

# **Drug Utilization Review Board**

## **Bylaws**

### **1. Name and Legal Authority**

The Drug Utilization Review Board ("Board") is established in accordance with Social Security Act § 1927(g)(3) and Texas Government Code § 531.0736.

Texas Government Code § 2110.008 (Duration of Advisory Committees) does not apply to the Board. This Board will not be considered for abolition unless Social Security Act § 1927(g)(3) permits it.

### **2. Purpose, Role, and Duties**

The purpose of the Board is to advise the Texas Health and Human Services Commission (HHSC) on matters as described below:

- A. Federally required Medicaid Drug Utilization Review Program duties under 42 CFR § 456.703;
- B. Prospective drug utilization review (DUR) 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;
- C. Retrospective DUR 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;
- D. 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);
- E. Texas Medicaid preferred drug lists by HHSC under Texas Government Code § 531.072, which considers the drugs' efficacy, clinical significance, cost effectiveness, and safety; and
- F. Other matters that may be specified by law and within the Board's jurisdiction.

In addition to performing any other duties set out by federal law, the Board shall:

- A. Develop and submit to HHSC recommendations for preferred drug lists;
- B. Suggest to HHSC restrictions or clinical edits on prescriptions drugs;
- C. Recommend to HHSC educational interventions for Medicaid providers;
- D. Review drug utilization across Medicaid; and
- E. Perform other duties that may be specified by law and otherwise make recommendations to HHSC.

The Board's activities are detailed in an annual report to the Centers for Medicare & Medicaid Services prepared by HHSC Vendor Drug Program staff.

### **3. Definitions**

Board: The Drug Utilization Review Board

Clinical prior authorization: Prospective-DUR prior authorization tool used at point of sale based on evidence-based clinical criteria and nationally recognized peer-reviewed information.

DUR: Drug Utilization Review (DUR) is a process required by federal law in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to assure that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical results.

Drug Utilization Review Program: Program operated by the Vendor Drug Program to improve the quality of pharmaceutical care under Medicaid consisting of prospective drug review, retrospective drug use review, and educational program.

Educational interventions: Method of educating providers on identified common drug therapy problems needing improved prescribing or dispensing practices, usually identified as part of the retrospective DUR reviews.

HHS: Health and Human Services System

HHSC: Health and Human Services Commission

Texas Medicaid Preferred Drug List (PDL): List of covered outpatient drugs reviewed by Board for their efficaciousness, clinical significance,

cost-effectiveness, and safety for patients and recommended as either preferred or non-preferred. PDL is a subset of products on the Texas Medicaid formulary.

Retrospective DUR: Review of prescription drug claims data to identify patterns of prescribing.

#### **4. Board Composition**

The Board is composed of 20 members appointed by the HHS Executive Commissioner as described in Texas Government Code § 531.0736. Except as specified, all members are voting members.

This membership includes:

- A. 17 physicians and pharmacists providing services across the entire population of Medicaid recipients representing at least one of each of the following physician types:
  - 1. Primary care physician;
  - 2. Provider of pediatrician services;
  - 3. Provider of obstetrician and gynecologist services;
  - 4. Provider of child and adult psychiatry services; and
  - 5. Provider of adult psychiatry.
- B. One physician provider representing Medicaid managed care organization (non-voting member);
- C. One pharmacist provider representing Medicaid managed care organization (non-voting member); and
- D. One consumer advocate, representing the Medicaid population.

Physician and pharmacist members must:

- A. Have experience in developing or practicing under a PDL.
- B. Have recognized knowledge and expertise in one or more of the following:
  - 1. Clinically appropriate prescribing of outpatient drugs;
  - 2. Clinically appropriate dispensing and monitoring of outpatient drugs;
  - 3. DUR, evaluation, and intervention; and
  - 4. Medical quality assurance; and
- C. Be licensed and in good standing with the Texas Medical Board or the Texas State Board of Pharmacy and actively providing services across the entire population of Medicaid in Texas.

Voting members have access to confidential drug pricing information and will attend executive session. The managed care organization representatives will not attend executive session or have access to confidential drug pricing information.

To the greatest extent possible, the HHS Executive Commissioner appoints members who reflect the diversity of the state.

