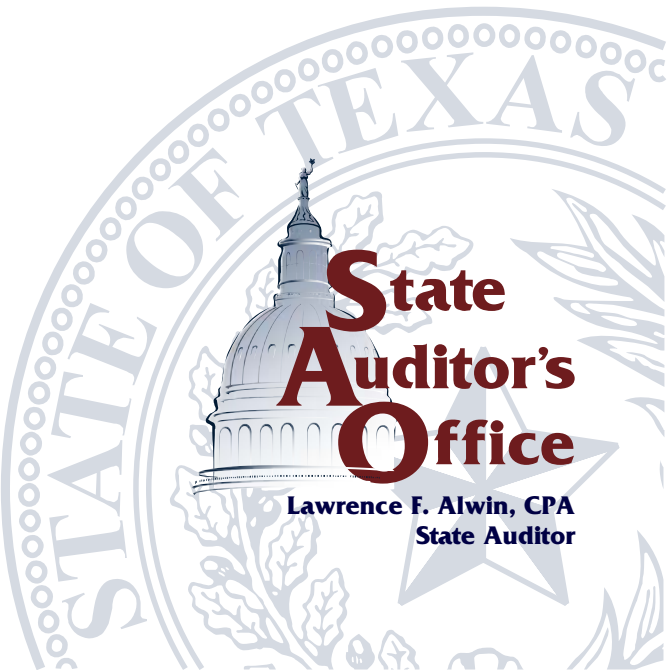
An Audit Report on

The Children's Health Insurance Program at the Health and Human Services Commission

March 2003

SAO Report No. 03-022



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Overall Conclusion

The Health and Human Services Commission (Commission) overestimated the revenue from the Children's Health Insurance Program (CHIP) drug rebate program it initiated, and it may not achieve the cost savings it anticipated from assuming responsibility for purchasing CHIP drugs. Specifically:

- Instead of implementing the $14 million supplemental Medicaid drug rebate program that was specified as one of several Medicaid cost containment measures in the General Appropriations Act (77th Legislature), the Commission implemented a CHIP drug rebate program. In fiscal year 2002, the State's share of CHIP drug rebate collected revenue totaled $30,016. As of December 19, 2002, the State's share of fiscal year 2003 collected revenue from the CHIP drug rebate totaled $148,414.

  According to Commission documentation, the Pharmaceutical Research and Manufacturers of America (PhRMA) proposed the CHIP drug rebate program. The supplemental Medicaid drug rebate was intended to be a new rebate in addition to the existing Medicaid drug rebate the Commission presently collects. The Commission considered the $14 million supplemental Medicaid drug rebate to be an optional cost containment measure.

  As a result of erroneous assumptions and inadequate analysis, the Commission's projections for CHIP drug rebate revenue decreased from $9.6 million to $4.5 million for the 2002–2003 biennium. These projections were significantly lower than the $14 million target for the supplemental Medicaid drug rebate specified in the General Appropriations Act.

Summary of the Commission's Drug Rebate Programs

The Commission participates in a federal Medicaid drug rebate program through which it bills drug manufacturers for rebates on drugs the State purchases for clients in its Medicaid program. Drug manufacturers are required to pay rebates as a condition of selling drugs to the Medicaid program.

In addition to participating in the federal Medicaid drug rebate program, states have established their own supplemental Medicaid drug rebate programs to receive additional rebates from drug manufacturers.

The anticipated cost savings in other states demonstrate the potential for significant cost savings from Medicaid supplemental rebates:

- Michigan is expected to save $42 million through its supplemental Medicaid drug rebate and preferred drug list programs in a single year.
- North Carolina is expected to save $15 million per year through its supplemental Medicaid drug rebate and preferred drug list programs.

Some states that have implemented supplemental Medicaid rebates have faced litigation from the Pharmaceutical Research and Manufacturers of America. Much of this litigation is still pending; however, these states are continuing to operate their supplemental Medicaid drug rebate programs.

- Early data produced since the Commission took over the management of the CHIP drug benefit indicates that the anticipated cost savings (excluding any CHIP drug rebate revenue) from this change may not be realized. In May 2002, the Commission specified that the State's portion of the projected cost savings from assuming the CHIP drug

State Auditor's Office
Lawrence F. Alwin, CPA
State Auditor

This audit was conducted in accordance with Texas Government Code, Sections 321.0131 and 321.0133.

For more information regarding this report, contact Joanna B. Peavy, CPA, Audit Manager, at (512) 936-9500.

benefit would be $7.9 million for the 2002–2003 biennium. However, as more actual cost data became available, the Commission updated its projections of estimated state cost savings to as low as $4.3 million for that biennium. Taking into account all administrative expenses, the total net cost savings in fiscal year 2002 was approximately $5.3 million in both federal and state funds. The State's share of the $5.3 million in cost savings was $1.5 million. Whether any actual cost savings will be achieved for the 2002–2003 biennium depends on drug utilization and the cost per member per month throughout the remainder of fiscal year 2003.

We also reviewed the Commission's development of CHIP health maintenance organization (HMO) premiums. The Commission used relevant data and made reasonable assumptions when it developed the initial CHIP HMO premiums. The Commission established second-year CHIP HMO premiums based on a comprehensive analysis. Overall, the HMOs requested a 50.7 percent increase (calculated on a weighted average basis) in premiums for the second year of CHIP. Based on its analysis and negotiations with HMOs, the Commission gave the CHIP HMOs a 13.9 percent increase (calculated on a weighted average basis). However, the Commission did not independently verify the HMO-provided data that it used to establish HMO premiums for the second year of CHIP.

Key Points

The Commission had to reduce its CHIP drug rebate revenue estimates due to deficiencies in planning and analysis.

The Commission's CHIP drug rebate revenue projections were based on erroneous assumptions regarding rebate percentages, the extent of drug labelers' participation, and pricing data it could use for the CHIP drug rebate. As a result, the Commission had to lower the CHIP drug rebate percentage on brand-name drugs. It also had to revise its rebate contracts with drug labelers, which delayed their participation in the voluntary program. As of October 2002, only 46 percent of the labelers whose products were used by children enrolled in CHIP in the second quarter of calendar year 2002 had signed contracts to participate in the CHIP drug rebate program.

The Commission's methodology for removing the drug benefit from CHIP HMO premiums was reasonable, but the anticipated cost savings from managing the drug benefit in-house may not be realized.

While the methodology the Commission used to reduce HMO premiums was reasonable, the Commission did not independently verify the HMO-provided data it used in this process although it had the authority to do so. Moreover, early cost data produced since the Commission took over the management of the CHIP drug benefit indicate that the anticipated cost savings from this change may not be realized.

Summary of Management's Response

The Commission is in general agreement with the audit recommendations.

Summary of Information Technology Review

We are reviewing the Pharmaceutical Rebate Information Management System, which the Commission uses to manage the CHIP drug rebate program, in a separate audit. We will report the results of that audit in spring 2003.

Summary of Objectives, Scope, and Methodology

The objectives of this audit were to determine whether:

- Projected savings from the Commission's in-house management of the CHIP drug benefit were realistic and attainable. Because savings from the Commission's assumption of the management of the CHIP drug benefit include the voluntary CHIP drug rebate program, the audit also included a review of the CHIP drug rebate implementation and its achievements.

- The Commission used accurate data and reasonable assumptions when developing initial HMO premiums for CHIP.

- The Commission established HMO premiums for the second year of CHIP based on reliable, accurate data and a comprehensive analysis.

The scope of the audit included reviewing the Commission's process of setting initial and second-year HMO premium rates for CHIP. We also reviewed the implementation of the CHIP drug rebate program and drug labeler participation in the CHIP drug rebate program.

The audit methodology consisted of collecting information and documentation, performing selected tests and other procedures, analyzing and evaluating the results of the tests, and conducting interviews with the Commission's management and staff.

Table of Results and Recommendations

The Commission based its CHIP drug rebate revenue projections on erroneous assumptions. Ultimately, this reduced the amount of potential revenue available from the CHIP drug rebate program. Page 4.

The Commission should perform a comprehensive cost-benefit analysis before implementing major policy changes to its programs.

Multiple contract revisions and the voluntary nature of the CHIP drug rebate program delayed and reduced drug labeler participation in the program. Ultimately, this reduced the amount of potential revenue available from the CHIP drug rebate program. Page 6.

The Commission should:

- Take into consideration all aspects of a policy change and perform a thorough analysis to determine the impact of the change based on accurate numbers for the program under consideration.
- Consider establishing a separate formulary for CHIP or seeking a legislative change that requires all manufacturers to provide a drug rebate in order to be eligible to participate in CHIP.

The Commission's CHIP drug rebate contracts do not permit verification of drug manufacturer pricing data and allow drug manufacturers unlimited opportunities to adjust pricing data. Because pricing data is used to calculate rebate amounts, these weaknesses could hinder the Commission's ability to maximize rebate revenue. Page 7.

The Commission should:

- Amend its CHIP contracts with drug labelers to limit the length of time during which prior-period adjustments can be made to three years.
- Amend its CHIP contracts with drug labelers to include a provision that allows the State to verify the accuracy of drug labelers' pricing data.

The Commission's methodology for removing the drug benefit from CHIP HMO premiums was reasonable and supported, but the Commission did not independently verify the HMO-provided data it used in this process. Page 12.

The Commission should establish a process to verify whether the HMO data its uses in its decision making are accurate and reliable.

The anticipated cost savings from managing the CHIP drug benefit in-house may not be realized. Page 13.

The Commission should:

- Continue to monitor the cost savings achieved from assuming management of the CHIP drug benefit.
- Consider all costs before implementing a new program or changing existing ones.
- Conduct a workload analysis prior to programmatic changes to identify the impact of the program changes.

The Commission used relevant data and made reasonable assumptions when developing the initial CHIP HMO premiums. Page 17.

(No recommendations.)

The Commission established second-year CHIP HMO premiums based on a comprehensive analysis, but it did not verify the HMO-provided data it used in this process. Page 18.

