
RIDER 49 REPORT

Strengthening the Texas Medicaid Drug Utilization Review Program

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

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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) submitted a report in December 2009 on the strategies implemented by the agency after September 1, 2009, to strengthen the Texas Medicaid Drug Utilization Review (DUR) Program. In addition, Rider 49 requires that a follow-up report be submitted by December 1, 2010, to describe continued or additional strategies to strengthen the program.

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:

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

The 2009 Rider 49 report described four strategies that HHSC would implement to strengthen each of these four program components. The 2010 follow-up report describes the three strategies that were implemented and describes the progress towards implementing the fourth strategy, the creation of a conflict-of-interest policy for the DUR Board. HHSC is currently developing a new rule to be incorporated into the Texas Administrative Code that will disallow DUR Board members from having contractual relationships or other conflicts of interest with pharmaceutical manufacturers. This new rule will strengthen the integrity of the board by ensuring members' impartiality when recommending drugs or drug classes for drug use reviews.

Retrospective drug use reviews include an evaluation of therapy and intervention after a prescription has been filled. For fiscal year 2009, the estimated general revenue cost savings resulting from retrospective drug use reviews was \$3,660,995. For fiscal year 2010, the number of retrospective drug use reviews was increased from six to eight reviews. Only four out of eight reviews have been completed. As a result, the total estimated cost savings for fiscal year 2010 retrospective drug use reviews is not yet available. However, the four completed reviews have yielded an estimated cost savings of \$25,753,443. For fiscal year 2011, a total of eight reviews will be performed, including two new interventions approved by the DUR Board.

Clinical prior authorization edits are a type of prospective review that determine if the prescribed medication is consistent with the patient's known medical conditions. The DUR Program currently has 28 clinical edits in effect. Seven clinical edits were implemented in fiscal year 2010, and one additional clinical edit will be presented to the DUR Board for approval on November 18, 2010. The estimated cost savings achieved through clinical prior authorization edits in fiscal year 2009 was \$79,269,826 all funds, as reported by the contractor for prior authorization services. Cost savings estimates for fiscal year 2010 and anticipated savings for fiscal year 2011 are not yet available.

HHSC has improved monitoring of the DUR Program in several ways. The DUR Program's annual report for fiscal year 2009 included estimated cost savings resulting from the program's performance of both prospective and retrospective drug use reviews, whereas the annual report has not previously included cost savings produced from prospective prior authorizations. In addition, the final report was posted on the Vendor Drug Program website in November 2010, allowing for increased access to and awareness of this program information. Finally, in November 2010 HHSC began posting data on its website regarding the prescription drug classes and top 100 individual prescription drugs that are most often prescribed to Medicaid patients and that represent the greatest expenditures.

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."

An initial report by HHSC was submitted in December 2009 to the Legislative Budget Board and the Governor. The report:

- Identified four specific strategies to strengthen the DUR Program.
- Indicated an expected increase in cost savings through retrospective drug use reviews for fiscal year 2010.
- Indicated that a methodology for estimating cost savings from prospective clinical prior authorization edits would be developed and that these estimates would be provided in the follow-up report.

Three of the four strategies described in the 2009 report have been implemented, and the fourth is being further developed for implementation in fiscal year 2011.

Cost savings realized through retrospective reviews in fiscal year 2010, although not finalized, have greatly exceeded savings achieved in fiscal year 2009. In addition, cost savings from clinical prior authorization edits have been determined at a total of \$79,269,826 all funds for fiscal year 2009. Although the cost savings from clinical edits are not yet available for fiscal year 2010, this information will continue to be made available by the contractor for incorporation into the DUR annual report, which is due to CMS by June 30 of each year.

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 to be a part of the Medicaid DUR Program. Point-of-sale prospective drug use reviews are conducted by pharmacists 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.) or the prescription fill is denied.

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 and medication histories support 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 38 retrospective reviews conducted in fiscal years 2004 through 2009 resulted in an estimated savings of \$69 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, which prescribe standards for drug use, HHSC has an interagency agreement with The University of Texas College of Pharmacy. HHSC 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. In December 2010, a new vendor, Health Information Designs (HID), will begin administering the prior authorization system and running the call center. ACS will continue to develop retrospective reviews under the direction of HHSC and present them to the DUR Board for revision, denial, or recommendation for implementation. HID will develop

prospective clinical prior authorizations under HHSC direction and present them to the DUR Board.