## **5. Member Terms**

Members shall be appointed to serve a four-year term. Individuals will normally serve only one term; however, at the discretion of the HHS Executive Commissioner, an individual may re-apply and be appointed for one additional term. These terms may be served consecutively.

The expiration of membership terms occurs on August 31<sup>st</sup> of each year. Regardless of the term limit, a member serves until his/her replacement has been appointed. This ensures sufficient, appropriate representation.

## **6. Resignations and Vacancies**

If any member of the Board wishes to resign, the member will contact, in writing, the current Chair and HHSC Board Liaison informing of the member's resignation date and requesting the appointment of a successor member.

In the event of a vacancy for any reason, agency staff will work with the HHS Executive Commissioner to solicit applications as appropriate to fill the vacancy with a representative of the same membership category to serve the unexpired portion of the term of the vacant position. Persons who submitted applications within the previous year through the HHSC may be reconsidered for membership.

Applicants may apply to become members of the Board by following the application process on the HHSC website.

## **7. Presiding Chair and Vice-Chair**

In compliance with Government Code § 531.0736, Board members will elect a Chair every two years. The Chair must be a physician, a voting member, and will serve a term of two years. The Chair will serve no more than two consecutive terms. In the event that the Chair is unable to complete his/her term for any reason, a new chair will be elected by members.

The members will also elect a Vice-Chair every two years to serve in the Chair's temporary absence. The Vice-Chair must be a physician or pharmacist, a voting member, and will serve a term of two years. Similar to the Chair, the Vice-Chair will serve no more than two consecutive terms. In the event the Vice-Chair is unable to complete his/her term for any reason, a new Vice-Chair will be elected by members.

Regardless of member term, the Chair and Vice-Chair will serve until the Board elects a successor; however, a presiding officer may not remain in office past his or her membership term.

The role of the Chair and Vice-Chair is to:

- A. Report to the HHSC;
- B. Provide leadership in conducting Board meetings;
- C. Promote, maintain, and encourage a participatory environment;
- D. Ensure the Board adheres to its charge;
- E. Confer with HHSC Board Liaison in:
  - 1. Identifying the need for and calling meetings to accomplish the work of the Board; and
  - 2. Agenda planning and preparation for Board meetings; and
- F. Confer with HHSC Board Liaison to acquire the support needed for Board operations.

## **8. Board Operations and Meetings**

Information regarding drug rebates, pricing, and negotiations is confidential in accordance with Texas Government Code § 531.071. The voting members will discuss information that is confidential under § 531.071 in an executive session, in accordance with 1 with Texas Administrative Code, Title 1, Part 15, Subchapter F, Section

354.1941(c)(2). All executive sessions will comply with the procedural requirements of the Texas Open Meetings Act, Texas Government Code Chapter 551.

A. Meetings

1. The Board meets quarterly during regular business hours.
2. The Board is subject to the Texas Open Meetings Act as if it were a governmental body.
3. Executive sessions are not open to the public nor to the managed care Board representatives.

B. Quorum

Ten voting members constitutes a quorum for the purpose of transacting official business. If less than a quorum of the Board is present, members may not vote upon action items, but may take testimony and public comments so long as the meeting is being conducted in accordance with the Texas Open Meetings Act.

C. Voting

1. Voting members have the right to vote on any subject listed on the agenda. However, members must abstain from deliberating or voting on issues that would provide monetary or other gain to the member, or the member's family, or that could present, or reasonably appear to present, a conflict of interest.
2. The Board may determine procedural matters by majority vote of the members attending the meeting, or may use Robert's Rules of Order as a guide to its operations and proceedings.
3. Voting Board members may also vote on operational or procedural matters that come before the Board.
4. A member may participate and, if the member is a voting member, vote by telephone conference as deemed necessary by agency staff. A member who attends and participates by telephone will count towards quorum tally.
5. A member may not authorize another individual to represent the member by proxy.
6. For all business except adopting or amending bylaws, a simple majority is needed on a motion duly made and seconded. (A simple majority is defined as more than half of the votes cast by persons entitled to vote who are in attendance with a quorum, excluding abstentions.)