The Commission should:

- Exercise its authority to audit the data CHIP HMOs provide.
- Establish an organized process for maintaining the supporting documentation for changes in HMOs' premium rates.

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Detailed Results

Chapter 1

The Health and Human Services Commission Overestimated Revenue from Voluntary CHIP Drug Rebates

The Health and Human Services Commission (Commission) produced a series of fiscal year 2002–2003 revenue projections for Children's Health Insurance Program (CHIP) drug rebates that decreased from $9.6 million in June 2002 to approximately $4.5 million in November 2002. The deterioration in projections occurred because of the erroneous assumptions the Commission made when it established the CHIP drug rebate program. For example, the Commission made erroneous assumptions regarding rebate percentages, the extent of drug labelers' participation, and the pricing data it could use for the CHIP drug rebate.

Background Information

The Health and Human Services Commission (Commission) administers the State's Children's Health Insurance Program (CHIP). CHIP provides primary and preventative health care to low-income, uninsured children in Texas who are not served by or eligible for other state-assisted health insurance programs. As of December 1, 2002, 500,576 children were enrolled in CHIP.

CHIP is not a part of the State's Medicaid program but, like Medicaid, is a joint state and federal program. The Commission contracts with health maintenance organizations to deliver services to children enrolled in CHIP.

In March, 2002, the Commission established a voluntary CHIP drug rebate program. Drug labelers that agree to participate in the rebate program pay the State rebates on the drugs they sell through CHIP.

Ultimately, these erroneous assumptions reduced the amount of potential revenue available from the CHIP drug rebate program. According to data in the Uniform Statewide Accounting System (USAS), the Commission had collected a total of $106,079 in CHIP drug rebate revenues as of the end of fiscal year 2002. CHIP is a joint federal and state program; therefore, the State's share of the $106,079 was $30,016. As of December 19, 2002, total fiscal year 2003 revenue from the CHIP drug rebate program was $437,809; the State's share of the amount was $148,414.

The Chronology of the Development of the CHIP Drug Rebate Program Demonstrates Significant Weaknesses in the Commission's Creation of this Program

The General Appropriations Act (77th Legislature) directed the Commission to save $174.1 million in General Revenue in the 2002–2003 biennium (see Appendix 2 for the full text of the cost containment requirement). A subsection of this cost containment requirement specified that the Commission should require supplemental Medicaid drug rebates in selected categories to achieve savings of $14 million in General Revenue. Despite the direction provided in this subsection, the Commission's May 2002 cost

What Are Drug Labelers?

Within the context of this report, the phrase "drug labelers" refers to both drug manufacturers and drug labelers that package drugs. Drug labelers that package drugs can do so on behalf of multiple drug manufacturers.

Drug labelers hold legal title to or possession of the unique National Drug Codes (NDC) assigned to specific drugs. Drug labelers pay CHIP drug rebates based on NDC utilization.

containment status report noted that, instead of implementing the $14 million supplemental Medicaid drug rebate program, the Commission initiated the CHIP drug rebate program proposed by Pharmaceutical Research and Manufacturers of America (PhRMA). The supplemental Medicaid drug rebate was intended to be a new rebate in addition to the existing Medicaid drug rebate the Commission presently collects. The Commission considered the $14 million supplemental Medicaid drug rebate to be an optional cost containment measure.

Medicaid Cost Containment Measures Implemented in Other States

Other states have implemented a variety of Medicaid cost containment measures:

- 12 states have implemented supplemental Medicaid drug rebate programs.
- 14 states have established preferred drug lists (PDLs).
- 29 states have established generic drug substitution programs.

The anticipated cost savings in other states demonstrate the potential for significant cost savings:

- Michigan is expected to save $42 million through its supplemental Medicaid drug rebate and PDL programs in a single year.
- North Carolina is expected to save $15 million per year through its supplemental Medicaid drug rebate and PDL programs.

See Appendix 3 for more information on other states' Medicaid cost containment measures.

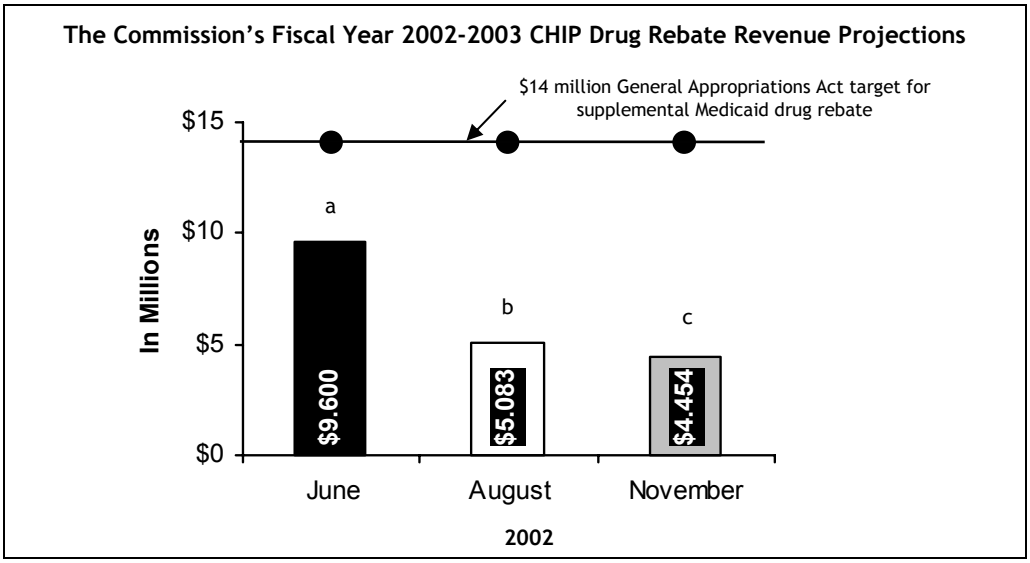
Source: *Medicaid Drug Cost Containment,* July 2002, National Conference of State Legislatures

The Commission chose to initiate a CHIP drug rebate program retroactive to March 1, 2002. The Commission did not maintain any documentation of its decision to substitute a CHIP drug rebate for a supplemental Medicaid drug rebate. In addition, it could not provide any analysis demonstrating that it compared the costs and benefits of a CHIP drug rebate with the costs and benefits of a Medicaid supplemental drug rebate.

It is worth noting that several other states have implemented a variety of Medicaid cost containment measures (including supplemental Medicaid drug rebate programs) that are expected to generate significant cost savings (see text box). Some states that have implemented supplemental Medicaid rebates have faced litigation from the PhRMA. Much of this litigation is still pending; however, these states are continuing to operate their supplemental Medicaid rebate programs.

The Commission's estimates of state revenue from a CHIP drug rebate program during the 2002–2003 biennium have decreased significantly from June 2002 to November 2002, as Figure 1 illustrates.

Figure 1 – The Commission's projections of fiscal year 2002-2003 CHIP drug rebate state revenue have decreased over time.



Sources:

a June 2002 HHSC presentation, "Overview of Health and Human Services Budget Issues FY02-03 Biennium"

b August 2002 Estimate in the Commission's Legislative Appropriations Request

c November 2002 Estimate in the Commission's Revised Legislative Appropriations Request

In June 2002, the Commission projected that CHIP drug rebate revenue for the 2002–2003 biennium would be $9.6 million. This projection was significantly lower than the $14 million target for the supplemental Medicaid drug rebate specified in the General Appropriations Act. In addition, this estimate was based on erroneous assumptions that (1) the Commission could bill drug labelers that participated in the CHIP drug rebate program using the same rebate percentages it uses in its existing Medicaid drug rebate program and (2) that 100 percent of drug labelers would participate in the voluntary CHIP drug rebate program. This issue is discussed in greater detail in Chapter 1-A.

The Commission Does Not Have Spending Authority for CHIP Drug Rebate Revenue

The Commission does not have budget authority to spend CHIP rebate revenue. The Legislative Budget Board established measures to track CHIP rebate revenue collection:

- The measure based on the Commission's August 2002 version of its Legislative Appropriations Request was $5 million in rebate revenue (estimated on an accrual basis).
- The measure based on the Commission's November 2002 version of its Legislative Appropriations Request was approximately $4.5 million in rebate revenue (estimated on a cash basis).

The Commission switched to a cash basis to remain consistent with the manner in which it tracks its existing Medicaid drug rebate revenue.

In the Legislative Appropriation Request (LAR) the Commission submitted on August 16, 2002, the Commission further reduced the estimated revenue from its CHIP drug rebate program for the 2002–2003 biennium to approximately $5 million. The Commission updated its LAR in November 2002 and lowered the estimated 2002–2003 CHIP drug rebate revenue again to approximately $4.5 million. These estimates are discussed in greater detail in Chapters 1-B and 1-C.

The Commission charged the division responsible for operating its existing Medicaid drug rebate program with operating the CHIP drug rebate program. We will issue a separate audit report on the Medicaid drug rebate program in spring 2003.

Chapter 1-A

The Commission Based Its CHIP Drug Rebate Revenue Projections on Erroneous Assumptions

The Commission based its June 10, 2002, CHIP drug rebate revenue estimate of $9.6 million for the 2002–2003 biennium on critical assumptions that later proved to be erroneous.

The Commission Estimated CHIP Drug Rebate Percentages Inaccurately

In its initial contracts with drug labelers participating in the CHIP drug rebate program, the Commission used the same drug rebate percentages that are used in its existing Medicaid drug rebate program. The rebate percentages in the Medicaid drug rebate program generate rebate revenue of approximately 20 percent of total Medicaid drug expenditures.[1] However, the Commission was subsequently forced to lower the CHIP drug rebate percentage for brand-name drugs due to the impact of this percentage rate on drug labelers participating in the existing Medicaid drug rebate program.

The Center for Medicare and Medicaid Services (CMS), the federal agency that administers the Medicaid drug rebate program, informed the Commission that if the Commission kept the CHIP rebate percentage for brand-name drugs equal to the Medicaid drug rebate percentage, this could ultimately increase the rebate amount drug labelers would have to pay in the Medicaid drug rebate program. Because of this, the majority of the drug labelers refused to participate in the Commission's CHIP drug rebate program (see text box for additional explanation).