Updates on Strategies to Strengthen the DUR Program

Federal law requires the DUR Program to:

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

The 2009 Rider 49 report identified strategies to strengthen each of the four program components listed above, including:

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

HHSC has successfully implemented Strategy 1 and Strategy 3. Within the past few months, HHSC determined that the most appropriate approach to implementing the DUR Board conflict-of-interest policy would be through the adoption of agency rules. Therefore, rather than pursue Strategy 2 as proposed in the 2009 report, HHSC staff is currently developing agency rules to define and prevent conflicts of interest among DUR Board members.

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. HHSC increased the number of reviews to eight for fiscal year 2010 and will continue to perform a minimum of eight reviews per year.

The 2009 Rider 49 report did not provide cost savings estimates for fiscal year 2009 because the information was not yet available. The six retrospective reviews conducted in fiscal year 2009 resulted in an estimated cost savings of \$3,660,995 general revenue, which represents a \$10,928,471 decrease in savings from the previous fiscal year. Although no specific level of cost savings was projected, this amount was notably less than the average \$13 million general revenue realized annually between fiscal years 2004 and 2008. However, H.B. 2030, 81st Legislature, Regular Session, 2009, directs HHSC to:

- Allow for the repeat of retrospective drug use reviews that have improved client outcomes and reduced Medicaid spending.
- Regularly examine Medicaid prescription drug claims data to identify occurrences of potential drug therapy problems that may be addressed by repeating successful retrospective drug use reviews performed in this state and other states.

In accordance with this legislative direction, HHSC has begun working with ACS to identify a mix of historically effective interventions and potentially effective new interventions to guide improvements in both client outcomes and cost savings in 2011.

Fiscal Year 2009 Cost Savings from Retrospective Drug Use Reviews

Retrospective Review	Number of Letters	12 mo. GR Savings
Brand to Generics: increase generic substitutions	2,578	\$7,475,078
Attention Deficit Hyperactivity Disorder	2,189	\$1,160,176
Anticonvulsants: drug use evaluation	1,907	\$437,236
Atypical Antipsychotics: coordination of care*	1,253	\$76,198
Migraine medications	1,075	\$466,907
Antidepressant medications	1,660	\$45,399
Total:	10,662	\$ 3,660,995

*The 2009 retrospective review of atypical antipsychotic drugs was a newly designed intervention that focused on the coordination of care and achieved \$76,198 general revenue annual cost savings. This new intervention was distinct from previous years' reviews of the appropriate usage of atypical antipsychotic drugs, which yielded average savings of \$4.9 million general revenue per year from fiscal year 2004 through 2007.

HHSC increased the number and types of retrospective drug reviews performed in fiscal year 2010. Once the retrospective DUR interventions have been mailed to providers, the calculation of the resulting cost savings requires an additional six months. The cost savings for retrospective reviews conducted in fiscal year 2010 have been determined for four of the eight reviews, which total \$25,753,443 general revenue.

Retrospective Review	Date Mailed	12 mo. GR Savings
Hyperlipidemia	8/31/2010	<i>Not yet available</i>
Coordination of Care	6/29/2010	<i>Not yet available</i>
Diabetes Mellitus Disease Management	5/28/2010	<i>Not yet available</i>
Gastrointestinal Agents Drug Use Evaluation	4/12/2010	<i>Not yet available</i>
Chronic Non-Malignant Pain	12/24/2009	\$310,052
Atypical Antipsychotics: Optimization of Use	12/22/2009	16,050,282
Multiple Drug Therapy Regimen/Polypharmacy	11/25/2009	7,044,681
Antibiotic Prescribing	10/30/2009	2,348,428
Total:		\$ 25,753,443

Fiscal Year 2010 Cost Savings from Retrospective Drug Use Reviews

HHSC with ACS has identified eight retrospective drug use reviews to be conducted in fiscal year 2011, including interventions that have historically generated significant cost savings and new interventions that will target drug therapies with known problems.

Recent Savings for Fiscal Year 2011 Proposed Retrospective Drug Use Reviews

Proposed Retrospective Review	Most Recent Year	GR Savings from Most Recent Year
Hypertension: Compliance with JNC-7 standards*	<i>New</i>	<i>N/A</i>
Multiple Drug Therapy Regimen/Polypharmacy*	2010	\$7,044,681
Chronic Non-Malignant Pain*	2010	\$310,052
Atypical Antipsychotics in Children*	<i>New</i>	<i>N/A</i>
Attention Deficit Hyperactivity Disorder	2009	\$1,160,176
Migraine medications	2009	\$466,907
Brand to Generics: increase generic substitutions	2009	\$7,475,078
Anticonvulsants: drug use evaluation	2009	\$437,236
Total of Historical Interventions:		\$16,894,130

*Approved by the DUR Board at time of reporting.

