Preferred Drug List Annual Report

Prepared by the Texas Health and Human Services Commission

January 2005

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Preferred Drug List Annual Report

Introduction

House Bill 2292, 78th Legislature, Regular Session, 2003 directed the Texas Health and Human Services Commission (HHSC) to implement preferred drug lists (PDLs) for Medicaid and the Children's Health Insurance Program (CHIP) by March 1, 2004.

House Bill (H.B.) 2292, Section 2.11 also requires that HHSC provide a written report on the PDL program to the Legislature and the Governor each year. The report is to include:

1. the cost of administering the PDLs;
2. an analysis of the utilization trends for medical services provided by the state and any correlation to the PDLs;
3. an analysis of the effect on health outcomes and results for recipients; and
4. statistical information related to the number of approvals granted or denied.

HHSC implemented the first phase of the Medicaid PDL on February 23, 2004, and has added drug classes to the PDL periodically since then for a total of 60 drug classes representing about 70 percent of Medicaid pharmacy expenditures. Since this is the first year of the program, HHSC has included in the January 2005 report:

- background information on preferred drug lists and the H.B. 2292 PDL requirements;
- how the Medicaid PDL was developed and implemented in the first year;
- the cost of administering the PDL;
- anticipated savings from the PDL;
- statistical information related to the prior authorization process and the number of approvals granted and denied in State Fiscal Year 2004; and
- next steps for the PDL development process.

As the PDL program has been operational for less than a year, HHSC needs additional time to compile clinical data to analyze the effect of the PDLs on health outcomes and results for recipients as well as utilization trends for medical services provided by the state and any correlation to the PDLs.

Background Information on Preferred Drug Lists and the H.B. 2292 PDL Requirements

What is a Preferred Drug List?

A preferred drug list is a tool used by many states to control growing Medicaid drug costs while also ensuring that program recipients get the medicines they need.

The Federal Omnibus Budget and Reconciliation Act of 1990 (OBRA 90) requires that state Medicaid outpatient drug programs cover all products for which a manufacturer has

signed a Medicaid rebate agreement with the Federal government. Based on Federal law, state Medicaid outpatient drug programs cover a broad array of drugs and drug classes.

Prescription drug costs have been the fastest growing element of state Medicaid budgets in recent years, with drug spending increasing by 15 to 20 percent per year. To help curb growing drug costs, many states have developed and implemented preferred drug lists.

With a preferred drug list, Medicaid clients still can receive all the drugs that Medicaid is required to cover under Federal law, including those covered before the PDL was established. The PDL controls spending growth by increasing the use of *preferred drugs* – prescription drugs selected for the PDL that are determined to be safe, clinically effective and cost effective compared to other drugs on the market. Non-preferred drugs, which are drugs reviewed but not selected to be on the PDL, require prior authorization. Unless Texas Medicaid has information that indicates a patient meets the State's prior authorization criteria, a physician's office must call to obtain prior approval before a non-preferred drug can be dispensed.

By containing drug costs, the PDL will help preserve in the long run Medicaid's ability to meet clients' increasing prescription drug needs and other health care needs.

Overview of House Bill 2292 Preferred Drug List Requirements

States have taken different approaches to developing preferred drug lists based on Federal and State law. In Texas, H.B. 2292, 78th Legislature, Regular Session, 2003 directed HHSC to implement PDLs for Medicaid and CHIP, and provided direction on how to do so. H.B. 2292 also allowed the adoption of PDLs for other state programs.

Below is a summary of the major PDL provisions from H.B. 2292:

- The PDL may contain only drugs for which the drug manufacturer or labeler has reached a supplemental rebate agreement or program benefit agreement with HHSC.
- HHSC or its designated contractor is to negotiate with manufacturers and labelers of both brand name and generic products for supplemental rebates.
- A governor-appointed Pharmaceutical and Therapeutics Committee (P&T Committee) of physicians and pharmacists makes recommendations to HHSC about which drugs to place on the PDL based on clinical efficacy, safety, cost effectiveness, and other program benefits.
- HHSC decides which drugs go on the PDL based on the recommendations of the P&T Committee, clinical efficacy, the net price of competing drugs to the state, and program benefit offers.
- HHSC must protect the confidentiality of drug pricing information.
- The physician or other prescriber must obtain prior authorization (PA) for non-preferred drugs, which are drugs reviewed by the P&T Committee but not selected to be on the PDL.

Medicaid PDL Development and Implementation

There were a number of steps involved in developing and implementing the Medicaid PDL, including: the appointment of the Texas P&T Committee, hiring of contractors, establishing a PDL phase-in timeline, frequent meetings of the P&T Committee followed by HHSC PDL decisions and communications, implementing a prior authorization process, and setting prior authorization criteria. More detail follows on these steps undertaken in the first year of the program.

In addition, Appendix A includes information on additional considerations in the first year PDL process, including the prior authorization study, the CHIP PDL, HHSC's approach to generic drugs, and how HHSC has handled program benefit proposals offered in lieu of cash supplemental rebates.

Texas Pharmaceutical and Therapeutics Committee

Governor Rick Perry appointed six physicians and five pharmacists to the Texas P&T Committee in November 2003. The committee provides recommendations to HHSC on which drugs to place on the PDL based on clinical efficacy, safety and cost effectiveness. The 11 P&T Committee members represent diverse specialties, geographic areas, and practice settings.