How CHIP Drug Rebates Can Affect Medicaid Drug Rebates

Under a complex set of federal Medicaid drug rebate program rules, the Medicaid drug rebate amounts that drug labelers pay on brand-name drugs are dependent on the "best price" they offer for those drugs.

If the CHIP drug rebate percentage were identical to the Medicaid drug rebate percentage, the price of a drug in CHIP (net of the rebate) would have become a drug labeler's best price. Ultimately, under federal Medicaid drug rebate program rules, this would have required drug labelers to pay higher Medicaid drug rebates.

The Social Security Act contains more detailed information on the calculation of Medicaid drug rebates.

To prevent the CHIP drug rebate rate from affecting the Medicaid drug rebate, the Commission removed a component from the CHIP drug rebate calculation for brand-name drugs from its contracts with drug labelers and lowered the rebate percentage on brand-name drugs. According to unaudited data in the Commission's database, approximately 80 percent of the drug expenditures in CHIP are for brand-name drugs. Currently, depending on the number of drug labelers participating in the CHIP drug rebate program, the approximate CHIP drug rebate revenue can be:

[1] This percentage can vary based on the relative utilization of brand-name and generic drugs, which have different rebate percentages.

- 11.3 percent of CHIP drug expenditures (with 50 percent drug labeler participation)
- 14.1 percent of CHIP drug expenditures (with 75 percent drug labeler participation)
- 16.8 percent of CHIP drug expenditures (with 100 percent drug labeler participation)

The Commission Overestimated Drug Labelers' Participation in the Voluntary CHIP Drug Rebate Program

In making its June 2002 estimate of $9.6 million in CHIP drug rebate revenue for the 2002–2003 biennium, the Commission unrealistically assumed that 100 percent of drug labelers would participate in the voluntary CHIP drug rebate program. In the Legislative Appropriations Request for the 2004–2005 biennium that the Commission prepared in August 2002, the Commission reduced its estimated drug labeler participation rate to 75 percent. As of October 2002, only 46 percent of the labelers whose products were used by children enrolled in CHIP in the second quarter of calendar year 2002 had signed contracts to participate in the CHIP drug rebate program.[2]

The Commission paid approximately $13.8 million (55 percent of total CHIP drug expenditures of $25.1 million) in the second quarter of calendar year 2002 to drug labelers that had agreed to pay CHIP drug rebates.[3] During that same time period, it paid $11.3 million (almost 45 percent of total CHIP drug expenditures from April to June 2002) to drug labelers that had not agreed to pay CHIP drug rebates.[4]

The Commission Exempted Certain Labelers from the Requirement that They Participate in the CHIP Drug Rebate Program as a Condition of Selling Drugs to CHIP

The Commission exempted certain labelers from paying CHIP drug rebates if the CHIP drug rebate calculation established a new best price for their drugs in the Medicaid drug rebate program. Drug labelers that the Commission has exempted from the CHIP drug rebate program do not have to pay CHIP drug rebates until they establish a best price in the Medicaid drug rebate program. Even though the Commission could not estimate the financial impact of its exemption of certain labelers because of the absence of pricing data from the drug labelers, this practice could potentially lower the revenue from the CHIP drug rebate program.

[2] We calculated the 46 percent participation rate using a list of labelers that had signed CHIP rebate contracts and unaudited data in the Commission's database.

[3] Total drug expenses of $25.1 million include CHIP participants' co-payments. This $25.1 million figure is not the total amount the Commission itself paid for drugs.

[4] Dollar amounts for the Commission's drug expenditures are from unaudited data in the Commission's database.

Chapter 1-B

Multiple Contract Revisions and the Voluntary Nature of the CHIP Drug Rebate Program Delayed and Reduced Drug Labeler Participation in the Program

The Commission erroneously assumed that it could use pricing data the federal government collects to support the Medicaid drug rebate program in order to calculate rebates for the Commission's CHIP drug rebate program. This led to multiple revisions to the CHIP drug rebate contracts the Commission signed with drug labelers and delays in signing contracts with drug labelers and collecting rebates. In addition, the Commission is unable to compel drug labelers to participate in the CHIP drug rebate program because it has not established a separate, non-Medicaid formulary for CHIP.

Problems Involving the Collection of Drug Labeler Pricing Data for CHIP Drug Rebate Calculations and the Effect of CHIP Drug Rebates on Medicaid Rebates Led to the First Contract Revision

The Commission published the initial CHIP drug rebate contracts with drug labelers under the assumption that it could use Medicaid drug pricing data to calculate CHIP drug rebates. The Commission published this version of the contract in May 2002. The Commission's records indicate that it signed contracts with drug labelers representing 67 drug manufacturers. However, CMS subsequently concluded that the state CHIP drug rebate program could not use Medicaid drug pricing data because the Medicaid and CHIP programs are founded under two separate titles of the Social Security Act and because of the confidentiality of Medicaid data.

In addition to the pricing data problem, as discussed in Chapter 1-A, the Commission also learned that if it kept the CHIP drug rebate percentage for brand-name drugs equal to the Medicaid drug rebate percentage, this would ultimately increase the rebate amount drug labelers would have to pay in the Medicaid program.

As a result of these two issues, in the spring of 2002, the Commission had to:

- Revise the contracts it had already signed with drug labelers to (1) specify that the Commission itself would be collecting the pricing data for the CHIP drug rebate calculation, (2) remove language regarding the portion of the CHIP drug rebate calculation that affected the Medicaid drug rebate, and (3) include a provision that would prevent the calculation of the CHIP drug rebate from resetting the Medicaid best price.

- Determine the methodology and identify human resources to collect the pricing data it would use to calculate the CHIP drug rebate amounts.

In May 2002, the Commission sent the first set of CHIP drug rebate bills to drug labelers based on CMS Medicaid drug pricing data without proper authorization from CMS. After CMS informed the Commission that it could not use Medicaid drug pricing data for the CHIP drug rebate program, the Commission asked drug labelers to recalculate the initial CHIP rebate bills using drug labelers' own pricing data. Since that time, in the absence of pricing data, the Commission has been billing drug labelers and requesting that the drug labelers self-report the pricing data necessary to calculate the CHIP drug rebate.

The Commission published the second version of its CHIP drug rebate contracts in July 2002 and set a deadline of September 1, 2002, for drug labelers to sign the new contracts. However, drug labelers raised concerns over the definition of the best price in the second version of the contract (the Commission had not included a portion of the federal language in the definition of the best price). On September 6, 2002, the Commission published a third version of the contracts.

The ultimate effect of multiple revisions of the CHIP drug rebate contract was that drug labelers' participation in the program was delayed and uncertainty over the revenue potential from the program increased.

Drug Labelers Are Not Required to Participate in the CHIP Drug Rebate Program and, Even When They Do Participate, the Lack of a Separate CHIP Drug Formulary Leaves the Commission Unable to Enforce Compliance with CHIP Rebate Contract Requirements

What Is a Drug Formulary?

A drug formulary is a list of drugs that are approved for use by a health plan. The list is subject to periodic review and modification.

Although the Commission encourages drug labelers to participate in the CHIP drug rebate program, it does not require their participation. In addition, the CHIP drug rebate contracts between the Commission and the drug labelers require drug labelers to participate in the CHIP drug rebate program to become or remain reimbursable by the Commission for covered outpatient drugs. This requirement, when enforced in concert with a separate CHIP drug formulary, would have potentially enabled the Commission to compel drug labelers to participate in the CHIP drug rebate program because the Commission could have removed from the CHIP drug formulary the drugs of the specific drug labelers that refused to participate in the CHIP drug rebate program.[5]

However, after assuming responsibility for managing the CHIP drug benefit in March 2002 (the CHIP health maintenance organizations managed the CHIP drug benefit until then; see Chapter 2 for additional details), the Commission did not establish a separate drug formulary for CHIP. Instead, the Commission uses the Medicaid drug formulary for CHIP drugs. Because the Commission cannot remove drug labelers' drugs from the Medicaid drug formulary, it cannot use the formulary of a different rebate program to compel drug labelers to participate in the CHIP drug rebate program.

Chapter 1-C

The Commission's CHIP Drug Rebate Contracts Do Not Permit Verification of Drug Manufacturer Pricing Data and Allow Manufacturers Unlimited Opportunities to Adjust Pricing Data

The Commission's CHIP drug rebate contracts with manufacturers lack provisions allowing the Commission to verify the accuracy of pricing data that drug manufacturers submit. In addition, the contracts allow manufacturers unlimited time to change pricing data they previously submitted so that they can obtain credits

[5] Assuming that comparable drugs in the therapeutic category are available.

against rebate payments they owe the State. These weaknesses could hinder the Commission's ability to maximize CHIP drug rebate revenue.

Without Contract Provisions to Verify Manufacturer Pricing Data, the Commission Cannot Ensure that It Is Maximizing Rebate Revenue

The Commission amended the second version of its CHIP drug rebate contract with drug manufacturers to remove an audit provision from the contract. It removed this provision because drug manufacturers objected to it and because of the voluntary nature of the CHIP drug rebate program. As a result, the Commission does not have a mechanism to verify whether the drug manufacturers submit accurate pricing data to the Commission. The Commission plans to calculate CHIP drug rebates using this data.

In comparison, the federal government's contracts with the drug manufacturers for Medicaid drug rebates specify that the U.S. Department of Health and Human Services may audit a manufacturer's calculation of prices used for Medicaid rebate calculation.

Permitting Drug Labelers to Have Unlimited Time to Make Prior-Period Pricing Data Adjustments Could Hinder the Commission's Ability to Maximize Rebate Revenue

The Commission did not include in its CHIP drug rebate contracts a deadline by which manufacturers must submit adjustments to prior-period pricing data. The Commission had full authority to include this deadline in these contracts. When drug manufacturers make prior-period adjustments that decrease the price of a drug, this requires the Commission to issue credits against future rebates the drug labelers owe, which effectively reduces the amount of CHIP drug rebate revenue the State collects.