D. Adoption and Revision to Bylaws

1. Bylaws will be adopted and amended pursuant to a two-thirds vote (of members attending the meeting) on a motion duly made and seconded.
2. Board members or HHSC staff may propose changes to these bylaws. All proposed changes from Board members, along with the rationale for the changes, should be submitted in writing to Board Liaison at least 45 days before the next Board meeting for inclusion in the publication of the agenda in the *Texas Register* and distribution to the members for their consideration.
3. The Board will review the Bylaws by December 31 of every even-numbered year. Board-proposed amendments that occur as a result of the biennial review will be considered in a meeting and will be passed and become effective based on a two-thirds vote of members attending the meeting, pending review and approval by HHSC staff.
4. All proposed changes are subject to review and approval by HHSC staff.
5. The Bylaws will become effective as of the date they are adopted by the Board. The Board will make note of the date of the adoption of the Bylaws in its minutes. Members will sign a Statement by Members when bylaws are amended.

E. Public Testimony, Written Testimony, and Other Materials

1. Public Testimony
  - a. The Board will hold a Public Comment session before voting on:
    - i. Any changes in a PDL;
    - ii. The adoption of or changes to drug use criteria; or
    - iii. The adoption of prior authorization or DUR proposals.
  - b. Public comment may be allowed on other agenda items.
  - c. Members of the public who would like to testify must follow the testimony registration process posted on the HHSC website.
  - d. Public testimony may be time-limited at the discretion of the Chair or HHSC. To accommodate testimony from a variety of organization and individuals, testimony is limited to one individual per organization or drug manufacturer per agenda item.
  - e. Members of the public who are testifying in person may provide relevant handouts to the Board at the time of testimony.
2. Written testimony must be submitted to HHSC program staff via mail or e-mail within the prescribed time period and instructions

as indicated on HHSC website. Written testimony is not to exceed ten pages.

3. Other Materials: Audiovisual equipment and promotional or marketing materials are not allowed.

## **9. Responsibilities of Members**

### **A. Attendance**

Members are expected to attend all meetings in person. A member unable to attend a meeting should notify the HHSC Board Liaison in advance. The HHSC Board Liaison will notify the Chair and appropriate program staff. Members may not send a substitute to attend a meeting in their place.

If any member misses three meetings within a 12-month period, with or without notice to the Board Liaison, the member may be removed from the Board.

### **B. Member expectations:**

1. Attend meetings in person;
2. Review agendas and other information sent by HHSC staff prior to each meeting;
3. Participate in discussions at meetings;
4. Participate in DUR Board Executive sessions, if a voting member;
5. Submit travel expenses (if reimbursement is desired) within 30 calendar days of the meeting;
6. Abstain from deliberating or voting on issues that would provide monetary or other gain to the member, or the member's family, or that could present, or reasonably appear to present, a conflict of interest;
7. Attend/participate in an orientation session, separate from the regular Board meeting, prior to new member's first meeting;
8. Complete the full Texas Open Meetings Act Training and Public Information Act Training within 90 days of appointment and submit the Certificates of Completion to the Board Liaison. If a member has taken the trainings within the last five years of initial appointment, a copy of the Certificates of Completion may be submitted to the HHSC Board Liaison in lieu of taking the full

training. The full Texas Open Meetings Act Training and Public Information Act Training must be completed every five years and refresher sessions biannually. Certificates of Completion must be submitted to the HHSC Board Liaison.

9. Sign and submit to the Board Liaison within 30 days after appointment, and annually thereafter, a Drug Utilization Review Board Annual Disclosure Form.
10. Sign and submit to the Board Liaison the Statement by Members document within 30 days after appointment. This document includes a Conflict of Interest Statement and a Nondisclosure Agreement to which Board members must agree;
11. Sign and submit to the HHSC Board Liaison immediately upon initial appointment and annually the Department of State Health Services Continuing Education Service Disclosure of Financial Interests;
12. Review the HHS Ethics Policy, sign, and submit to the Board liaison within 30 days after initial appointment and annually;
13. Notify the Board Chair and HHSC Board Liaison if a change of member's licensure status results in loss of good licensure standing;
14. Notify the Board Chair and Board Liaison if a change of status alters the category of membership the member was filling or if any circumstance occurs that prevents the member from being able to discharge his or her duties;
15. Maintain a high level of integrity that warrants public trust, including complying with all applicable ethics guidance provided by HHSC's Ethics Officers and all aspects of the Texas Open Meetings Act and Public Information Act; and
16. Hold and maintain in strictest confidence all confidential information and all agency-generated information, including in draft form, until such time as the information or document is released and made public, the HHS Executive Commissioner has approved the release in writing, or the HHS Ethics Policy permits release. This requirement survives the member's tenure on the Board. For purposes of these bylaws and the Nondisclosure Agreement, the term "confidential information" includes all information protected by the Health Insurance Portability and Accountability Act (HIPAA), information that has

