I) Authority
The Texas Medicaid Drug Utilization Review (DUR) Board (Board) is established under the authority of Section 1927(g)(3) of the Social Security Act and Section 531.0736 of the Texas Government Code. In accordance with Section 1927(g)(3)(D) of the Social Security Act, the Board’s activities are detailed in an annual report submitted to the Centers for Medicare & Medicaid Services (CMS).

Senate Bill (S.B.) 200 (Section 3.08), 84th Legislature, Regular Session, 2015, amended the Texas Government Code by eliminating the Pharmaceutical and Therapeutics Committee and transferring its functions to the Board. The duties of the restructured Board include: (1) Develop and submit recommendations to the Texas Health and Human Services Commission (HHSC) for the preferred drug list (PDL); (2) Suggest to HHSC restrictions or clinical prior authorizations on prescription drugs; (3) Recommend to HHSC educational interventions for Medicaid providers; (4) Review drug utilization across Medicaid; and (5) Perform other duties that may be specified by law and otherwise make recommendations to HHSC.

II) Function
A) Application of predetermined criteria and standards. The Board will perform the following activities:
   I) Recommend medical criteria using predetermined standards for development of retrospective and prospective DUR. Retrospective and prospective DUR will monitor for potential drug therapy problems including:
      a. Therapeutic appropriateness
      b. Overutilization or underutilization
      c. Therapeutic duplication
      d. Drug-disease contraindications
      e. Drug-drug interactions
      f. Incorrect drug dosage or duration of treatment
      g. Clinical abuse and misuse
   II) Evaluate the use and effect of criteria and predetermined standards in the identification of inappropriate care provided by healthcare professionals with prescribing authority to Medicaid beneficiaries. The goal of the state's DUR program is to ensure drug therapy is appropriate, necessary, and safe while allowing adequate professional discretion.

B) Develop and review of educational programs and interventions. The Board will perform the following activities:
   I) Identify and develop educational programs and interventions to improve prescribing and dispensing practices.
   II) Determine the scope and type of educational programs and interventions that most effectively improve the quality of drug therapy.
   III) Evaluate and modify educational interventions and programs on a periodic basis.
C) Review and make recommendations to HHSC to develop and maintain the PDL in accordance to Section 531.072 of the Texas Government Code. The Board recommends drugs to the PDL based on their efficacy, clinical significance, cost effectiveness, and safety.

D) Maintain HHSC/DUR Board Relationship. HHSC is ultimately responsible for ensuring the DUR and PDL program is operational and conforms to all requirements or decision of the Board.

III) Composition

A) The Board is composed of 18 members. Of the 18 members, 16 are voting members and two are non-voting members.

B) The composition of the voting members is as follows:

I) 15 physicians and pharmacists who:
   a. Provide services across the entire population of Medicaid recipients;
   b. Represent different specialties, including at least one each of the following types of physicians: A pediatrician; A primary care physician; An obstetrician and gynecologist; A child and adolescent psychiatrist; and An adult psychiatrist;
   c. Have experience in developing or practicing under a PDL;
   d. Have recognized knowledge and expertise in one or more of the following: Clinically appropriate prescribing of outpatient drugs; clinically appropriate dispensing and monitoring of outpatient drugs; Drug utilization review, evaluation, and intervention; and Medical quality assurance; and
   e. Are licensed and in good standing with the Texas Medical Board or the Texas State Board of Pharmacy and are actively practicing in Texas seeing Medicaid beneficiaries.

II) One consumer advocate who represents Medicaid recipients. As voting physicians and pharmacists, the consumer advocate will have access to confidential information, will attend executive session, and will vote on action items presented to the Board.

C) The composition of the two non-voting members is as follows: one pharmacist and one physician that will represent Medicaid managed care organizations. These members will not access confidential information, will not attend executive session, and will not vote on action items presented to the Board.

D) A member is required to notify HHSC if the member's licensure status changes or if the member no longer represents the specialty he or she was appointed to represent.
IV) **Board Appointments and Terms**

A) The Executive Commissioner of HHSC (or the designated agent) appoints Board members.

B) Members of the Board serve staggered four-year terms. Each term expires at the end of the fourth year of the term on August 31.

C) Members of the Board will be required to complete an annual Conflicts of Interest (COI) form as part of their yearly attestation.

D) In the case of a vacancy on the Board, the Executive Commissioner (or the designated agent) will appoint an individual representing the same profession to serve the unexpired portion of that particular term.

E) Reappointments are at the discretion of the Executive Commissioner.

F) Absence without just cause from three Board meetings in a year grounds for removal.