The potential significance of this issue is demonstrated by evidence from the Commission's own Medicaid drug rebate program. Unaudited data the Commission reported to the federal government show that from the third quarter of 1995 to the fourth quarter of 2001, the Commission issued approximately $13.6 million in credits against future Medicaid drug rebate payments to the 12 manufacturers that made the highest dollar amount of drug price adjustments.

It is important to note that at the federal level in the Medicaid drug rebate program, CMS indicates that it is considering limiting the length of time during which a manufacturer can change pricing data to three years.

Recommendations

The Commission should:

- Perform a comprehensive cost-benefit analysis before implementing major policy changes to its programs.
- Take into consideration all aspects of a policy change and perform a thorough analysis to determine the impact of the change based on the accurate numbers for the program under consideration.

- Consider establishing a separate formulary for CHIP or seeking a legislative change that requires all manufacturers to provide a drug rebate in order to be eligible to participate in CHIP.

- Amend its CHIP contracts with drug labelers to limit the length of time during which prior-period adjustments can be made to three years.

- Amend its CHIP contracts with drug labelers to include a provision that allows the State to verify the accuracy of drug labelers' pricing data.

Management's Response

SAO Recommendation: *The Commission should perform a comprehensive cost-benefit analysis before implementing major policy changes to its programs.*

SAO Recommendation: *The Commission should take into consideration all aspects of the policy change and perform a thorough analysis to determine the impact of the change based on the numbers relevant for the program under consideration.*

Management Response:

HHSC agrees with the SAO recommendations and it is, in every case, HHSC's practice to consider all aspects of potential or anticipated policy changes and to perform thorough analysis to determine the likely impact and outcome of those program changes. The reliability of analysis of this kind, however, is subject to the accuracy of the data that is used, assumptions or projections of uncertain future outcomes, and predictions of events that may or may not come to pass. To mitigate the risk that analysis in conditions of uncertainty holds, it is HHSC's practice to continually update its analysis throughout time as more and better information becomes available.

SAO Recommendation: *The Commission should consider establishing a separate formulary for CHIP or seeking legislative change that requires all manufacturers to provide a drug rebate in order to be eligible to participate in CHIP.*

Management Response:

We agree that establishing a separate formulary for CHIP would allow the State to restrict coverage of certain drugs within CHIP. A formulary could be established based on CHIP clientele and their specific needs, and would be an improvement over the current practice of using the Medicaid list.

Because participation in the CHIP rebate program is encouraged but not required, not all manufacturers participate. A number of manufacturers have told us that their companies, as a matter of policy, do not participate in any voluntary/optional rebate programs. Because of this, we agree that a legislative change that would require manufacturers to provide drug rebates as a condition for a manufacturer's products to be included in the CHIP formulary would result in rebates for all CHIP drugs and increase revenues from CHIP rebates.

Legislation would also need to include confidentiality provisions similar to CMS' 42 U.S.C. 1396r-8 (b)(3)(D). In the absence of any guarantee that pricing information provided pursuant to the rebate agreement will be held in the strictest confidence and not be subject to the Texas Open Records Law, manufacturers are unwilling to allow the state to audit their records or to collect the raw data necessary to calculate the unit rebate amount set forth in the rebate agreement. Louisiana's law S66 exempts from public record the terms and conditions of the rebate agreement, rebate amounts, percent of rebate, and manufacturer's pricing and supplemental rebates. Texas would need to pass such a law as well to allay manufacturers' concerns regarding any drug rebate agreements other than the federally mandated Medicaid rebates.

In addition to state legislation, federal legislation clarifying the scope of 42 U.S.C. 1396r-8 would also benefit SCHIP rebate programs. The CMS has conservatively interpreted 42 U.S.C. 1396r-8 and determined that rebates calculated under the current Texas CHIP rebate program must be included in manufacturers' Medicaid Average Manufacturers Price (AMP) and Best Price (BP) calculations. Based on this interpretation, rebates calculated under the Texas CHIP program could have the effect of resetting manufacturers' best prices. Given the fact that states were given the option of either rolling CHIP kids into Medicaid (and getting Medicaid-level rebates) or offering a benefit package at least comparable to Medicaid, it seems that CMS is penalizing the states that chose to implement SCHIP programs. If federal laws were changed to specifically include SCHIP programs in the excluded category, CHIP rebate calculations would be exempt from Medicaid AMP and BP rules and fall within the 42 U.S.C. 1396r-8 confidentiality protection. The current CMS interpretation reduces both the state and federal opportunity for increased rebate revenues on the SCHIP programs. Consequently, HHSC feels that federal legislation clarifying that 42 U.S.C. 1396r-8 applies to SCHIP programs is necessary.

Action Planned:

As the current claims processing software (ECM) is updated and brought into compliance with HIPAA requirements, a CHIP formulary will be established. It is currently anticipated that this activity will be completed in October 2003. At that time HHSC will have the ability to include or exclude drugs specific to the needs of CHIP clients.

HHSC will also work with the Texas Office of State-Federal Relations to inform the Texas Congressional delegation of the need for federal legislation clarifying the scope of 42 U.S.C. 1396r-8.

SAO Recommendation: *The Commission should amend its CHIP contracts with drug labelers to limit the length of time during which prior-period adjustments can be made to three years.*

Management Response:

Staff recognizes the need for this type of provision. Since the program is less than three years old, however, there is no current threat of manufacturers going back past the three-year period to adjust pricing and take credits.

Action Planned:

Although the contract does not require modification for this change alone at this time, HHSC will include this revision with other necessary changes in a future amendment. We plan to execute the amendment before the program has been in existence more than three years.

SAO Recommendation: *The Commission should amend its CHIP contract with drug labelers to include a provision that allows the State to verify the accuracy of drug labelers' pricing data.*

Management Response:

The original March 2001 version of the contract included audit provisions. In response to labelers' unwillingness to sign the contract because the confidentiality of their information could not be guaranteed under Texas' Open Records Law, the audit provisions were dropped and manufacturers were allowed to produce data that did not specifically identify their Average Manufacturer's Price or Best Price.

When CMS said HHSC could not use the information from Medicaid to administer the CHIP rebate program, the confidentiality provisions of 42 U.S.C.1396r-8 no longer protected manufacturer's pricing data. Unless the State passes a law similar to 42 U.S.C.1396r-8, or Louisiana's S66, manufacturers will not allow the State to audit their records because of the highly confidential nature of the pricing data. Unless or until their pricing data can be protected, manufacturers will not sign a rebate agreement.

Actions Planned:

HHSC will work with OSFR to inform the Texas Congressional delegation of the need for federal statutory clarification of the scope of the federal law that protects the confidentiality of all rebate-related data (from any rebate agreements created outside of 42 U.S.C. 1396r-8). In the event state statute is enacted, the CHIP rebate contracts will be modified to include provisions that allow the State to verify the accuracy of drug labelers' pricing data.

Chapter 2

The Commission's Methodology for Removing the Drug Benefit from CHIP HMO Premiums Was Reasonable, but the Anticipated Cost Savings from Managing the Drug Benefit In-House May Not Be Realized

To reduce CHIP drug benefit costs, the Commission took over the management of the purchasing of CHIP drugs in March 2002 and removed this responsibility from the CHIP health maintenance organizations (HMOs). While the methodology the Commission used to reduce the premiums it pays HMOs was reasonable, early cost data produced since the Commission took over the management of the CHIP drug benefit indicate that the anticipated cost savings from this change may not be realized. Ultimately, cost savings will be achieved only if the amount of funds saved through the reduction in HMO premiums continues to exceed what the Commission must now pay for CHIP drugs and the administrative costs it incurs in managing the CHIP drug benefit.

Chapter 2-A

The Commission's Methodology for Removing Drug Benefits from CHIP HMO Premiums Was Reasonable and Supported

The Commission's methodology for determining the amount by which to reduce HMO premiums was reasonable and supported by the Commission's analysis. The Commission determined the reduction in premiums based on data that HMOs provided and that its consulting actuary analyzed. The Commission established a premium-reduction percentage based on the HMOs' reported expenditures for medical and drug categories. The amount identified as drug expenditures determined the percentage for the premium reduction. According to the Commission, it reduced the premiums it paid to the HMOs by an average of 15.6 percent when it assumed management of the CHIP drug benefit.

The Commission's decision to assume responsibility for administration of the drug benefit was driven in part by information it had indicating that it could purchase drugs at a lower cost than the CHIP HMOs. After the Commission's staff and its actuary reached agreement with the HMOs on the rates for the second year of the CHIP contract, the Commission announced its decision to remove the drug benefit from the HMOs' coverage and manage the CHIP drug benefit in-house. The Commission then proceeded with the arrangements for reducing HMO premiums and involved the contracted actuary in the determination of the methodology for this reduction. The actuary and the Commission's staff used available data from HMOs, but the Commission did not audit or verify this data although it had the authority to do so. We are reviewing the Commission's monitoring of CHIP HMOs in a separate audit and will issue a separate audit report on that topic in early 2003.

Recommendation

The Commission should establish a process to verify whether the HMO data it uses in its decision making are accurate and reliable.

Management's Response

CHIP was designed pursuant to legislative intent to function like a private insurance product to the extent permitted by federal law and regulation. Consistent with private insurance market practices, HHSC and its contracted actuary currently conduct various reasonableness checks on the information used in the CHIP rate setting process. Data in HMO claims lag reports are compared against data in financial statistical reports. This enables HHSC to determine inconsistencies that would highlight potential errors in either report. Claims lag reports from previous periods are also compared to current claims lag reports. If any variances are identified, HHSC and its contracted actuary meet with the HMO to resolve the issues identified. On several occasions, HHSC has detected errors in claims lag reports using this method. In addition, the contracted actuary compares the reported claims experience between health plans and uses his professional judgment to determine whether additional information is warranted.

Actions Planned:

Although HHSC currently has safeguards in place, it agrees with the SAO that more can be done. HHSC intends to procure the services of an independent auditor in the spring of 2003, with the contract for services effective September 1, 2004. These audits will review the financial information submitted to HHSC by HMOs for the contract periods that have been closed. These audits will be conducted in conjunction with the Medicaid audits.