commercial value or use, such as trade secrets, and information communicated in confidence by the HHS System.

Failure to comply with 6-16 above are grounds for dismissal and may result in removal from the Board.

C. A Board member may not:

1. Claim or appear to represent HHSC or the Board in legislative or advocacy activities without written approval from the Board Chair and the HHS Ethics Office in coordination with the HHS Government Relations Office and the Board Liaison. A member may, however, represent him- or herself or another entity in the legislative or advocacy process.
2. Accept payment for any services offered to the member because of his/her position on the Board.
3. Disclose confidential information or draft information (from any source including grants, requests for proposals, and contracts) acquired through his or her participation on the Board until such time as that information or document is released and made public, the HHS Executive Commissioner has approved the release in writing, or the HHS Ethics Policy permits release. This includes all forms of communication including written, verbal, and social media.

A violation of any of these items are grounds for dismissal and may result in removal from the Board.

## **10. Removal from the Board**

The HHS Executive Commissioner may remove a member from the Board for the following reasons:

- A. A member votes or deliberates on an issue that would provide monetary or other gain or that presents a conflict of interest to the member, the member's family, or an entity with which the member is closely affiliated.
- B. A member refuses to sign or violates the Conflict of Interest statement or Nondisclosure Agreement or any documents required in the Bylaws, or another Nondisclosure Agreement.

- C. A member does not maintain a high level of integrity that warrants public trust, including complying with all applicable ethics guidance provided by HHSC's Ethics Officers and all aspects of the Texas Open Meetings Act and Public Information Act.
- D. A member changes status that alters the category of membership that the member was filling.
- E. A member loses his/her license or no longer actively practices.
- F. A member claims or appears to represent HHSC or the board in a legislative or advocacy without approval from the Board Chair and the HHS Ethics Office in coordination with the HHS Government Relations Office and the Board Liaison.
- G. A member receives payment for any services requested because he or she holds a position on the Board.
- H. A member discloses confidential or draft information acquired through his or her participation on the Board not in accordance with the Bylaws.
- I. A member, in a 12-month period, misses three meetings with or without notice to HHSC Board Liaison staff.
- J. The HHS Executive Commissioner may remove a member who has violated the conflict of interest provisions or made a statement in violation of the Statements by Members form. Decisions to remove a member of the Board due to violations of this nature will require input from HHS legal counsel.

## **11. Subject Matter Experts**

HHSC recognizes the value of subject matter experts (SMEs) to provide information to the Board as it develops recommendations and initiatives relative to its charge(s). The primary role of a SME is to provide objective, independent information and analysis to be considered by the Board. SME participation will be subject to the request of voting Board members and will fall within the following guidelines:

- A. A SME may be invited to provide information on specific subjects and topics at the discretion of voting Board members, the Chair or Vice-Chair, and HHSC staff;
- B. An invited SME may be recognized by staff, the Board Chair, or Vice-Chair to provide information or analysis during allotted time periods at a specified Board;

- C. SMEs will participate in questions and answers at the direction of the staff, Board Chair, or Vice-Chair;
- D. All SMEs will participate and serve at the pleasure of the Board;
- E. SMEs do not hold any official capacity on the Board and do not have rights of deliberation or the right to vote on any Board activities or decisions;
- F. SMEs should disclose any conflicts of interest they may have prior to providing information to the Board; and
- G. None of the information or guidance contained in this section shall prevent any individual from participating in or providing comments to the Board as allowed under the Texas Open Meetings Act.