G) Applicants may apply to become members of the Board by following the application process on the HHSC website. In the event of a vacancy that occurs within three months of an appointment, the Executive Commissioner may use the same pool of applicants.

V) **Meetings**

A) Board meetings will be held at least quarterly at a time and place to be specified by HHSC Vendor Drug Program staff. The meeting time and place will be published in the *Texas Register* at least one week prior to the meeting. Board meetings are open to the public unless confidential information is discussed, in which case the Board will meet in executive session.

B) Executive sessions in which confidential information is discussed are not open to the public or to the managed care Board representatives.

C) The state's recording of a meeting will be the only formal recording of the activities of the Board meetings.

D) Nine members (voting and non-voting) of the Board at a called meeting constitute a quorum. If quorum is not reached, a meeting will not be held. Nine voting members must be in attendance in order for the Board to vote on action items.

E) A quorum may be established by teleconference. If nine voting members are at the meeting location, a member may participate via teleconference in very limited circumstances as approved by HHSC VDP staff, and the proceedings are subject to special requirements set forth in the Texas Open Meetings Act. Teleconferencing is never to routinely take the place of physical attendance.
VI) **Board Officers**

A) The Board, in open session, will elect the chair of the Board (Chair) for a term of two years. The Chair must be physician and a voting member.

B) The Board will elect a Chair every two years during the first meeting of the Board of that state fiscal year (i.e., first meeting that occurs after September 1).

C) The Board, in open session, will elect the Vice-chair of the Board. The vice-chair must be a voting member.

D) Chair or Vice-chair vacancies will be elected at first quarterly Board meeting following the vacancy.

E) Election of Chair and Vice-chair requires at least five votes from the membership in attendance at a meeting in which a quorum is present. Nominations will be accepted from the floor by the Chair. Voting members will nominate the Chair and Vice-chair. If no one member receives a simple majority of the votes, the nominee who received the lowest number of votes is dropped, and the members cast votes from the remaining nominees. This procedure is repeated until a nominee receives a majority of the votes.

F) The Chair, Board, or HHSC staff may make recommendations to the Executive Commissioner regarding the removal of any member of the Board for a cause including:

   a. Absence without just cause from three Board meetings in a year.
   b. Wrongdoing or misconduct.
   c. A finding of fraud, waste or abuse in relation to Texas Medicaid or any other state or federally funded program.
   d. A violation of an applicable professional code of conduct.
   e. Violation of the conflict of interest policy, including failure to submit the required COI form annually.
   f. Loss of license.
   g. No longer representing the specialty or industry a member was appointed to represent.
   h. Releasing confidential information to the public.

VII) **Responsibilities of Chair and Vice-Chair**

A) The Chair will:
   I) Preside over meetings of the Board.
   II) Provide democratic leadership.
   III) Be sensitive to the views and opinions of members and maintain an atmosphere in which all members have the opportunity to express their views freely.
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<th>B)</th>
<th>The chair may confer with Vendor Drug Program and other HHSC agency staff in:</th>
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<tbody>
<tr>
<td>I)</td>
<td>Preparing suitable agendas.</td>
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<td>II)</td>
<td>Planning Board activities.</td>
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<td>III)</td>
<td>Establishing meeting dates and calling meetings.</td>
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<td>IV)</td>
<td>Establishing subcommittees and ad hoc committees.</td>
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<td>V)</td>
<td>Appointing Board members to lead and serve on subcommittees.</td>
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| C)  | If the Chair is absent or otherwise unable to perform the functions of the office, the Vice-chair will perform the functions as the Chair. If during meeting both the Chair and Vice-chair are absent, the Board members will designate a temporary Chair. |

**VIII) Operational Procedures**

| A) | Board meetings will be conducted in accordance with the HHSC Policy, the Texas Open Meetings Act, and DUR Bylaws. If issues are not addressed in the HHSC Policy, Texas Open Meetings Act, or DUR Bylaws, the Board will follow the current edition of Robert's Rules of Order. |

| B) | A vote of at least five members is required to carry motions duly made and seconded in any official Board meeting. |

**IX) Public Attendance and Testimony**

| A) | The Board will permit public comment on any action item under consideration, including any changes to the PDL, the adoption of or changes to drug use criteria, adoption of clinical prior authorization criteria, or drug utilization review retrospective proposals. |

| B) | Members of the public wishing to testify must follow the testimony registration process on the HHSC internet website. Members of the public who are testifying in person may provide relevant handouts to HHSC staff facilitating the meeting to distribute to Board. |

| C) | Testimony registration requires providing the name and the address of the person wishing to testify and organization represented. The person must also disclose whether he or she receives any direct or indirect compensation from a drug manufacturer. Testimony may be time-limited at the discretion of the Chair or HHSC as required. To accommodate testimony from a variety of organizations and individuals, testimony may be limited to one individual per organization or drug manufacturer per agenda item. |

| D) | Members of the public may provide written testimony for consideration by the Board. Written testimony must be submitted to Vendor Drug Program via mail or e-mail within the prescribed time period as indicated on the HHSC internet website. Written comments are not to exceed ten pages. |
E) Audiovisual equipment and promotional or marketing materials are not allowed.