Chapter 2-B

The Anticipated Cost Savings from Managing the CHIP Drug Benefit In-House May Not Be Realized

In fiscal year 2002, after assuming management of the CHIP drug benefit, the Commission paid $43.8 million less in CHIP HMO premiums but paid $36.6 million for drugs. This resulted in state and federal savings of $7.2 million. While the Commission's initial experience with managing the drug benefit produced savings, the Commission also incurred $1.9 million in additional administrative costs for information system changes and claims processing in fiscal year 2002.

The additional administrative costs in fiscal year 2002 included:

- $764,171 in one-time start-up expenses associated with necessary changes in automated systems at the Department of Human Services (DHS) and Birch and Davis, ACS, the enrollment broker for CHIP.

- $1,179,141 in ongoing expenses for March through August 2002 that were related to the processing of claims at DHS and administrative tasks not previously included in the contract with Birch and Davis, ACS.

Taking into account all administrative expenses, the total net cost savings in fiscal year 2002 were approximately $5.3 million in both federal and state funds. The State's portion of the $5.3 million in cost savings was approximately $1.5 million. The Commission achieved the majority of the fiscal year 2002 cost savings during the summer months, when drug utilization is usually relatively low.

Although the Commission achieved cost savings in fiscal year 2002, whether it will continue to achieve cost savings in fiscal year 2003 depends on several key issues, including drug utilization and the average monthly cost per member. The Commission relies on the ability of its vendor drug program to purchase drugs at lower prices than HMOs pay.

The Commission Has Not Considered Personnel Costs to Administer the CHIP Drug Benefit

When the Commission assumed the management of the CHIP drug benefit, certain Commission employees working in the Medicaid program assumed additional responsibilities related either to the initial preparations for or the ongoing management of the CHIP drug benefit. These employees worked in the Commission's vendor drug program, Medicaid formulary section, information resource management, and rebate section.

We estimate that the Commission incurred a minimum of $94,520 in one-time personnel costs to take over management of the CHIP drug benefit. In addition, the Commission did not analyze what impact its administration of the CHIP drug benefit would have on the workloads of existing staff in the Medicaid program. Based on employees' workload in March through June 2002, we estimate the increased workload to be approximately 18 FTEs, with combined salaries equivalent to $59,826 per month. This translates into $717,919 in annual ongoing costs.[6]

The Commission's decision to create additional responsibilities without analyzing existing workloads could create backlogs in the primary areas of responsibility related to management of the drug benefit in the Medicaid program.

The Commission's Estimate of Projected Cost Savings for the 2002–2003 Biennium May Not Be Achieved

On May 14, 2002, the Commission presented a report titled Details of CHIP Tobacco Funds Deficits of May 10, 2002 to the Legislative Budget Board. In that report, the Commission specified that the State's portion of the projected cost savings from assuming the CHIP drug benefit would be $7.9 million for the 2002–2003 biennium because of lower drug purchase costs. At the time the Commission conducted this analysis, however, it had only one month of actual cost data (March 2002), which limited its ability to accurately project savings.

As more actual cost data became available, the Commission updated its projections of estimated state savings. As Table 1 shows, estimated savings for the 2002–2003 biennium began to decrease to as low as $4.3 million under various scenarios. The Commission estimated these cost savings by using relatively low projections for HMO premiums for the period from June 2002 through August 2003. According to the Commission, the average premium the Commission actually paid to the HMOs for health coverage without drug benefits was $81.72 per member per month in March 2002. Nevertheless, for the months of June through August 2002, the Commission estimated the average HMO premium at $78.33 per member per month. The average HMO premium that the Commission actually paid from June through

[6] Our analysis of costs associated with the Commission's assumption of the drug benefit was based on unaudited data the Commission provided.

August 2002 was $80.43 per member per month, more than $2 higher than what it had originally projected.[7] The difference of $2.00 in the average HMO premium reduced the estimated fiscal year 2002 cost savings by $2.3 million.

To project cost savings for fiscal year 2003, the Commission used $77.02 per member per month as an estimated average for HMO premiums. This relatively lower projected average HMO premium resulted in an increase in projected cost savings.

As Table 1 indicates, when we estimated the cost savings using the Commission's methodology and *average* HMO premium rates for June through November 2002, which are based on actual costs, our calculation showed that estimated cost savings for the 2002–2003 biennium would be lower than the Commission's projections.

Table 1 – The Commission's cost savings estimates vary under different scenarios.

Estimated Cost Savings from Managing CHIP Drug Benefit In-House Fiscal Years 2002 and 2003					
Basis of Cost per Member per Month	Drug Cost per Member per Month	The Commission's Projected State and Federal Cost Savings[a]	Estimated State Share of the Commission's Cost Savings	State Auditor's Office Calculation of Projected State and Federal Cost Savings[b]	State Auditor's Office Estimate of the State Share of Cost Savings or (Loss)
The Commission's estimate	$12.90	$28,224,728	$7,893,059	$11,743,567	$ 3,288,199
Average of March and April 2002 actual costs	$13.37	$24,154,144	$6,754,700	$ 7,672,983	$ 2,148,435
Average of March, April, and May 2002 actual costs	$13.69	$21,040,839	$5,884,409	$ 4,559,678	$ 1,276,710
Average of April and May 2002 actual cost	$14.37	$15,511,347	$4,337,679	$(969,814)	$(271,548)

a The Commission's estimates are based on projected HMO premium amounts for June 2002 through August 2003.

b State Auditor's Office estimates are based on actual HMO premium amounts for June through November 2002.

Source: Health and Human Services Commission analysis and State Auditor's Office analysis

Based on the Commission's reports, during the first two months of fiscal year 2003, the actual drug cost per member per month remained higher than $14.37, which was the average of April and May 2002 actual costs. It was $16.46 in September 2002 and $15.86 in October 2002.

[7] The average premium the Commission pays the HMOs fluctuates because the number of children in each age group who are enrolled in CHIP changes from month to month. Each age group has a different premium rate.

Recommendations

The Commission should:

- Continue to monitor the cost savings achieved from assuming management of the CHIP drug benefit.
- Consider all costs before implementing a new program or changing existing ones.
- Conduct a workload analysis prior to programmatic changes to identify the impact of the program changes.

Management's Response

SAO Recommendation: *The Commission should continue to monitor the cost savings achieved from assuming management of the CHIP drug benefit.*

Management Response:

After the SAO audit fieldwork was completed, we began receiving and using output generated from the DHS system (ECM) that reports dollars expended, numbers of prescriptions, and cost per prescription for CHIP prescriptions. This data is based on actual payment activity and accurately accounts for expenditures and the number of prescriptions by month.

Before these reports were available, our data sources did not provide amounts and numbers by month and we were required to estimate monthly activity using a variety of estimation methods. Now that we are using data that reports monthly expenditures and number of prescriptions, our ability to report actual amounts and to project future costs has significantly improved.

SAO Recommendation: *The Commission should consider all costs before implementing a new program or changing existing ones.*

Management Response:

HHSC agrees with the SAO recommendation (see response to Chapter 1-C).

SAO Recommendation: *The Commission should conduct a workload analysis prior to programmatic changes to identify the impact of program change.*

Management Response:

HHSC agrees with the SAO recommendation (see response to Chapter 1-C).

Chapter 3

The Commission Used Relevant Data and Made Reasonable Assumptions When Developing the Initial CHIP HMO Premiums

The Commission used existing data from its Medicaid program, along with the relevant data from other sources, to set initial HMO premium rates for CHIP. The Commission and a consulting actuary conducted negotiations and reviewed proposals from interested HMOs.

The Commission's Rate-Setting Methodology for the Initial Premiums Was Adequate

The Commission used an appropriate methodology to develop initial HMO premium rates for CHIP. Because CHIP was new, the Commission did not have the historical data necessary for the CHIP rate-setting process. Therefore, the Commission's actuary staff used Medicaid fee-for-service data that was associated with children. The Commission also used data from commercial health plans to analyze items not covered by the Medicaid fee-for-service program. To determine the number of children eligible for enrollment in CHIP, the Commission used U.S. census information. The Commission's actuary analyzed the cost of the services in insurance plans to determine the difference in the cost that was attributable to geographic location.

Chronology of CHIP HMO Premiums

- Initial premiums were in effect from May 1, 2000, through September 30, 2001.
- Second-year premiums became effective on October 1, 2001, and they were in effect until February 28, 2002.
- On March 1, 2002, the Commission assumed the management of the CHIP drug benefits and reduced HMO premiums accordingly. The reduced premiums were in effect from March 1, 2002, until September 30, 2002.
- The Commission renegotiated new HMO premiums that became effective on October 1, 2002. The Commission was still negotiating these premiums during our audit, and we did not audit the Commission's calculation of the premiums.

The Commission's Procedures for Negotiating with HMOs Were Reasonable

The Commission and the consulting actuary negotiated initial premium rates for CHIP based on the analysis performed by the actuary and the Commission's staff. The Commission established targeted rates for the CHIP HMO premiums. The Commission based these rates on age groups and geographic service areas. HMOs interested in participating in CHIP could propose different rates along with a justification for the difference. Nine of the 12 HMOs signed the contracts with the Commission based on the targeted rates the Commission set. In cases in which the Commission and an HMO had a difference in opinion regarding the rates in specific geographic areas, both sides involved actuaries in the analysis and negotiations.

Chapter 4

The Commission Established Second-Year CHIP HMO Premiums Based on a Comprehensive Analysis, but It Did Not Verify the HMO-Provided Data It Used in This Process

To determine CHIP HMO premiums in the second year of CHIP, the Commission used data the HMOs provided. The Commission and the actuary conducted a comprehensive analysis based on that data and, when necessary, conducted negotiations with HMOs to reach a reasonable increase in premiums for the second year of the program. However, the Commission did not independently verify whether the financial data the HMOs provided were accurate and reliable. It used this data to establish premiums for the second year of CHIP.