## **12. Responsibilities of Support Staff**

The HHSC Board Liaison and support staff will provide reasonable administrative and technical support and coordination for all Board activities. HHSC will coordinate as needed to provide the accommodations and support needed by a Board member who has a disability to enable him/her to fully participate in Board meetings and activities.

The HHSC Board Liaison and support staff is expected to perform the following tasks:

- A. Develop effective working relationships with Board members;
- B. Solicit nominations for membership in accordance with the appropriate HHS procedures;
- C. Prepare the Centers for Medicare & Medicaid Services DUR annual report;
- D. Serve as liaison between members and operating agencies' staff; and
- E. Plan, coordinate, and organize Board meetings and activities, including:
  - 1. Schedule meeting dates and ensure meeting sites are set up;
  - 2. Notify members of upcoming meeting dates, times, and locations;
  - 3. Develop agenda and support materials for each meeting;
  - 4. Prepare and oversee that the agenda is posted in the *Texas Register* in a timely manner and on the HHS website;

5. Act as point of contact for the public including ensuring contact information, agendas, and meeting support materials are easily accessible on the HHS website;
  6. Prepare and distribute information and materials for member review;
  7. Prepare and maintain Board records and documentation in accordance with the HHSC records retention policy; and
  8. Assist eligible members with travel arrangements and reimbursement.
- F. Staff may perform other duties within staff discretion provided the necessary resources are available.

### **13. Compensation and Travel Reimbursement**

To the extent permitted by the current General Appropriations Act, a member of the Drug Utilization Review Board may be reimbursed for his/her travel expenses to and from Board meetings if funds are available and in accordance with the HHS Travel Policy.

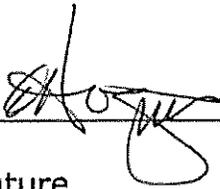
Members eligible for such reimbursement are subject to rates established in the General Appropriations Act. Support staff will assist members in requesting reimbursement. Board members are responsible for providing the required information as per instructions provided within 30 calendar days of the meeting.

A member who would like to seek travel reimbursement must:

- A. Keep accurate record of allowable travel expenses (as per the HHS Travel Policy) during travel to attend Board meetings, and
- B. Submit receipts and appropriate documentation to the Board Liaison in a timely manner.

Bylaws approved on 7-27-18 by a two-thirds vote of members attending the meeting.

Robert L. Hogue, MD  
Chairperson  
Printed Name

  
Signature

Maribel O Castoreno  
HHSC  
Printed Name

  
Signature

## Statement by Members

- The HHSC and the Drug Utilization Review Board (Board) are not bound in any way by any statement or action on the part of any Board member except when a statement or action is in pursuit of specific instructions from HHSC or the Board.
- The Board and its members may not claim or appear to represent HHSC or the Board in any legislative or advocacy activity without approval from the Board Chair and the HHS Ethics Office in coordination with the Government Relations Office. 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 this 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 complete the full Texas Open Meetings Act Training and the Public Information Act Training within 90 days of appointment and submit the Certificates of Completion to the Board Liaison. If a member has taken the training within the last five years, a copy of the Certificate of Completion may be submitted to the Board Liaison in lieu of taking the training. A Board member shall complete full Texas Open Meetings Act Training and the Public Information Act Training every five years and complete biannual refresher sessions.
- 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 HHSC has released and made public the information or document, the HHS Executive Commissioner has approved the release in writing, or the HHS Ethics Policy permits release. 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 (HIPAA), information that has commercial value or use, such as trade secrets, and information communicated in confidence by the HHS System.
- Conflict of Interest Statement. I agree to disclose any personal or private interest that myself or my family have in a measure, proposal, or decision pending before HHSC. ("Personal or private interest" does not include the member's engagement in a profession, trade, or occupation when the member's interest is the same as all others similarly engaged in the profession, trade, or occupation, or if the member merely provides a personal experience, with no personal or private financial interest, in giving feedback on the subject matter.) If there is a direct personal or financial interest in a motion under consideration, I further agree to disclose that fact in a public meeting and will recuse myself from any Board deliberations or decisions on that matter.

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 the bylaws.

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Board Member Signature

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Printed Name

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Date