutes and other relevant materials shall be accessible via the DHCFP public notices website. Individuals who do not have access to the Internet may request hard copies by calling the DHCFP at (775) 684-3600.

ARTICLE IX- COMPENSATION & PER DIEM

Section I. Compensation

- A. Members of the DUR Board serve without compensation.
- B. Each member of the DUR Board who is an officer or employee of the State of Nevada or a local government must be relieved from his/her duties without loss of his regular compensation so that he/she may prepare for and attend meetings of the Board and perform any work necessary to carry out the duties of the Board in the most timely manner practicable. A state agency or local governmental entity shall not require an officer or employee who is a member of the DUR Board to make up the time that he/she is absent from work to carry out his/her duties as a member of the Board or to use annual vacation or compensatory time for the absence.

Section II. Per Diem and Other Expenses

A member of the DUR Board is entitled, while engaged in the business of the Board, to receive travel expenses provided for state officers and employees generally, including per diem, transportation, lodging and associated miscellaneous expenses.

ARTICLE X- ADOPTION AND AMENDMENTS TO THE BYLAWS

Proposed amendments to these Bylaws must be submitted, in writing, to the Director 15 days in advance of a scheduled meeting in order to be reviewed by the DUR Board Members. Approval by DHCFP shall be required to adopt a proposed amendment, and such amendments must be approved by the Director to become effective. All proposed amendments are subject to review and approval by the DHCFP Coordinator.

The Bylaws become effective as of the date they are approved by the Director. The board will make note of the date of the adoption of the Bylaws in the meeting minutes.

DRUG UTILIZATION REVIEW BOARD DISCLOSURE AGREEMENT

- The DHCFP and the Drug Utilization Review Board (Board) are not bound in any way by any statement of action on the part of any Board member except when a statement or action is in pursuit of specific instructions from the DHCFP or the Board.
- The Board and its members may not claim or appear to represent the DHCFP or the Board in any legislative or advocacy activity without approval from the DHCFP Coordinator and the Director. A member may, however, represent him- or herself or another entity in the legislative or advocacy process.
- A Board member may not accept payment for services that are requested because of the members' title or position on the Board.
- A Board member should not accept or solicit any benefit that might reasonably tend to influence the member in the discharge of the member's official Board duties.
- A Board member should not knowingly solicit, accept, or agree to accept any benefit for having exercised the member's official powers or duties in favor of another person.
- A Board member shall make themselves aware of and follow Open Meeting Law policy as set forth in chapter 241 of the Nevada Revised Statutes as it applies to the Drug Use Review Board.
- Nondisclosure Agreement: A Board member may not disclose confidential information or agency-generated information in draft form acquired through his or her board membership, unless DHCFP has released and made public the information or document and/or the DHCFP Coordinator has approved the release in writing. This requirement survives the member's tenure on the Board. For purposes of the Nondisclosure Agreement, the term "confidential information" includes all information protected by the Health Insurance Portability and Accountability Act (HIPPA), information that has commercial value or use, such as trade secrets, and information communicated in the confidence by the DHHS System.
- Conflict of Interest Statement: I agree to disclose any current affiliation with a business or corporation that manufactures prescription drugs. This includes direct compensation through employment and contractual activities.

I have been provided a copy of the Drug Utilization Review Board Bylaws. I understand that as a member of the Board I must adhere to these Bylaws.

Board Member Signature

Date

Printed Name