P&T Committee Members

- Dr. Harris Hauser, MD, Chairman, Psychiatrist and Neurologist
- Donna Rogers, RPh, Vice Chair, Director of Pharmacy at the TexSan Heart Hospital
- Dr. Richard Adams, MD, Developmental Pediatrician
- Dr. Anthony Busti, PharmD, Assistant Professor at Texas Tech University Health Sciences Center School of Pharmacy
- Dr. Melbert "Bob" Hillert, MD, Cardiologist
- J.C. Jackson, RPh, Retail Pharmacy Manager, Kelsey-Seybold Clinic
- David King, RPh, Managed Care Manager at Randalls/Safeway Inc.
- Julie Lewis, RPh, Lead Consultant Pharmacist at PharMerica
- Dr. Valerie Robinson, MD, Pediatric Psychiatrist
- Dr. Guadalupe Zamora, MD, Family Practitioner
- Dr. John Zerwas, MD, Anesthesiologist

H.B. 2292 required that the P&T Committee meet monthly for the first six months and at least quarterly thereafter. The committee has met eight times, meeting monthly from December 2003 through May 2004, and then quarterly in August and November 2004.

Hiring of Contractors

As allowed by H.B. 2292, HHSC, through a competitive bid process, awarded contracts for PDL and prior authorization services.

HHSC awarded a contract to Provider Synergies, LLC to negotiate rebates on behalf of the state, to provide information to the P&T Committee on the clinical efficacy, safety and cost effectiveness of products in each drug class, and to assist HHSC and the P&T

Committee with PDL development and maintenance, including PDL communications to stakeholders and identifying which drug classes the state may want to include on the PDL. HHSC's contract with Provider Synergies is a fixed fee contract through August 31, 2006.

HHSC also awarded a contract to Heritage Information Systems, Inc. (now ACS-Heritage Information Systems) for prior authorization services. ACS-Heritage provides prior authorization services both through a prior authorization call center with a toll-free number, and through an automated prior authorization system called SmartPA. HHSC's contract with ACS-Heritage is a transaction-based contract through August 31, 2006.

PDL Development Timeline

H.B. 2292 included the following major PDL development milestones:

- The Governor was to appoint the P&T Committee by November 2003;
- The P&T Committee was to make PDL recommendations to HHSC by January 1, 2004; and
- HHSC was to implement the PDLs by March 1, 2004.

HHSC developed the Medicaid PDL in several stages in order to meet these milestones and to stagger new prior authorization requirements for Medicaid physicians, pharmacies and other stakeholders. See Appendix B for the prior authorization implementation schedule by drug class.

PDL Development Process

Based on the parameters in H.B. 2292, HHSC worked with the P&T Committee and other stakeholders to establish the PDL development process.

The P&T Committee reviews drugs for the PDL by pharmacologically determined drug class. Once HHSC decides which drug classes will be reviewed at the upcoming P&T Committee meeting, the PDL contractor solicits rebate offers from drug manufacturers and labelers on HHSC's behalf. After the rebate offers are received and reviewed, the PDL contractor provides HHSC and the P&T Committee with clinical efficacy, safety and cost effectiveness information on the products in each drug class. Also, drug manufacturers, labelers and other interested parties may submit written evidence to the P&T Committee supporting the inclusion of a drug on the PDL in advance of the P&T Committee meeting.

At each meeting, the P&T Committee accepts public testimony on the drugs being reviewed at that meeting. For some meetings, the P&T Committee has heard testimony from over 60 people. Following the public testimony, the PDL contractor provides the P&T Committee and the audience a verbal summary of the clinical and safety information provided to the P&T Committee in advance of the meeting.

Since HHSC and the P&T Committee must protect confidential pricing information, the P&T Committee then adjourns to a working session to decide which products in each drug class it will recommend be placed on the PDL taking into account three factors – clinical efficacy, safety and cost effectiveness. The P&T Committee then returns to the public meeting and announces its recommendations for each drug class.

Following the P&T Committee meeting, HHSC makes a PDL decision, posts the decision on the website, and then posts the updated Medicaid PDL with prior authorization criteria. HHSC must provide a minimum of 30 days notice before implementing new PDL prior authorization requirements.

For the first several phases of the PDL, HHSC mailed information about pending PDL changes and prior authorization requirements to Medicaid physicians and pharmacies before the prior authorization implementation date. In addition, for some large drug classes, HHSC sent targeted letters to high-volume physicians letting them know which of their patients were taking non-preferred drugs that would either need to be switched to preferred drugs or obtain prior authorization once the PDL went into effect. Now that the program is up and running, HHSC notifies stakeholders via e-mail about P&T Committee meetings and changes to the PDL or PA criteria. There will also be a PDL mailing to providers and pharmacies at least once a year.

As required in H.B. 2292, the P&T Committee reviews PDL drug classes at least once a year to the extent feasible. The committee completed its first year reviews of 60 drug classes for the Medicaid PDL in August 2004, and did its second review of 15 drug classes in November 2004.

Prior Authorization Process

H.B. 2292 requires that the prescribing physician or other prescribing practitioner obtain prior authorization (PA) for non-preferred drugs before the drug can be dispensed. Non-preferred drugs are drugs that have been reviewed by the P&T Committee, but were not selected for placement on the PDL. PDL-related prior authorization is *not* required for drugs and drug classes that the P&T Committee has not reviewed. These drugs continue to be available to Medicaid clients according to HHSC Vendor Drug Program policies.

HHSC contracted with Heritage Information Systems, Inc. (now ACS-Heritage Information Systems) to provide prior authorization services. ACS-Heritage provides prior authorization services both through a prior authorization call center with a toll-free number, and through an automated prior authorization system called SmartPA.

