
RIDER 49 REPORT

Strengthening the Texas Medicaid Drug Utilization Review Program

**As Required By
The 2010-11 General Appropriations Act
S.B. 1, 81st Legislature, Regular Session, 2009
(Article II, Health and Human Services Commission, Rider 49)**

**Health and Human Services Commission
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Executive Summary

Pursuant to the 2010-11 General Appropriations Act (Article II, Health and Human Services Commission, Rider 49, S.B. 1, 81st Legislature, Regular Session, 2009), the Health and Human Services Commission (HHSC) is required to submit a report by December 1, 2009, on the strategies implemented by the agency after September 1, 2009, to strengthen the Texas Medicaid Drug Utilization Review (DUR) Program. A follow-up report is due by December 1, 2010.

The Texas Medicaid Vendor Drug Program has administered the DUR Program since it was established in 1992. The goals of the DUR Program are to promote the appropriate use of drug therapy and to reduce Medicaid drug costs. The DUR Program is required by federal law to:

1. Perform retrospective drug use reviews.
2. Perform prospective drug use reviews.
3. Have in place a DUR Board for the consideration and approval of drug use review criteria.
4. Provide an annual report to the Centers for Medicare & Medicaid Services (CMS), the federal oversight agency for state Medicaid programs.

HHSC will implement strategies to strengthen each of these four program components in the upcoming year.

Retrospective drug use reviews include an evaluation of therapy and intervention after a prescription has been filled. For fiscal year 2008, the estimated general revenue cost savings resulting from retrospective drug use reviews was \$14,589,466. The estimated cost savings for fiscal year 2009 retrospective drug use reviews is not yet available, but will be included in the December 1, 2010 report. The DUR Program has traditionally conducted six retrospective drug use reviews per fiscal year. For fiscal year 2010, the number of retrospective drug use reviews will be increased to eight reviews, pending DUR Board approval. Five of the eight retrospective drug use reviews proposed for fiscal year 2010 are repeats of reviews that were approved by the board in previous years. Based on historical savings for these five interventions, the estimated general revenue savings for fiscal year 2010 exceeds the total estimated general revenue savings for fiscal year 2008.

Clinical prior authorization edits are one type of prospective review used to determine if the prescribed medication is consistent with the patient's known medical conditions. The DUR Program currently has 28 clinical edits in effect. One clinical prior authorization edit was implemented in fiscal year 2009, and seven clinical edits have been reviewed and approved by the DUR Board for implementation in fiscal year 2010. While a key goal of clinical prior authorizations is to improve clinical efficacy and safety in drug prescribing and usage, clinical prior authorization edits also may provide cost savings by deterring inappropriate or duplicative prescribing of medications.

HHSC will require the DUR Board to incorporate a conflict-of-interest policy into its bylaws. The policy will prevent board members from having contractual relationships or other conflicts

of interest with pharmaceutical manufacturers that could call into question board members' impartiality when recommending that drugs or drug classes be subject to drug use reviews.

HHSC will improve monitoring of the DUR Program in several ways. HHSC will expand the DUR Program's annual report to include estimated cost savings resulting from the program's performance of both prospective and retrospective drug use reviews. The annual report has not previously included cost savings from prospective prior authorizations. Inclusion of this information will allow for more accurate evaluation of program effectiveness and the development of program improvements. In addition, the final report will be posted on the HHSC website to increase access to and awareness of program information. Finally, HHSC will post quarterly on its website data regarding the prescription drug classes and individual prescription drugs that are most often prescribed to Medicaid patients or that represent the greatest expenditures.

HHSC will develop and submit a follow-up report by December 1, 2010, to describe continued or additional strategies to strengthen the DUR Program, realized cost savings, and anticipated cost savings for fiscal year 2011.

Introduction

HHSC submits this report pursuant to the 2010-11 General Appropriations Act (Article II, HHSC, Rider 49, S.B. 1, 81st Legislature, Regular Session, 2009). The Legislative Budget Board's (LBB) publication *Texas State Government Effectiveness and Efficiency* (2009) included a report entitled "Strengthen the Texas Medicaid Drug Utilization Review Program to Promote Safety and Contain Spending" (pp. 229-238). The report made five recommendations, four of which were included in H.B. 2030, 81st Legislature, Regular Session, 2009. Rider 49 encompasses the fifth recommendation. Specifically, Rider 49 requires the following:

"Out of funds appropriated above in Goal B, Medicaid, the Health and Human Services Commission shall develop and submit a report on strategies implemented by the agency after the effective date of this Act to strengthen the Texas Medicaid Drug Utilization Review Program to the Legislative Budget Board and the Governor by December 1, 2009 and provide a follow-up report on December 1, 2010. Each report should include savings realized during the previous fiscal year and anticipated savings for the following fiscal year."