The Commission's Rate-Setting Methodology for the Second-Year Premiums Was Adequate

The Commission negotiated second-year rates with each individual HMO based on the financial data each HMO provided. Each HMO provided the Commission with proposed rates and the supporting documentation to allow the Commission's staff and the consulting actuaries to confirm the calculation of the rates. The Commission and its actuary performed their own analysis based on the HMOs' data to determine the financial status of the plans and to derive the assumptions for the premium increase. In their analysis of premiums, the Commission and the actuary used various documents, including HMOs' data for monthly enrollment, estimated incurred claims, administrative charges, and reinsurance arrangements.

Overall, based on the Commission's data, the HMOs requested a 50.7 percent increase (calculated on a weighted average basis) in premiums for the second year of CHIP. Based on its analysis and negotiations with HMOs, the Commission gave the CHIP HMOs a 13.9 percent increase (calculated on a weighted average basis).

The Commission's Negotiations with the CHIP HMOs Regarding the Second-Year Premium Increase Were Thorough

After analyzing each HMO's financial data and estimated projections, the Commission and the actuary conducted negotiations with each HMO to establish the second-year premiums. Our review of selected negotiations with HMOs that cover 48.8 percent of CHIP participants indicated that the contracted actuary negotiated in the State's interest.

Although the Rate-Setting Methodology and Negotiations Were Adequate, the Commission Did Not Verify the HMO Data It Used in Its Analysis

HMO premiums for the second year of CHIP were based on data the HMOs provided. As was discussed in Chapter 2-A, however, the Commission did not independently verify whether the financial data the HMOs provided was accurate and reliable. Its CHIP contracts with the HMOs specify that the Commission has the authority to audit HMOs' data; however, the Commission has not done so.

In addition, we noted that the Commission does not maintain support for the increases in the premiums in a central location. We were able to obtain some

supporting documentation from the Commission, but the majority of supporting documentation was maintained by the contracted actuary.

Recommendations

The Commission should:

- Exercise its authority to audit the data CHIP HMOs provide.
- Establish an organized process for maintaining the supporting documentation for changes in HMOs' premium rates.

Management's Response

SAO Recommendation: *The Commission should exercise its authority to audit the data CHIP HMOs provide.*

Management Response:

HHSC agrees with the SAO recommendation.

Action Planned:

HHSC intends to procure the services of an independent auditor in the spring of 2003, with the contract for services effective September 1, 2004. These audits will review the financial information submitted to HHSC for the contract periods that have been closed. These audits will be conducted in conjunction with the Medicaid audits.

SAO Recommendation: *The Commission should establish an organized process for maintaining the supporting documentation for changes in HMOs' premium rates.*

Management Response:

HHSC agrees with the SAO recommendation.

Action Planned:

HHSC has been meeting with its contracted actuary to develop a process for maintaining all supporting documentation at HHSC. HHSC has notified the Exclusive Provider Organizations (EPO) that all documents should be sent directly to HHSC rather than to the contracted actuary. Similar notification will be sent to all HMOs. HHSC anticipates having all supporting documentation centrally located at HHSC no later than March 31, 2003.

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Appendices

Appendix 1

Objectives, Scope, and Methodology

Objectives

The objectives of this audit were to determine whether:

- Projected savings from the Health and Human Services Commission's (Commission) in-house management of the Children's Health Insurance Program (CHIP) drug benefit were realistic and attainable. Because savings from the Commission's assumption of the management of the CHIP drug benefit depend, in part, on the participation of drug labelers in the voluntary CHIP drug rebate program, the audit also included a review of the CHIP drug rebate program's implementation and its achievements.

- The Commission used accurate data and reasonable assumptions when developing initial health maintenance organization (HMO) premiums for CHIP.

- The Commission established HMO premiums for the second year of CHIP based on reliable, accurate data and a comprehensive analysis.

Scope

The scope of the audit included the Commission's process of setting initial and second-year HMO premium rates for CHIP (these premiums were in effect from May 1, 2000, until September 30, 2002). The scope also included the implementation of the CHIP drug rebate program and drug labeler participation in the CHIP drug rebate program during fiscal years 2002 and the first four months of fiscal year 2003.

Methodology

The audit methodology consisted of collecting information and documentation, performing selected tests and other procedures, analyzing and evaluating the results of the tests, and conducting interviews with the Commission's management, staff, and contracted actuary.

- We reviewed the Commission's determination of second-year CHIP premium rates and the reduction in the premium to remove the drug benefit for one exclusive provider organization (EPO) and two HMOs. As of February 2002, these providers covered 48.8 percent of all children enrolled in CHIP.

- We performed a limited review of the Commission's methodology for the initial rate-setting process.

- We reviewed three versions of the contract between the Commission and the drug labelers that participated in the CHIP drug rebate program. We analyzed the differences in the contract versions and evaluated the impact of these differences.

- We obtained the CHIP drug utilization data for the second quarter of calendar year 2002 from the Commission. We analyzed drug expenditures based on whether the Commission will be receiving rebates on these expenditures and compared this information with the list of drug labelers that agreed to participate in the CHIP drug rebate program.

- We researched the status of the supplemental Medicaid drug rebates and other Medicaid cost containment initiatives in other states.

- Procedures used to gather general information included:

  - Interviews with the Commission's management and staff.

  - A review of information from the Centers on Medicare and Medicaid Services (CMS) and the CMS operations manual.

  - Interviews with the Legislative Budget Board.

- Criteria used included:

  - The General Appropriation Act (77th Legislature).

  - The Social Security Act, Titles 19 and 21.

  - The CMS agreement with the drug manufacturers.

  - Texas's contract with the HMOs.

  - The agreement between the Commission and the drug labelers for participation in the CHIP drug rebate program.

Other Information

We conducted fieldwork from June 2002 through October 2002. We conducted this audit in accordance with generally accepted government auditing standards. The following members of the State Auditor's Office performed the audit work:

- John Young, MPAff (Project Manager)

- Natasha Boston, MPAff

- Brenda Bradshaw, CPA

- Chiemi Perry, CPA

- Leslie Ashton, CPA (Quality Control Reviewer)

- Joanna B. Peavy, CPA (Audit Manager)

- Frank Vito, CPA (Audit Director)

Appendix 2

Medicaid Cost Containment Requirement in the General Appropriations Act (77th Legislature)

Section 33 of the Special Provisions Relating to All Health and Human Services Agencies in the General Appropriations Act (77th Legislature) specifies the following:

> Sec. 33. **Medicaid Cost Containment**. Appropriations to the Health and Human Services Commission shall be reduced by $174.1 million in General Revenue and an estimated $261.2 million in Federal Funds during the 2002–03 biennium for items "a" through "m" below due to cost-containment and savings mechanisms to be implemented by the Health and Human Services Commission. Appropriations to agencies identified in Chapter 531 of the Government Code shall be reduced by $30.9 million in General Revenue and an estimated $13.7 million in Federal Funds during the 2002–03 biennium for items "o" through "q" below due to cost-containment and savings mechanisms to be implemented by the Health and Human Services Commission. Cost-containment and savings initiatives include, but are not limited to, initiatives outlined in Senate Bill 1156* or similar legislation and the following items proposed by the Commissioner of Health and Human Services:
>
> a. Statewide rollout for TANF population (unlimited prescriptions) ($17.9 million in General Revenue);
>
> b. Require SSI population to participate in STAR ($6.1 million in General Revenue);
>
> c. Establish a case-management program for complex cases ($3.0 million in General Revenue);
>
> d. Selective contracting in urban areas for inpatient services ($24.5 million in General Revenue);
>
> e. Move from current formula for drug pricing in Medicaid to a "best price" structure ($22.0 million in General Revenue);
>
> f. Require supplemental rebates in selected therapeutic categories ($14.0 million in General Revenue);
>
> g. Reduce outlier payment percentage ($6.1 million in General Revenue);
>
> h. Competitive pricing for medical equipment and supplies ($7.3 million in General Revenue);
>
> i. Vision care ($1.0 million in General Revenue);
>
> j. Expand Health Insurance Premium Payments System (HIPPS) ($3.2 million in General Revenue);
>
> k. Establish sliding-scale copayments ($3.0 million in General Revenue);
>
> l. Use the Title XIX Trust Fund balance ($60.0 million in General Revenue);
>
> m. Increase utilization review activities through Pharmacy Benefit Managers or in-house function ($6.0 million in General Revenue);
>
> n. Pilot automatic dispensing machines in nursing facilities ($3.2 million in General Revenue);

o. Savings due to Children's Health Insurance Program ($18.8 million in General Revenue);

p. Lowest contract price/Medicaid pricing for all retail purchases ($3.0 million in General Revenue);

q. Medicaid waiver for psychotropic medications ($5.9 million in General Revenue).

The Health and Human Services Commission shall identify the agencies, strategies, and mechanisms used to achieve the reductions, timeline for achieving the reductions, and impact to performance measures and full-time-equivalent positions by May 1, 2002, in a report to the Legislative Budget Board and the Governor. Reductions totaling $205 million in General Revenue and an estimated $274.9 million in Federal Funds shall be made to the Health and Human Services Commission and other agencies by August 31, 2003. All reductions shall be documented in agencies' Legislative Appropriations Requests and adjustments included in reported expenditures for the 2002–03 biennium to the Seventy-eighth Legislature.

*Senate Bill 1156 was vetoed.

Appendix 3

Medicaid Drug Cost-Containment Measures in Other States

The following text is excerpted from *Medicaid Drug Cost Containment* from the July 2002 Health Policy Tracking Service of the National Conference of State Legislatures (NCSL) and is reproduced with NCSL's permission.

OVERVIEW

Since 1990, with the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), states have had the option of offering pharmaceutical benefits within their Medicaid programs. However OBRA '90 placed restrictions on the states' flexibility to control what drugs they would cover. OBRA '90 requires the states to reimburse outpatient drugs of those manufacturers that have signed rebate agreements with the US Department of Health and Human Services. Approximately 520 pharmaceutical companies currently participate in this program. Forty-nine states—Arizona is excluded—and the District of Columbia cover drugs under the Medicaid Drug Rebate Program.