When a pharmacy submits a Medicaid claim for a product subject to prior authorization, the SmartPA system 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 State's established criteria. If the patient's medical and claims histories demonstrate the criteria are met, the claim will be approved in seconds at the pharmacy point of sale and no prior authorization phone call is required. If the patient's

medical and claims histories do not demonstrate that the patient meets the criteria, the pharmacy will receive a message indicating that the prescriber needs to call the Texas Prior Authorization Call Center at 1-877-PA-TEXAS. HHSC has allowed the prescriber or their representative, such as an office nurse, to request a prior authorization.

In compliance with Federal law, ACS-Heritage must respond to prior authorization requests within 24 hours, and a 72-hour supply of a drug must be provided in an emergency or if a response to a PA request cannot be provided within 24 hours. The call center is open Monday through Friday from 7:30 am to 6:30 pm Central Time. If a patient goes to the pharmacy to pick up a non-preferred drug outside of call center hours and a PA call is required, then the pharmacy can provide a 72-hour supply of the drug to give the physician's office time to request the prior authorization.

Approved requests for prior authorization are valid for one year. If the call center denies the prior authorization request, the prescriber can either prescribe a preferred product or request reconsideration. If the prescriber's request for reconsideration is denied, ACS-Heritage sends the client a letter notifying them of their right to appeal the decision and how to appeal.

Prior Authorization Criteria

Each public or private insurance program that has a drug prior authorization program establishes prior authorization criteria that are used to determine whether a prior authorization request is approved or denied. The PA criteria provide physicians and other providers with information when writing prescriptions. For instance, if a physician knows that his Medicaid patients must try and fail on Drug A before Medicaid will pay for Drug B for that patient, then the physician will prescribe Drug A first unless he knows of a clinical or safety reason why the patient cannot take Drug A, such as a drug allergy or a drug interaction with another drug the patient is already taking.

Given legislative deadlines and anticipated savings for the Medicaid PDL, HHSC initially published the following three general prior authorization criteria for most drug classes on the PDL: therapeutic failure, allergy, or contraindication with preferred product(s). HHSC selected these three criteria based on other states' PDL experience as well as prevailing and generally accepted medical practices. HHSC instructed the call center to approve non-preferred prescriptions if the patient met one of these three general criteria or if the physician provided another clinical reason why the patient needed to receive a non-preferred product instead of a preferred product.

For three mental health drug classes – Atypical Antipsychotics, SSRI Antidepressants and Atypical Antidepressants – HHSC enacted an exception to the prior authorization requirements to maintain continuity of care. For these three drug classes, Medicaid patients who are stable on a non-preferred drug are allowed to continue receiving that drug without a prior authorization phone call. For clients new to Medicaid or in cases where HHSC is not aware that a patient is stable on a non-preferred drug, the physician's

office must call one time to let HHSC know that the patient is stable on a non-preferred drug.

Once the Texas P&T Committee had made recommendations for most drug classes to be included on the Medicaid PDL, HHSC began the process of customizing PA criteria for each drug class. In the summer of 2004, HHSC implemented more specific prior authorization criteria for three drug classes – Proton Pump Inhibitors (gastric acid reducers), Lipotropics, Statins (cholesterol lowering drugs), and Minimally Sedating Antihistamines.

HHSC also notified stakeholders that the HHSC Drug Utilization Review Board (DUR Board), which like the P&T Committee is comprised of Texas physicians and pharmacists, would be accepting public comments and making recommendations to HHSC on possible changes to PDL prior authorization criteria at its August 2004 meeting and future meetings.

In August and November, HHSC staff proposed more specific PA criteria for certain PDL drug classes to the DUR Board based on written input from stakeholders, other states' and private sector experience, and generally accepted medical practices.

At its August and December meetings, the DUR Board heard public testimony on the proposed PA criteria for certain PDL drug classes as well as the PDL PA criteria already in place, and made several PA criteria recommendations to HHSC. HHSC implemented the DUR Board's August recommendation for the Beta Agonist Bronchodilators drug class (for asthma treatment), and is reviewing the DUR Board's December recommendations.

Cost of PDL Administration

Costs for PDL administration are included in the Provider Synergies and ACS-Heritage contracts, which totaled $3,342,780 from November 2003 through August 2004. Aside from the contracts, state staff time and resources have been provided within HHSC's existing budget.

HHSC's contract with Provider Synergies is a fixed fee contract with HHSC options for additional services. From November 2003 through August 2004, Provider Synergies provided HHSC $1,261,867 in services. The base price of the Provider Synergies contract was $1,078,508. In addition, in SFY 2004 HHSC exercised contract options for $183,367 for review of additional drug classes and extra PDL mailings to Medicaid providers and pharmacies.

The ACS-Heritage prior authorization contract is reimbursed on a per prior authorization transaction basis with several HHSC options for additional services. HHSC pays $5.25 or less per PA transaction, with the cost per transaction decreasing as a higher percentage of prior authorization requests are handled through ACS-Heritage's automated SmartPA system instead of through the PA call center. For November 2003 through August 2004,

ACS-Heritage provided a total of $2,080,913 in prior authorization services to HHSC. This included $1,744,163 in PA transaction costs and $336,750 for services prior to the February 23, 2004 PDL implementation date and for two targeted mailings to high volume Medicaid physicians at the start of the program.