Although cost savings projections are difficult to determine, an analysis of the most recent utilization of each of the proposed interventions provides an applicable comparison. Without the addition of possible savings provided by the two new reviews, the sum of the most recent cost savings for six of the eight interventions totals \$16,894,130 general revenue.

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. Seven clinical prior authorizations were approved by the DUR Board and implemented in fiscal year 2010. 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).

In addition, two clinical prior authorization edits were presented for approval at the DUR Board meeting on November 18, 2010. One edit addresses the use of antipsychotic medication in children under the age of three and the concomitant use of three different antipsychotic medications in any age group. Another edit involves the appropriate use of the laxative Amitiza. Both edits were approved by the Board.

The cost savings estimates from clinical edits are determined by ACS. Although fiscal year 2010 cost savings estimates are not yet available, HHSC was able to provide cost savings information for fiscal year 2009 prospective drug use reviews for the first time in the 2009 DUR annual

report to CMS. The total savings reported by ACS for fiscal year 2009 were \$79,269,826 all funds.

The cost savings estimates for clinical prior authorization edits are determined based on: 1) the number of claims evaluated at both the point of sale and through the call center, 2) how many claims were denied, and 3) the average cost of denied claims. Because this information is variable, and because fiscal year 2009 was the first year for which estimates were made, projections for future savings cannot be calculated accurately. However, HHSC will continue to require its prior authorization services contractor to provide an analysis each year of cost savings resulting from prospective drug use review practices.

Conflict-of-Interest Policy for DUR Board

H.B. 2030 requires that HHSC develop a conflict-of-interest policy that applies to the DUR Board. The bill allows the HHSC Executive Commissioner the option to implement this requirement through the adoption of rules. Although HHSC reported in the 2009 Rider 49 report its initial plan to incorporate the conflict-of-interest policy by requiring that the board adopt an amendment to its bylaws, leadership has recently determined that an agency rule would be a more appropriate approach.

The new rule language will be proposed as more exhaustive than the requirements of H.B. 2030 and will define conflicting relationships, require board members to disclose potential conflicts of interest, and require board members to sign a document acknowledging member duties and responsibilities. HHSC staff plan to present the proposed rule at the January 2011 Medical Care Advisory Committee meeting.

In addition, a conflict-of-interest resolution was presented at the November 18, 2010, DUR Board meeting. A resolution to adopt a conflict-of-interest rule was approved by the Board. The draft rule language was also presented, and board members provided input and comments.

Improved Data Monitoring

H.B. 2030 required HHSC to expand the DUR Program's annual report, which is a federally required report submitted to CMS. HHSC expanded the fiscal year 2009 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 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 including this information will allow for more complete evaluation of program effectiveness and the development of program improvements. Future annual reports will continue to include this cost savings information. The next report for fiscal year 2010 is due to CMS by June 30, 2011.

In addition, H.B. 2030 required that HHSC monitor and analyze prescription drug use and expenditure patterns in the Medicaid program. 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.

HHSC has identified the prescription drug classes and the 100 individual prescription drugs that are most often prescribed to patients and that represent the greatest expenditures. HHSC staff has endeavored to present the information in a user-friendly manner that can be easily assimilated by both pharmacy subject matter experts and public consumers. The information is being published quarterly on the HHSC website, beginning in November 2010.

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. HHSC has continued to practice and further develop the strategies outlined in the 2009 Rider 49 report. These strategies will strengthen the program by ensuring cost savings, continuing to meet the medical needs of Medicaid prescription drug recipients, and by providing the necessary data for future policy analysis and development of initiatives.

As a result of the strategies developed and implemented by HHSC to strengthen the Medicaid Drug Utilization Review Program:

- Prescribers and pharmacists will continue to have access to education and feedback provided by retrospective drug use review letters each year.
- Clinical prior authorizations will reduce inappropriate prescription provision and use, thereby enhancing the safety of patients and increasing the possibilities for prudent payment of allowable claims.
- A new agency rule will provide assurance that DUR Board members make decisions based definitively on patient and/or programmatic interests.
- Improved data monitoring will allow HHSC to present more complete and useful program information to the Texas Legislature, CMS, and the public.