Now, states fight to control escalating drug expenditures in the midst of cost overruns and budget shortfalls; they are instituting a variety of cost control measures, including copayments, reductions in pharmacy dispensing fees and limiting the number of prescriptions a recipient receives. However three methods—preferred drug lists (PDLs), supplemental rebates and generic drug substitution—have gained acceptance, momentum and controversy in the past few years.

To date, at least 34 states have enacted legislation or crafted policies addressing Medicaid supplemental rebates (12), PDLs (14) or generic drug substitution (29). Several of these states have implemented more than one measure.

Medicaid Pharmaceutical Cost Control Measures			
State	Supplemental Rebate	Preferred Drug List	Generic Drug Substitution
AL	--	--	M
AK	--	--	--
AR	--	--	--
AZ	--	--	--
CA	X	--	--
CO	--	--	--
CT	--	--	PA
DE	--	--	--
FL	X	X	M
GA	--	X	M
HI	--	--	M
ID	--	--	PA
IL	X	X	R
IN	--	X	M
IA	--	--	PA
KS	--	X	M
KY	--	X	PA

Medicaid Pharmaceutical Cost Control Measures			
State	Supplemental Rebate	Preferred Drug List	Generic Drug Substitution
LA	X	X	--
ME	X	X	M*
MD	--	--	M
MA	--	--	PA
MI	X	X	--
MN	X	--	M
MS	--	X	M
MO	--	--	--
MT	--	--	--
NE	--	--	--
NV	--	--	--
NH	--	--	M
NJ	--	--	--
NM	X	X	M
NY	--	--	M
NC	X	X	M
ND	--	--	--
OH	X	--	--
OK	--	--	M
OR	--	X	R
PA	--	--	PA
RI	--	--	M
SC	--	--	M
SD	--	--	--
TN	--	--	--
TX	--	--	--
UT	--	--	M
VT	X	X	--
VA	--	--	M
WA	--	--	--
WV	X	--	M
WI	--	--	M
WY	--	--	--
TOTALS	12	14	29

M = Mandatory Substitution

PA = Prior Authorization required for brand name drug

R = Reimbursement based on generic drug price

* = (only if generic is lower in price)

PREFERRED DRUG LISTS/SUPPLEMENTAL REBATES

PDL

In 1993, OBRA '90 was amended to allow state Medicaid programs to control the utilization of certain formulary drugs. Those drugs that lacked a "significant clinically meaningful therapeutic advantage" over comparable drugs would have to be considered through the state's Medicaid program prior authorization process for approval and use by the Medicaid program enrollees.

The result of this scrutiny and the desire to control pharmaceutical expenditures has resulted in states implementing a preferred drug list (PDL). A PDL helps the state reduce program expenditures by establishing cost effective pharmaceutical utilization criteria based on nationally accepted medical best practice standards. In order for a drug to be considered for inclusion on a PDL, the state's Pharmaceutical and Therapeutics Committee or Drug Utilization Review Board must review it's therapeutic indications and clinical effectiveness. The review committee or board is usually composed of physician specialists and pharmacists. The committee evaluates medications according to therapeutic classification—medications with similar clinical indications and/or chemical composition—using current clinical outcome studies and other pertinent data.

Pharmaceutical products chosen for review generally include drugs with similar clinical indications, therapeutic actions, [and] expected outcomes and are readily available in a generic form. In the review process, priority is given to the most expensive of the classes of drugs.

Several drugs from each class are selected as "preferred drugs" based on the board's or committee's findings in relation to the products' therapeutic action, safety, clinical outcome data and cost. Cost alone does not exclude a drug from inclusion on the list. If a less expensive version of a drug is available, but lacks "a significantly, clinically meaningful therapeutic advantage" over other drugs in its class, it will be excluded.

Most states that operate PDLs have excluded drugs for the treatment of mental illness, HIV and AIDS from the standard prior authorization requirements. This is done to prevent a delay in access to timely medications for the treatment of these individuals.

Once the PDL is formalized, the state or its representative negotiates with the pharmaceutical manufacturer or wholesalers for the best purchase price for the drugs. The PDL gives the state an advantage in negotiating lower drug purchasing prices by essentially guaranteeing the manufacturer and wholesalers a large volume of sales. The PDL is generally reviewed on a quarterly basis for inclusion of new pharmaceutical products or changes in accepted clinical practice standards.

Supplemental Rebate

As previously stated, federal statute (OBRA '90) requires drug manufacturers to enter into national rebate agreements with the US Department of Health and Human Services for states to receive federal funding for drugs dispensed to Medicaid patients. Supplemental rebates are additional rebates to a state's Medicaid program that are above and beyond those required by federal law. The supplemental rebate to the state is not necessarily received in the form of cash. It can come in the form of other services such as disease management programs.

PDL/Supplemental Rebate Link

Most states that operate a PDL use supplemental rebates to negotiate with pharmaceutical manufacturers and wholesalers who want their product to be available to Medicaid patients without prior authorization. First drugs have to be reviewed for inclusion on the PDL based on the clinical criteria. Then the state will render its decision to include the drug based upon the cost of the product. At this point manufacturers can offer a supplemental rebate for placement of their drugs on the PDL. Supplemental rebates provide the states bargaining power to reduce their drug expenditures. The larger the rebate negotiated by the state, the greater the savings the state will have for drugs it

covers. The state also saves money because it conducts fewer prior authorization reviews.

The practice of using PDLs and supplemental rebates has been opposed by the Pharmaceutical Research and Manufacturers of America (PhRMA), an association representing the pharmaceutical industry. According to PhRMA, a state violates federal Medicaid statute when it fails to include a drug on its formulary that [has] a rebate agreement with the federal government. PhRMA questions the state's authority to create such a preferred drug list which can exclude a manufacturer's product based upon price. PhRMA has filed and lost lawsuits against two states—**Florida** and **Michigan**, claiming that the states violate federal Medicaid statute by not covering drugs that have a rebate agreement with the US Department of Health and Human Services. In late June, PhRMA filed a new suit against the US Department of Health and Human Services with regards to **Michigan's** program. These law suits are described in further detail under the following state activity section.

PDL/SUPPLEMENTAL REBATE STATE ACTIVITY

Many state programs are in the process of being implemented. As of July 2002, a total of 18 states operate or are in the process of implementing a PDL and/or supplemental rebate program. Of these 18 states, nine—**California, Georgia, Indiana, Kansas, Kentucky, Minnesota, Mississippi, Ohio** and **West Virginia**—are doing one or the other, seven—**Florida, Illinois, Louisiana, Michigan, New Mexico, North Carolina, Vermont**—are doing both, and one—**Maine**—has both but they operate independent of each other.

The following state information briefly describes the activities in establishing a PDL and/or supplemental rebate program in the state.

Alabama

In 1996, the Medicaid Agency created a PDL through its voluntary Preferred Drug Program. The Agency used a panel of clinicians with medical and pharmacological backgrounds to evaluate and select drug products considered most appropriate for use from an effectiveness, safety and cost perspective. Clinical consideration takes precedence over all other factors when determining preferred status. If a brand name drug within a specific class is clinically superior to the available generics within that class, the brand name drug is given preferred status. Cost is not a factor unless all other therapeutic considerations are equal.

California

California was the first state to establish a supplemental drug rebate program and did so prior to the federal government's implementing a nationwide drug rebate program in January 1991. In July 1990, the Medi-Cal Drug Discount Program was established and created the Medi-Cal List of Contract Drugs (LCD). The department could add drugs to the list through a negotiation process. Under this program, the department entered into contracts with several drug manufacturers and achieved price reductions based on the discount prices provided to other third-party drug purchasers. The discounts were in the form of rebates, or equalization payment amounts and were based on the difference between the price that the manufacturer charged to wholesalers and the manufacturer's "best price." Best price is the negotiated price, or the manufacturer's lowest price available to any other customer.

In 1992 new state legislation was enacted that significantly amended the program. The new legislation allowed the department to expand the current

contracting activities to include those drug manufacturers without state rebate contracts. The legislation also allowed the department to aggressively negotiate with drug manufacturers. To achieve savings, the department implemented the provisions of the 1992 legislation in a manner that required manufacturers to negotiate a higher rebate than the federal rebate. If the manufacturer refused to negotiate a higher rebate, the department could counter by removing the manufacturer's product line from the LCD. However, supplemental rebates are not a requirement for being on the LCD.

Florida

In 2001 Florida enacted a measure that requires supplemental rebates from manufacturers for consideration on the state's Medicaid formulary. If a manufacturer agrees to pay the minimum supplemental rebate percentage, the Medicaid Pharmaceutical and Therapeutics Committee will consider the manufacturer's product for inclusion on the preferred drug formulary. However the product is not guaranteed placement on the formulary. The Agency for Health Care Administration's (AHCA) decisions will be based on the clinical efficacy of a drug, and the recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, and the price of competing products minus federal and state rebates.

Drugs from the Florida Negative Formulary, as well as products from drug categories that are exempt by statute, are included on the list to inform clinicians of cost effective choices. However, all antipsychotics, antidepressants, anticonvulsants and HIV related antiretroviral agents are exempt from prior authorization restrictions. Generic drugs with federal or state pricing limits are included on the PDL. Other generic drug products may or may not be included.

The product is not guaranteed placement on the PDL. These rebates may include cash rebates and other program benefits that offset Medicaid expenditures. Florida has already negotiated two separate supplemental rebate contracts with Pfizer and Bristol-Myers Squibb.

In August 2001, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit against the state in federal court. PhRMA contended that the Florida statute authorized creation of a formulary and not simply a preferred drug list. According to PhRMA, the creation of a formulary violates federal Medicaid law. It claims that federal Medicaid law obligates states to include on its formulary the drugs of a manufacturer who has signed a rebate agreement with the federal government, unless the state has made a written determination that a drug has no "significant clinically meaningful therapeutic advantage" over alternative drugs. In the opinion of PhRMA, Florida has failed to prove this exception. Meanwhile, the US Department of Health and Human Services approved Florida's plan. In December 2001, the matter was settled when the court dismissed the challenge by PhRMA and ruled in Florida's favor. PhRMA is expected to appeal the ruling.