PDL Savings

The fiscal note for H.B. 2292 assumed that Texas would save about $150 million General Revenue in the 2004-2005 biennium on an incurred basis through the implementation of the PDLs. PDL savings are generated from new supplemental rebates and from shifting prescribing patterns toward less expensive preferred drugs.

HHSC's first supplemental rebate agreements took effect January 1, 2004, and HHSC implemented prior authorization for the first 15 PDL drug classes on February 23, 2004. HHSC has invoiced manufacturers for supplemental rebates for the first three quarters of calendar year 2004. For January 2004 through September 2004, HHSC has invoiced manufacturers for supplemental rebates totaling about $82 million All Funds. Rebate billings have increased each quarter as more drug classes have been added to the PDL and prescribing patterns have shifted to preferred products.

Based on HHSC's PDL actual savings to date and future forecasts, HHSC now estimates PDL savings of approximately $140.5 million General Revenue in the 2004-2005 biennium on an incurred basis before administrative costs. The $140.5 million savings estimate includes $90.5 million in supplemental rebates and $50 million from shifting prescribing patterns toward less expensive preferred drugs. On a cash basis, HHSC projects savings of about $114.3 million General Revenue for the 2004-2005 biennium, which includes $64.3 million in supplemental rebates and $50 million from shifting prescribing patterns toward less expensive preferred drugs. Cash savings are lower than incurred savings because it takes several months to invoice and collect supplemental rebates from drug manufacturers at the end of each quarter.

Projected savings for the 2004-2005 biennium are estimated to be lower than the fiscal note amount for several reasons. First, the fiscal note assumed a full PDL implementation by March 1, 2004. HHSC set an ambitious PDL phase-in timeline and worked with the P&T Committee and contractors to implement the first phase of the PDL for 15 drug classes on February 23, 2004. HHSC implemented 45 additional PDL drug classes in later phases, so HHSC did not begin to generate savings for these drug classes until after March 1, 2004.

Second, part of the fiscal note savings estimate assumed that under the PDL, Texas prescribers would shift their prescribing patterns toward less expensive preferred drugs. Since the Medicaid PDL was implemented, prescribing patterns have shifted toward preferred products over time. Texas, however, has not generated as much of a shift in prescribing patterns as some other states have experienced. This is probably attributable to HHSC's broad prior authorization criteria, the fact that HHSC allows physicians' staff to request a prior authorization, and high prior authorization approval rates. HHSC

continues to work with the DUR Board on the PDL prior authorization criteria, and will also continue to educate physicians and other prescribers about the goals of the PDL program.

Statistical Information on Prior Authorization

HHSC implemented prior authorization for the first 15 PDL drug classes on February 23, 2004, and implemented prior authorization for additional drug classes in late March, late April, early June and late July. See Appendix B for the prior authorization implementation schedule by drug class.

Chart 1 and Table 1 show the trend in PDL prior authorization transactions from February 2004 through August 2004. Automated prior authorizations are approved through the SmartPA system at the pharmacy point of sale without the need for a phone call if the patient's Medicaid medical and claims histories demonstrate the patient meets the PDL prior authorization criteria. If the claims history does not demonstrate the patient meets the prior authorization criteria, then the prescriber or his representative must request a prior authorization through the call center.

Chart 1

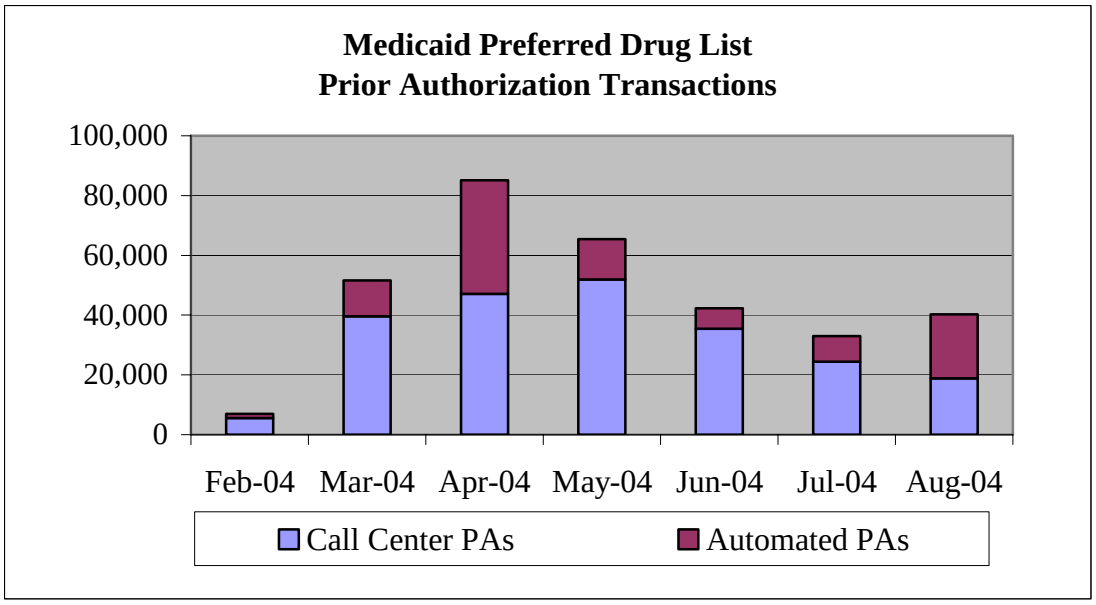


Table 1

	Feb-04	Mar-04	Apr-04	May-04	Jun-04	Jul-04	Aug-04
Call Center PAs	5,602	39,639	47,114	51,962	35,452	24,418	18,792
Automated PAs	1,376	11,945	37,983	13,427	6,878	8,535	21,518
Total PAs	6,978	51,584	85,097	65,389	42,330	32,953	40,310

Based on ACS-Heritage invoiced prior authorizations as of December 22, 2004.