The goal of the Medicaid Drug Utilization Review (DUR) Program is to promote the appropriate use of drug therapy and to contain costs. Although the program has been effective, additional cost savings may be realized through further efforts by HHSC.

For fiscal year 2008, the estimated general revenue general revenue cost savings resulting from retrospective drug use reviews was \$14,589,466. A methodology for determining cost savings from clinical edit prior authorizations is being developed and refined and will be included in the follow-up report to be provided December 1, 2010. The strategies outlined herein are expected to result in an increase in cost savings for fiscal year 2010. HHSC projects a minimum estimated

cost savings of \$14,672,536 from retrospective drug use reviews for fiscal year 2010, which does not include possible cost savings realized through additional strategies outlined in this report.

Background

Beginning in the 1980s, the availability of drug information, including quality of drug therapy and potential interactions, resulted in large-scale initiatives to promote evaluations of the use of drug therapy. Subsequently, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) required drug utilization reviews for all outpatient Medicaid patients. The Texas Medicaid Vendor Drug Program, which provides outpatient prescription drugs to Medicaid recipients enrolled in Medicaid fee-for-service and managed care, has administered the Texas DUR Program since it was established in 1992. The purpose of the DUR Program is to monitor and increase the appropriate use of drug therapy while reducing drug program costs by preventing unnecessary or inappropriate therapies and encouraging the use of cost-effective drugs.

Under OBRA '90, both prospective and retrospective reviews are required as part of the Medicaid DUR Program. Prospective drug use reviews are conducted by pharmacists at the point-of-sale for all new and refill prescription medications before dispensing to the patient. Reviews involve an examination of each prescription and the patient's medication record with a focus on whether a drug is being used appropriately. If the prescription conflicts with the established DUR criteria (such as maximum dosing, age-based restrictions, drug interactions, ingredient duplication, etc.), the pharmacist receives an educational alert and is able to take appropriate action (confer with the prescriber about changing the prescription, discuss potential drug interactions with the patient, etc.).

Clinical prior authorization edits are another type of prospective review. Before a prescription is filled, clinical edits check a patient's Medicaid medical and drug claims histories to determine whether the information on file indicates that the patient's medical condition matches the edit criteria for dispensing the requested drug without need of additional prior authorization. Prescriptions found to be in conflict with patient records based on clinical edit criteria will require a prior authorization request by the prescriber before it can be filled by the pharmacist.

Retrospective drug use reviews include an evaluation of therapy and intervention after a prescription has been filled. These reviews may examine claims data to analyze prescribing practices, medication use by clients, and pharmacy dispensing practices. A minimum of six retrospective reviews are conducted each fiscal year, each with criteria focusing on a specific pattern of drug misuse, medically unnecessary prescribing, or inappropriate prescribing. Review findings result in educational outreach to practitioners with information that may improve prescribing or dispensing practices. The 26 retrospective reviews conducted in fiscal years 2004 through 2007 resulted in an estimated savings of \$50.8 million general revenue.

The DUR Board is an advisory board to HHSC and is a required component of the DUR Program per OBRA '90. The board consists of five practicing physicians and five practicing pharmacists who are appointed by the HHSC Executive Commissioner. The DUR Board reviews and approves the therapeutic criteria for prospective DUR, retrospective DUR, and clinical prior authorizations.

To assist the board with the development and review of DUR criteria and standards, HHSC has an interagency agreement with The University of Texas College of Pharmacy. HHSC also contracts with Affiliated Computer Systems, Inc. (ACS) to develop and conduct the retrospective reviews using a prescribed methodology, to administer the point-of-sale prior authorization system (including clinical prior authorizations), and to run a call center for prior authorization requests. ACS develops retrospective reviews and prospective clinical prior authorizations under the direction of HHSC and presents them to the DUR Board for revision, denial, or recommendation for implementation.

Strategies to Strengthen the DUR Program

Federal law requires the DUR Program to:

1. Perform retrospective drug use reviews.
2. Perform prospective drug use reviews.
3. Have in place a DUR Board for the consideration and approval of drug use review criteria.
4. Provide an annual report to the Centers for Medicare & Medicaid Services (CMS), the federal oversight agency for state Medicaid programs.

During fiscal year 2010, to strengthen each of the four program components listed above, HHSC is implementing the following strategies:

1. Increasing the number of retrospective drug use reviews and prospective clinical prior authorization edits.
2. Proposing a conflict-of-interest policy to the DUR Board for adoption into its bylaws.
3. Improving data monitoring through:
 - a. Expansion of the DUR annual report to include estimated savings from prospective prior authorizations.
 - b. Quarterly reporting of drug utilization and expenditure data on the HHSC website.