X) **Amendments**

A) Amendments to the Board bylaws can be recommended by the Board or HHSC.

B) Written notice of the proposed amendment(s) will be sent Board members at least ten business days prior to the meeting.

C) Amendments must be ratified by a majority of the members present at the next scheduled Board meeting at which a quorum is present.

XI) **Compensation**

A) Each member of the Board is entitled to a travel per diem as set by legislative appropriation for each day that the member engages in the business of the Board.

B) Each member of the Board is entitled to compensation for transportation expenses incurred in connection with the member's duties as provided by the General Appropriations Act.

XII) **Confidentiality**

A) The Board members will maintain the confidentiality of any information that HHSC deems confidential.

B) Confident information includes the names of recipients, providers, or the particular circumstances pertaining to a specific case. A member may not release confidential information to the public. Any proprietary drug, drug pricing, or drug rebate information discussed during the executive session of the Board meeting will be kept confidential.

XIII) **Conflict of Interest**

A) Members must comply with Texas conflict of interest laws including Section 354.1941 of the Texas Administrative Code (relating to the DUR Board Conflict of Interest Policy).

XIV) **Definitions**

1. **Adverse medical outcome**: a clinically significant undesirable effect that occurs as a result of a course of drug therapy.

2. **Appropriate and medically necessary**: drug prescribing and dispensing that conforms with specific criteria and standards.

3. **Appropriate use of generic products**: use that conforms with state product selection laws.

4. **Clinical abuse/misuse**: provider and/or recipient practices inconsistent with sound fiscal, business, or medical practices that result in unnecessary cost to the Medicaid program or in reimbursement for
services that are not medically necessary, or that fail to meet professionally recognized standards for health care.

5. **Criteria**: the predetermined and explicit elements of drug use, developed by health care professionals, with which aspects of the quality, medical necessity, and appropriateness of drug use may be compared.

6. **Drug-Allergy interaction**: a situation where a drug is prescribed and dispensed to a patient who has experienced in the past or who, as a result of the prescription, experiences an allergic reaction.

7. **Drug-Disease contraindication**: a situation where the prescribing of a drug may have an adverse impact on a patient's disease condition or the therapeutic effect of a medication may be altered by the presence of a disease condition in the patient.

8. **Drug-Drug interactions**: a situation where two or more drugs are taken by a patient leading to effects that are different from those obtained when the drugs are used independently.

9. **Drug rebate**: the Medicaid Drug Rebate Program is a program in the United States that was created by the Omnibus Budget Reconciliation Act of 1990 (OBRA'90). It requires that drug manufacturers have a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in order for states to receive federal Medicaid coverage of their products.

10. **Incorrect dosage**: a dosage of drug that lies outside the range specified in the criteria and standards as necessary to achieve therapeutic benefit.

11. **Incorrect duration of drug dosage**: duration of therapy that exceeds or falls short of the recommendations in the criteria and standards.

12. **Overutilization**: the use of a drug in sufficient quantities or for durations that put the patient at risk of an adverse medical result.

13. **Preferred Drug List (PDL)**: The Texas Medicaid PDL is a subset of approved products on the Texas Medicaid Formulary. The PDL consists of medications recommended by the Board for their efficaciousness, clinical significance, cost effectiveness and safety for patients.

14. **Prospective Drug Use Review**: a review of drug therapy before a prescription is filled, typically at the point-of-sale or distribution.

15. **Retrospective Drug Use Review**: an ongoing periodic examination of paid claims data and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

16. **Robert's Rule of Order**: Short title of a book, written by Henry Martyn Robert that is intended to be a guide for conducting meetings and making decisions as a group.

17. **Standards**: professionally developed expressions of the range of acceptable variation from a criterion.

18. **State Fiscal Year**: September 1 to August 31.

19. **Therapeutic appropriateness**: drug prescribing and dispensing that is consistent with criteria and standards.

20. **Therapeutic duplication**: the prescribing or dispensing of two or more drugs from the same therapeutic class in overlapping periods of time.

21. **Underutilization**: the use of a drug by a patient in insufficient quantity to achieve a desired therapeutic goal.