HHSC rolled out prior authorization for the largest PDL drug classes on February 23, 2004 and March 29, 2004. The number of PDL prior authorizations peaked in April at 85,097, and declined to 32,953 by July as physicians and other prescribers became familiar with the PDL and began to prescribe more preferred drugs.

In late July, HHSC and ACS-Heritage established a real-time interface between the HHSC pharmacy claims processing system and the SmartPA system. As a result, while the number of call center prior authorizations has continued to decline since July, automated prior authorizations increased in August as the SmartPA system identified more patients who met the PDL prior authorization criteria for non-preferred drugs based on their Medicaid claims histories.

Table 2 lists the drug classes for which HHSC has received the most prior authorization requests for non-preferred drugs.

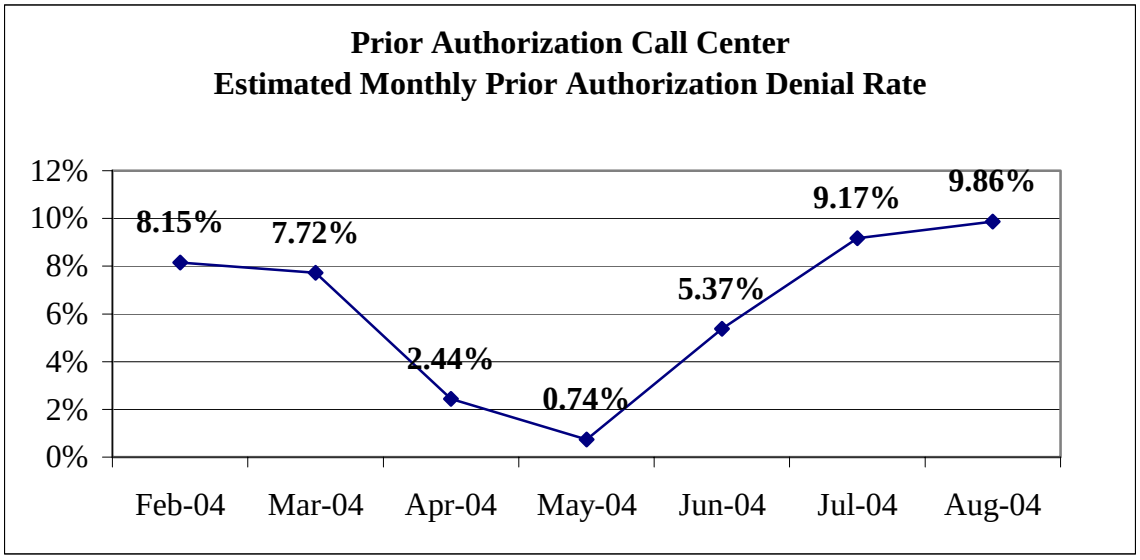
Table 2

Drug Classes With the Most PDL Prior Authorization Requests February 2004 – August 2004
Antifungals, Topical
Antihistamines, Minimally Sedating
Bronchodilators, Beta Agonist (asthma treatment)
Fluroquinolones, Oral (antibiotics)
Hypoglygemics, Insulins (diabetes treatment)
Lipotropics, Statins (cholesterol lowering agents)
Proton Pump Inhibitors (gastric acid reducers)
Stimulants and Related Agents (for attention-deficit/hyperactivity disorder)

In alphabetical order

Since the Medicaid PDL was implemented, the percent of prior authorization requests denied by the prior authorization call center has been below 10 percent each month. Chart 2 shows the percent of prior authorization requests denied by the Prior Authorization Call Center from February 2004 through August 2004.

Chart 2



Estimates based on ad hoc reports of raw call center data run in December 2004. The August 2004 PA denial rate reflects both PDL prior authorization requests and non-PDL clinical prior authorization requests.

HHSC initially published the following three general prior authorization criteria for most drug classes on the PDL: therapeutic failure, allergy, or contraindication with preferred product(s). HHSC instructed the call center to approve non-preferred prescriptions if the patient met one of these three criteria or if the prescriber provided another clinical reason why the patient needed to receive a non-preferred product instead of a preferred product.

Low call center prior authorization denial rates since the beginning of the program are due in part to HHSC's fairly broad prior authorization criteria. Call center prior authorization rates decreased from February to May as prescribers and their staff became more familiar with what information they needed to provide the call center representatives to get a prior authorization request approved. In mid-June 2004, HHSC established more specific prior authorization criteria for three large drug classes– Proton Pump Inhibitors, Minimally Sedating Antihistamines and Lipotropics, Statins. Based on these more specific criteria, call center prior authorization denial rates for these three drug classes increased in June, July and August.

Next Steps for the PDL Development Process

Twice a Year PDL Updates

In response to feedback from providers, HHSC plans to make major updates to the Medicaid PDL twice - rather than quarterly - in 2005. The majority of PDL changes will be implemented in January and July. HHSC may make other minimal changes to the PDL throughout the year for new products or new clinical/safety developments. HHSC

will continue to work with stakeholders on the feasibility of moving to an annual PDL update schedule in 2006.