Increased Retrospective Reviews

Every fiscal year, HHSC conducts a minimum of six retrospective reviews. The criteria for these reviews focus on a specific pattern of drug misuse, medically unnecessary prescribing, or inappropriate prescribing. The retrospective reviews conducted in fiscal year 2008 resulted in an estimated cost savings of \$14,589,466 general revenue, which represents an increase of \$1,195,402 from the previous fiscal year.

Fiscal Year 2008 Cost Savings from Retrospective Drug Use Reviews

Retrospective Review	Number of Letters	12-Month General Revenue Savings
Advair/Symbicort Inhalers	2,933	\$1,690,317.86
Attention Deficit Hyperactivity Disorder	1,104	\$1,088,456.11
Diabetes	3,496	\$1,267,152.47
Gastrointestinal D.U.E.*	3,907	\$418,088.45
Non-steroidal anti-inflammatory D.U.E.*	6,012	\$25,361.86
Polypharmacy	5,287	\$10,100,089.64
Totals	22,739	\$14,589,466.39

*Drug Use Evaluation.

HHSC completed another six retrospective reviews in fiscal year 2009. However, the resulting estimated cost savings have not yet been determined, so this information will be included in next year's report. The retrospective reviews conducted in fiscal year 2009 focused on the following topics:

1. Migraine medications
2. Antidepressant medications
3. Atypical antipsychotics
4. Anticonvulsants: drug use evaluation
5. Attention Deficit Hyperactivity Disorder (ADHD): Medication management
6. Brand to generic: increase generic substitutions

H.B. 2030, 81st Legislature, Regular Session, 2009, requires HHSC to increase the number and types of retrospective drug use reviews performed each year in comparison to the number and types performed in fiscal year 2009. In addition, H.B. 2030:

1. Allows for the repeat of retrospective drug use reviews that have improved client outcomes and reduced Medicaid spending.
2. Recommends that HHSC consider implementing disease-specific retrospective drug use reviews.

In accordance with this direction, HHSC will increase the number and types of retrospective drug reviews performed in fiscal year 2010. Pending DUR Board approval, HHSC intends to perform a minimum of 8 reviews in fiscal year 2010 as compared to the 6 performed in fiscal year 2009.

The DUR Board has reviewed and approved the following seven retrospective interventions for fiscal year 2010. Others will be proposed at the DUR meeting in February 2010.

- Antibiotic Prescribing
- Coordination of Care (New)
- Chronic Non-Malignant Pain (New)

- Multiple Drug Therapy Regimen/Polypharmacy
- Atypical Antipsychotic Optimization of Use
- Diabetes Mellitus Disease Management
- Gastrointestinal Agents, Drug Use Evaluation

Out of the seven proposed interventions to be performed in fiscal year 2010, five have been utilized in the past. The historical average of annual general revenue savings for these five interventions is displayed in the chart below. The sum of the average cost savings per intervention represents an increase in estimated cost savings for fiscal year 2010 over fiscal year 2008, the latest year for which data is available. This increase does not include potential cost savings resulting from the additional three interventions that will be implemented in fiscal year 2010.

Mean Annual Cost Savings for Interventions Performed Since Fiscal Year 2004

Intervention	Mean Annual General Revenue Cost Savings	Fiscal Years Performed
Polypharmacy	\$ 7,174,903	2005, 2006, 2008
Antibiotic Prescribing	890,378	2004, 2006, 2007
Atypical Antipsychotics	4,930,507	2004, 2005, 2006, 2007
Diabetes	1,267,152	2008
Gastrointestinal Agents D.U.E.	409,597	2006, 2008
Total	\$14,672,536	

Increased Clinical Prior Authorizations

Clinical prior authorization edits are one component of the prospective drug utilization reviews. The edits are based on evidence-based clinical criteria and nationally recognized, peer-reviewed information. A key goal of clinical prior authorizations is improved clinical efficacy and appropriateness of care for the patient. In addition, clinical prior authorizations may also provide cost savings for the Medicaid Vendor Drug Program, and the Medicaid program, in general by deterring inappropriate prescribing of medications.

When a pharmacy submits a Medicaid claim for a product subject to a clinical edit, an automated, point-of-sale system called SmartPA checks the patient's available medical and prescription drug claims histories to determine whether the information in the system shows that the patient's condition meets the established criteria. If the patient's medical and claims histories demonstrate the criteria are met, the claim will be approved without the need for a prior authorization phone call. If the patient's medical and claims histories do not meet the criteria, the prescriber must call to request prior authorization.