Possible Changes to the P&T Committee Process

When the P&T Committee initially met in December 2003, most of the committee members were meeting each other for the first time and learning about how they would work with HHSC to develop the PDL. HHSC continues to work with the P&T Committee to increase the clinical and safety dialogue in the public sessions while protecting confidential drug pricing information as required in H.B. 2292.
As part of ongoing efforts to improve the PDL program, HHSC and the P&T Committee are considering the following:

- Simplifying the presentation process to provide committee members with the most critical information needed from the public to deliberate on which drugs to include on the preferred list and which drugs to exclude.
- Documenting the basis of the Committee's recommendation for each drug class and providing this documentation to the public.

Appendix C is a letter from the P&T Committee chairman to the Texas Legislature and the Governor with his perspective on the committee's current process.

Appendix A

Additional Considerations in the Preferred Drug List Development Process

In developing the Texas Medicaid Preferred drug list in 2004, HHSC considered the following additional issues pursuant to H.B. 2292, 78th Legislature, Regular Session, 2003.

Prior Authorization Study

H.B. 2292 required that HHSC complete a study evaluating the impact of prior authorization on recipients of drugs used to treat patients with illnesses that are life threatening, chronic, and require complex medical management strategies before requiring prior authorization for those drugs.

Based on the requirement that a condition meet all three of these requirements to be included in the study, HHSC medical staff determined that cancer, HIV/AIDS and hemophilia should be included in the study. HHSC later learned that it was also legislative intent to include in the study cancer supportive drugs and drugs used to treat multiple sclerosis (MS) and end stage renal disease (ESRD).

HHSC contracted with the Center for Pharmacoeconomic Studies at the University of Texas at Austin (UT) to conduct a prior authorization study on drugs used to treat these illnesses. The UT study concluded that due to the limited literature on the prior authorization impact on these classes, HHSC should consider the risks and benefits before implementing PA for these drug classes. Based on the study's conclusions, drugs used to treat HIV/AIDS (antiretroviral agents), cancer (antineoplastic agents), hemophilia (antihemophilic agents) and MS (multiple sclerosis agents) will not be reviewed for placement on the PDL, and therefore will not require prior authorization. The PDL does include certain drug classes used to treat symptoms that may develop from these conditions and ESRD.

CHIP PDL

H.B. 2292 required that HHSC implement PDLs for both Medicaid and the Children's Health Insurance Program (CHIP). HHSC requested that the P&T Committee focus on the Medicaid PDL during its first six meetings because the Medicaid PDL is expected to generate most of Texas' PDL savings. HHSC expects minimal savings from the CHIP PDL for three reasons. First, Texas' CHIP drug expenditures only represent about 5 percent of Medicaid drug expenditures ($94.5 million for CHIP in SFY 2003 vs. $1.87 billion for Medicaid). Second, HHSC cannot receive the same rebates for CHIP drugs as it does for Medicaid drugs due to Federal Medicaid best price law. Finally, HHSC already had a voluntary CHIP drug rebate program in place before the passage of H.B. 2292.

HHSC has not yet implemented a CHIP preferred drug list. The P&T Committee reviewed some CHIP PDL information at its August 2004 and November 2004 meetings, but deferred action on the CHIP PDL at both meetings. HHSC staff is working with the P&T Committee to determine which drug classes to include on the CHIP PDL and to provide available pediatric-specific clinical and safety information for the committee's CHIP PDL consideration. Until a CHIP PDL is implemented, prescription drugs will continue to be available to CHIP clients based on HHSC Vendor Drug Program policies.

Generic PDL Strategy

H.B. 2292 required that the PDLs contain only drugs for which the drug manufacturer or labeler reaches a supplemental rebate agreement or program benefit agreement with HHSC. HHSC or its designated contractor is to negotiate with manufacturers and labelers of both brand name and generic products for supplemental rebates.

Texas is the first state to require that generic manufacturers and labelers sign supplemental rebate agreements for their drugs to be placed on the PDL. HHSC has worked with generic manufacturers and labelers to comply with H.B. 2292, taking into account that generics may usually be, but are not always, less expensive than brand name products.

All generic drugs available through Texas Medicaid must meet federal standards such that one manufacturer's version of the drug can be relied upon to perform in a manner similar to the brand name, as well as all other generic versions. Therefore, when pharmacists judge all other factors to be equal, they frequently purchase generic drugs based on price. For this reason, generics are different than brand name products in that pharmacies rather than physicians decide which specific generic a patient receives. If a physician writes a prescription for a drug and does not specify that the patient receive the brand name product, then the pharmacy fills the prescription with a generic version of the drug that the pharmacy stocks. Each pharmacy has contracts to buy generic products from certain manufacturers or labelers, so Pharmacy A would fill a prescription with a generic product from Generic Manufacturer C while Pharmacy B would fill the same prescription with a generic product from Generic Manufacturer D.

In just a few cases, the Texas P&T Committee recommended and HHSC decided that certain generics be non-preferred and require prior authorization for clinical, safety, or cost effectiveness reasons. For all other generics, HHSC has asked that generic manufacturers and labelers offer HHSC a supplemental rebate of some value in order for their products to be classified as Premium Preferred Generics. Effective December 1, 2004, pharmacies that dispense Premium Preferred Generics receive a 50 cent increase in the pharmacy dispensing fee for those products.