The DUR Program currently has 28 clinical prior authorization edits in effect. One clinical prior authorization edit was implemented in fiscal year 2009 to promote the prudent prescribing of fentanyl buccal tablets (Fentora®), which are used to treat breakthrough pain in adult patients with cancer. In addition, seven clinical prior authorizations have been proposed to and approved

by the DUR Board for implementation in the coming months. These clinical edits focus on the following medications:

- Acetaminophen – to monitor maximum daily dose.
- DDAVP® - to promote prudent prescribing of desmopressin acetate (used to stop bleeding in certain hemophilia patients and to control water loss for patients with diabetes insipidus).
- ESAs – to promote prudent prescribing of Erythropoiesis Stimulating Agents (used to treat certain types of anemia by stimulating the bone marrow to produce red blood cells).
- Ketorolac – to promote prudent prescribing of ketorolac (Toradol®) (a non-steroidal anti-inflammatory drug).
- Provigil® – to promote prudent prescribing of modafinil (Provigil®) (used to improve wakefulness for adults with sleep disorders).
- Regranex – to promote prudent prescribing of becaplermin (Regranex®) (a gel used to help heal ulcers of the foot, ankle, or leg in people who have diabetes).
- Tramadol – to promote prudent prescribing of tramadol products (a narcotic-like pain reliever).

ACS is contractually responsible for incorporating new clinical prior authorizations into the SmartPA software system. The precise timeline for implementing the seven approved edits is indeterminable because the required system changes must be programmed and tested to provide reasonable assurance that the change will be successful and not problematic for clients or providers.

Clinical edits, which promote safe and effective prescribing practices, improve the quality of Medicaid services. A methodology is under development for determining the cost savings that result from clinical edits. HHSC will include the information in the fiscal year 2010 DUR Program annual report to CMS.

Conflict of Interest Policy for DUR Board

Currently, the Medicaid DUR Board bylaws do not include a conflict of interest provision to prevent board members from having contractual relationships or other conflicts of interest with pharmaceutical manufacturers that could call into question board members' impartiality when recommending that drugs or drug classes be subject to drug use reviews. H.B. 2030 requires that the HHSC Executive Commissioner require the board to develop a conflict of interest policy that applies to the board.

HHSC staff will present proposed bylaws to the DUR Board during its upcoming meeting on February 25, 2010. The proposed bylaws will include, at minimum, the following language contained in H.B. 2030, 81st Legislature, Regular Session, 2009, relating to DUR Board conflicts of interest:

“A member of the board of the Medicaid Drug Utilization Review Program may not have a contractual relationship, ownership interest, or other conflict of interest with a pharmaceutical manufacturer or labeler

or with an entity engaged by the commission to assist in the administration of the Medicaid Drug Utilization Review Program.”

Improved Data Monitoring

H.B. 2030, 81st Legislature, Regular Session, 2009, requires HHSC to expand the DUR Program’s annual report, which is a federally required report. HHSC will expand the report to include estimated cost savings resulting from the program’s performance of both prospective and retrospective drug use reviews. The cost-saving estimates for prospective drug use reviews will include savings attributed to the electronic claims processing system and clinical edits screened through the prior authorization system. Previous annual reports did not include cost savings from prospective drug use reviews, and adding this information will allow for more complete evaluation of program effectiveness and the development of program improvements.

In addition, H.B. 2030, 81st Legislature, Regular Session, 2009, requires that HHSC monitor and analyze prescription drug use and expenditure patterns in the Medicaid program. HHSC must identify the prescription drug classes and individual prescription drugs that are most often prescribed to patients or that represent the greatest expenditures. This data will be published quarterly on the HHSC website. Tracking this drug utilization and expenditure data may improve the DUR Program’s process for identifying retrospective drug use reviews and clinical edits that may be most useful and provide the most savings.

Conclusion

The Texas Medicaid Drug Utilization Review Program improves patient outcomes by monitoring and encouraging the appropriate use of drug therapy. The program also supports the reduction of drug program costs by preventing unsuitable therapies and encouraging the use of cost-effective drugs. The strategies outlined in this report will further strengthen the program by increasing cost savings while continuing to meet the medical needs of Medicaid prescription drug recipients. Prescribers and pharmacists will have access to increased education and feedback provided by retrospective drug use review letters; increased clinical prior authorizations will reduce inappropriate prescription provision and use; a new conflict-of-interest policy will provide assurance that DUR Board members make decisions based only on patient or programmatic interests; and improved data monitoring will allow HHSC to present more complete and useful program information to CMS and the public.

The 2010-11 General Appropriations Act, S.B. 1, 81st Legislature, Regular Session, 2009 (Article II, Health and Human Services Commission, Rider 49), requires a follow-up report on strengthening the Medicaid DUR program to be developed and submitted by December 1, 2010. The report will describe continued and additional strategies to strengthen the DUR Program, realized cost savings, and anticipated cost savings for fiscal year 2011.