Program Benefit Proposals

H.B. 2292 allows HHSC to sign a program benefit agreement with a drug manufacturer in lieu of a cash supplemental rebate agreement if the program benefit yields savings that

are at least equal to the amount the manufacturer would have provided under a supplemental rebate agreement. Program benefits may include but are not limited to disease management, drug product donation, drug utilization control programs, and education and counseling.

In order to maintain a competitive supplemental rebate process for all drug manufacturers, HHSC requires that manufacturers who want to offer a program benefit proposal for a drug must first offer a cash supplemental rebate. The drug's net price after supplemental rebates can then be compared to competing drugs as the P&T Committee recommends and HHSC decides which drugs to place on the PDL. If a product is placed on the PDL, then a manufacturer can work with HHSC to offer a program benefit with expenditures tied to the supplemental rebate amount offered. For instance, if a manufacturer signs a supplemental rebate agreement for $1 per unit and Texas Medicaid pays for one million units of the drug during the supplemental rebate contract term, then the manufacturer must pay HHSC a total of $1,000,000 either in cash, program benefits or a combination of the two. Only the funds invested in the program benefit count to reduce the amount of supplemental rebate owed the state. Any savings that the program may generate to reduce future Medicaid costs do not count towards offsetting the pharmaceutical manufacturer's/labeler's supplemental rebate owed to the state. Such savings represent a value to the state Medicaid program in addition to the supplemental rebate. HHSC is currently negotiating six program benefit agreements with a total annual value of less than $5 million per year.

Appendix B

Texas Medicaid Preferred Drug List
Prior Authorization Implementation Dates by Drug Class

Drug Class	Initial Prior Authorization Implementation Date
Ace Inhibitor/CCB Combinations	February 23, 2004
Ace Inhibitors	April 28, 2004
Alzheimer's Agents	June 9, 2004
Analgesics, Narcotic	February 23, 2004
Angiotensin Receptor Blockers	February 23, 2004
Anticoagulants, Injectable	January 10, 2005
Antidepressants, Other	March 29, 2004
Antidepressants, SSRIs	March 29, 2004
Antiemetics	April 28, 2004
Antifungals, Oral	March 29, 2004
Antifungals, Topical	March 29, 2004
Antihistamines, Minimally Sedating	February 23, 2004
Antimigraine Agents, Triptans	February 23, 2004
Antiparkinson's Agents (Oral)	June 9, 2004
Antipsychotics, Atypical (Oral)	March 29, 2004
Antivirals (Oral)	April 28, 2004
Atopic Dermatitis	July 28, 2004
Beta Blockers	February 23, 2004
Bladder Relaxant Preparations	February 23, 2004
Bone Resorption Suppression and Related Agents	March 29, 2004
BPH Treatments	April 28, 2004
Bronchodilators, Anticholinergic	February 23, 2004
Bronchodilators, Beta Agonist	February 23, 2004
Calcium Channel Blockers (Oral)	February 23, 2004
Cephalosporins and Related Antibiotics (Oral)	April 28, 2004
DMARDs, Immunomodulators and IL-1 RA	June 9, 2004
Erythropoiesis Stimulating Proteins	June 9, 2004
Estrogen Agents, Combination	July 28, 2004
Estrogen Agents, Vaginal	July 28, 2004
Fluroquinolones, Oral	March 29, 2004

Drug Class	Prior Authorization Implementation Date
Growth Hormone	June 9, 2004
Glucocorticoids, Inhaled	February 23, 2004
Hepatitis B Treatments	July 28, 2004
Hepatitis C Treatments	June 9, 2004
Hypoglycemics, Alpha-Glucosidase Inhibitors	April 28, 2004
Hypoglycemics, Insulins	March 29, 2004
Hypoglycemics, Meglitinides	March 29, 2004
Hypoglycemics, Metformins	April 28, 2004
Hypoglycemics, Sulfonylureas	April 28, 2004
Hypoglycemics, TZDs	March 29, 2004
Intermittent Claudication	July 28, 2004
Intranasal Rhinitis Agents	February 23, 2004
Iron, Parenteral	July 28, 2004
Leukotriene Receptor Antagonists	February 23, 2004
Lipotropics, Other	February 23, 2004
Lipotropics, Statins	March 29, 2004
Macrolides/Ketolides	March 29, 2004
NSAIDS	March 29, 2004
Opthalmic Antibiotics	July 28, 2004
Opthalmic Antibiotic-Steroid Combinations	July 28, 2004
Opthalmic Anti-Inflammatories	July 28, 2004
Opthalmics for Allergic Conjunctivitis	July 28, 2004
Opthalmics, Glaucoma Agents	June 9, 2004
Otic Antibiotic Preparations	July 28, 2004
Phosphate Binders	January 10, 2005
Platelet Aggregation Inhibitors	January 10, 2005
Proton Pump Inhibitors (Oral)	February 23, 2004
Sedative Hypnotics	June 9, 2004
Stimulants and Related Agents	April 28, 2004
Ulcerative Colitis Agents	April 28, 2004

Appendix C
Letter from the Chairman of the Texas Pharmaceutical and Therapeutics Committee

HARRIS M. HAUSER, M.D., P.A.

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January 24, 2005

Texas Legislature
c/o Texas Health and Human Services Commission
Austin, TX 78711

Re: House Bill (H.B.) 2292 and the Pharmaceutical & Therapeutics Committee's work on the preferred drug lists for Medicaid and the Children's Health Insurance Program.

This letter from Dr. Harris M. Hauser, Chair of the Pharmaceutical & Therapeutics (P&T) Committee is presented to provide you our perspective regarding our work since the committee's inception one year ago and also on the proposed changes to H.B. 2292 being suggested by various special interest groups.

Recommendation:
We recommend that no changes be made to H.B. 2292 during this legislative session.

Rationale:
H.B. 2292 from the 78th Texas Legislature, Regular Session, 2003 required that the Texas Health and Human Services Commission (HHSC) implement a preferred drug list (PDL) for Medicaid and CHIP. H.B. 2292 also created the Governor-appointed Pharmaceutical & Therapeutics (P&T) Committee of six physicians and five pharmacists to make recommendations to HHSC about which drugs to place on the PDLs. Our committee makes its recommendations based on three criteria: the safety of a drug, its clinical efficacy, and the cost effectiveness of drugs in each class. We take all of these factors into consideration, with the safety of each drug as our first concern. This is the pattern we have established and will continue to follow.

Our Committee has just completed one full year of work during which we were given a very difficult task that the state of Texas has never faced before; to establish and implement a PDL for the Medicaid program and Children's Health Insurance Program (CHIP). As you may already know, the goals of the PDLs are to reduce state expenditures while ensuring quality of care and access to recipients of these programs.

Our committee has accomplished all that we were asked of by you through H.B. 2292 in a very short time frame while also facing a large amount of pressure from multiple special interest groups. This initial success by our committee occurred largely because of our existing approach to the process and our existing policies and procedures. Changes made now could impair our abilities to adequately assess our initial work, the impact we have made on health care within these programs, and our ability to effectively implement the PDL in a manner needed to accomplish our objectives. We have already made and will continue to make the necessary changes in the process that are in the best interest of all participants, including special interest groups. In our opinion, further changes to H.B. 2292 would be premature.

One of the concerns brought up by those who wish to make changes to H.B. 2292 is that our committee approves many of the recommendations that are made by Provider Synergies, L.L.C. during executive session. (Provider Synergies, L.L.C. is the company hired by HHSC to negotiate drug rebate contracts.) This has not been the case. We have made many recommendations that were different from those initially recommended by Provider Synergies, L.L.C. We have made decisions to include additional medications not suggested by Provider Synergies, L.L.C., mainly for the reasons of quality of care, and have recommended others to be removed because of safety and efficacy concerns. For example, we recommended a drug with a combination of medications so that it would not only increase the number of medications covered by Medicaid, but to improve adherence for the patients this program is serving. In addition, we have tailored our recommendations, mainly for safety and efficacy reasons, to the patient population utilizing these programs within the state of Texas. This is another area where our recommendations have differed with those of Provider Synergies, L.L.C., who also works with several other states with different patient demographics. Lastly, we have postponed recommendations for the CHIP PDL because of a need to obtain more information regarding pediatric information for the medications we will be recommending. To avoid making recommendations that would compromise any one of our three criteria (safety, efficacy & cost effectiveness) or the quality of care being provided to patients of this program, we elected to postpone some cost savings to the state. In this situation, we put the patients and the health care providers ahead of the initial interests to cut costs.

Another criticism we have received is the brevity of discussion amongst the committee that takes place during the sessions of our meetings with the public. We are pleased to report that we have already made changes to address this concern. Since our inception, we have met eight times, each time gaining a greater understanding of the process. By our own initiative, we have steadily increased the public discussions to the point that we will now be extending our meetings an additional day to allow for adequate discussion time. Due to the changes we as a committee have already made, we see no reason to further change H.B. 2292.

In addition, the full effects of our work cannot be appropriately assessed at this time. To comply with HB 2292, PDLs were implemented in five segments this first year. This will be reduced to twice a year PDL updates in 2005. Results of the first 12 month cycle of the initial PDL segment will be completed in January 2005. The committee and HHSC

are currently in the process of reviewing cost savings data, impact on health care outcomes, and the impact on providers implementing the PDLs. Preliminary analysis indicates we are on track for meeting our objectives as outlined in H.B. 2292. There is no need to change the bill.

We would like to address one final concern that our critics have regarding the confidentiality of our vote as individual committee members. After our committee addresses the safety and efficacy of a drug, we are left to consider the third point of our criteria: cost effectiveness. Discussions regarding cost effectiveness take place in executive session. The pharmaceutical companies have requested that their contract information established through Provider Synergies, L.L.C. be kept confidential. Therefore, we as a committee cannot discuss the cost effective aspects of our decision in a public session due to the interests of the pharmaceutical companies involved in such discussions, thus necessitating a confidential vote.

In summary, you have very recently created our committee and process through H.B. 2292 and we ask that you continue to give us the ability to further the work that has already been started. Therefore, we again ask that you not make any changes to H.B. 2292 since we believe the process is working very well and our committee has made and can continue to make appropriate changes within the existing statutory provisions.

We are grateful for your time and consideration of our recommendation and observations regarding the first year of our work. Please feel free to contact us for any additional information that you might need in making your decision.

Sincerely,

Harris M. Hauser, M.D.

Harris M. Hauser, M.D., Chairman
Donna Burkett Rogers, M.S., R.Ph., Vice Chair
Richard C. Adams, M.D.
Anthony J. Busti, Pharm.D., R.Ph., BCPS
Melbert C. Hillert Jr., M.D.
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David E. King, R.Ph.
Julie Elaine Lewis, M.S., R.Ph.
Valerie Robinson, M.D.
Guadalupe Zamora, M.D.
John Zerwas, M.D

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Governor Rick Perry
Lieutenant Governor David Dewhurst
House Speaker Tom Craddick