Georgia

In 1999 a measure was enacted creating the Department of Community Health consolidating the state's public health insurance programs under one agency, the Department of Community Health. As a result of this legislation, the Department of Community Health solicited bids from pharmaceutical benefits managers (PBMs) to implement an intrastate drug purchasing program for the state's Medicaid, PeachCare for Kids, Board of Regents for higher education health insurance benefits and State Health Benefit Plan for state employees programs.

In 2000 Georgia selected Express Scripts as the pharmacy benefits manager (PBM) for the program and the state Drug Utilization Review Board established a single preferred drug list to be used across these programs. The PDL was developed from both Express Scripts and the Drug Utilization Review Board's recommendations. The list is composed of both brand name and generic drugs. However, all generic drugs are automatically considered preferred drugs, and once a generic equivalent becomes available for a brand drug on the PDL, that brand will automatically be moved to the non-preferred status.

Illinois

During 2002 the Illinois Department of Public Aid (IDPA) announced that it was creating a PDL based on clinical efficacy and safety, as well as cost to the Medicaid program. Drugs will be reviewed by therapeutic classes and on a continuous basis. Manufacturers of medications within the therapeutic classes under review are given the opportunity to make the medications more cost-effective for the Illinois Medicaid program by providing supplemental rebates. Provider Synergies, L.L.C. of Loveland, Ohio is providing PDL management and supplemental rebate contracting services to the IDPA.

Indiana

In 2002 Governor Frank O'Bannon (D) signed into law a measure that charges the state's existing Drug Utilization Board to develop and maintain a PDL. The law states that drugs used for treating mental illness will be included on the PDL. The Board must submit the initial PDL before August 1, 2002. The Medicaid program must implement the PDL before September 1, 2002.

Kansas

A 2002 law signed by Governor Bill Graves (R) allows the Department of Social and Rehabilitation Services to maintain a PDL. Drugs used to treat mental illness are exempt from prior authorization. This law also gives the Department the authority to limit reimbursement to the generic drugs unless the prescriber indicates that the brand name drug is necessary.

Kentucky

In 2002, the legislature enacted a measure creating the Pharmacy and Therapeutics Advisory Committee within the Department for Medicaid Services. The Committee is in the process of performing drug reviews for a PDL and making recommendations on prior authorization.

Louisiana

Prior to 2001 Louisiana was prohibited from establishing a prior approval process within the Louisiana Medicaid Program. In 2001, legislation was enacted that removed this restriction and authorized the creation of a PDL that uses a prior approval process or any other cost-effective process. The law also created the Pharmaceutical and Therapeutics Committee to oversee the creation of the PDL.

In January 2002 providers were notified that the Department of Health and Hospitals (DHH) planned to establish a pharmacy prior authorization process with a PDL. The Department of Health and Hospitals is utilizing the services of both Unisys and the University of Louisiana at Monroe (ULM) College of Pharmacy to operate the prior authorization system. The process will be implemented effective June 10, 2002 and will be phased-in by therapeutic classes.

While the statute does not specifically refer to supplemental rebate negotiations, the state is in the process of negotiating rebates. During the 2002 legislative session, Governor Mike Foster (R) signed into law S 66 which exempts from Public record the terms and conditions of the rebate agreement, rebate amounts, percent of rebate, manufacturer's pricing and supplemental rebates. However, the total amount of supplemental rebates recouped by the Department of Health and Hospitals will be a public record. All information may be subject to review by the legislative auditor and Legislative Fiscal Officer.

Maine

Maine has both a supplemental rebate program and a PDL. However, they are not linked to each other.

In 1998 a measure was enacted establishing a supplemental rebate program. Pharmaceutical manufacturers are not required to participate. The program seeks a rebate of at least 6 percent higher than the federal rebate and individual rebate agreements vary. The majority of rebate agreements are with generic drug labelers or manufacturers.

In late 1999 the Bureau of Medical Services announced a voluntary, physician directed program utilizing physicians and other prescribers participating in the Maine Medicaid Program. The program encourages the use of certain medications for specific conditions that pose a high risk to patient health, while encouraging increased use of appropriate lower cost medication alternatives. The goal of the program is to have enough physicians utilize preferred products, so that prior authorizations will be much more limited.

From this effort, a voluntary PDL was created. The list has preferred products in most of the drug categories that are currently subject to prior authorization and in groups that are under active consideration for prior authorization. Physicians who regularly prescribe preferred drugs in particular categories will be granted exemptions in those specific prior authorization categories. The Exemption will remain in effect as long as the percentage of preferred scripts [is] at or above the threshold. This report will be run quarterly, at which time prior authorization exemptions will then be granted, extended or revoked.

Michigan

During 2001 Michigan Governor John Engler (R), issued Executive Order 2001-8 creating the Michigan Pharmaceutical Best practices Initiative. Part of the initiative was to develop a PDL. The Medicaid drug list remains unchanged and Medicaid recipients and doctors will have access to the same FDA approved drugs. However, drugs recommended by the gubernatorial appointed Michigan Pharmacy and Therapeutics Committee as "best in class" will not require prior authorization. Pharmaceutical manufacturers have the option of offering supplemental rebates to be excluded from prior authorization. All persons currently receiving certain specialized anti-psychotic drugs will [be] grandfathered into the new pharmacy initiatives and will not have these drugs subject to prior authorization. The state expects to save a considerable amount of money through this initiative. In anticipation of implementing this program, the state legislature reduced funding to the Department of Community Health for its current year budget by $42 million.

As in Florida, the initiative has created a controversy with the pharmaceutical industry. The pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit against the state to block the policy. According to PhRMA the policy violates both the Michigan and United States Constitutions.

PhRMA objects to requiring doctors to obtain prior authorization from the state before prescribing medicines for which the state does not receive rebates in excess of those already required by Medicaid [law]. In early January 2002, the Ingham County Circuit Court issued an injunction against the plan. However, on January 17, the state court of appeals lifted the injunction, allowing the state to implement the initiative.

On June 28, 2002, PhRMA filed a lawsuit in the federal district court for the District of Columbia against the secretary of Health and Human Services, Tommy Thompson and the Administrator of the Centers for Medicare and Medicaid Services, Thomas Scully. PhRMA contends that the Secretary overstepped his authority in approving the Michigan program because the program violates the Medicaid statute and harms Medicaid beneficiaries. The lawsuits ask the federal court to issue a preliminary injunction invalidating the Michigan program.

Minnesota

During 2002 the state budget bill was vetoed by Governor Jesse Ventura (I). However, both the House and Senate overrode his veto making the bill a law. Among the health related provisions in the measure is the establishment of prior authorization requests based on the cost of a drug. In addition, the Commissioner of Human Services is given the authority to enter into supplemental rebate contracts and to require prior authorization for drugs from manufacturers that have not signed supplemental rebate contracts.

Mississippi

During the 2002 legislative session, legislators overrode Governor Ronnie Musgrove's (D) veto of S 2189, which directed the state to opt out of the federal Medicaid drug rebate program and develop a closed drug formulary. Unfortunately, the state had been misinformed to proceed in this manner. Instead, the Division of Medicaid is in the process of developing a PDL. The Executive Director of the Division has statutory authority to implement cost control measures to balance the state Medicaid budget.

New Mexico

During 2002 Governor Gary F. Johnson (R) signed into law the "Pharmaceutical Supplemental Rebate Act." The law requires the state Human Services Department to develop a PDL. Those drugs not on the PDL require prior authorization before being dispensed. The department will also negotiate supplemental rebates or discount prices from drug manufacturers. If an agreement has failed to be reached, a review will take place on whether to place the product on the prior authorization list.

North Carolina

In June 2002 Governor Michael Easley (D) announced the state was creating a PDL for the Medicaid program. To create the PDL, an impartial party, Physicians Advisory Group, will identify and recommend clinically effective, brand name drugs for each drug class, regardless of cost. The state Division of Medical Assistance will then [choose] the two most cost-effective drugs for the list, plus all the drugs in the class that are less expensive. All manufacturers whose drugs do not initially meet the best value test will have the opportunity to offer rebates to the state in order to have their drugs added to the PDL. Doctors may still prescribe drugs that are not on the list, but they must first obtain prior authorization. Medicaid will still pay for the higher cost drug provided there is no lower cost drug that will provide the same benefit. All drugs to treat HIV

will automatically be preferred. Also, patients taking certain drugs to treat psychosis and depression and Medicaid patients in long-term care facilities will be grandfathered into the program. The measure is expected to save the state $15 million a year. The list will be phased in over time and the most expensive drug classes will be addressed first. Preferred drugs for those classes are scheduled to be announced in December 2002.

Ohio

During the 2002 legislative session, Governor Robert Taft (R) signed into law a bill that directs the Director of Job and Family Services to establish and implement a supplemental drug rebate program. Drug manufacturers may be required to provide a supplemental rebate as a condition of having the manufacturers' drug products covered by the Medicaid program without prior authorization. Drugs used for the treatment of mental illness and HIV or AIDS are exempt from prior authorization.

Oregon

In 2001 Governor John Kitzhaber (D) signed into law a measure that directs the Department of Human Services (DHS) to adopt a Practitioner-managed Prescription Drug Plan for Medicaid. DHS is prohibited from limiting the use of drugs for mental illness HIV, AIDS or cancer. A byproduct of the Prescription Drug Plan was the development of a PDL.

Oregon has taken a different approach in forming its PDL. The method used by the state is intended to shift emphasis [away] from the drug price/rebate approach typically utilized for drug coverage decisions to a total cost and health impact approach to health care delivery. Drugs chosen to be on the PDL are those considered to represent the most effective prescription drug available at the best possible price in the clinical judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and promotion of health. Those drugs not on the list can still be provided if the prescriber indicates on prescription that the drug is medically necessary.

The Health Resources Commission within the Oregon Health Plan, worked with the Oregon Health and Science University Evidence-based Practice Center to gather and evaluate clinical data. In addition, manufacturers were allowed to submit outcomes and cost-effectiveness data to support the value of their products in the evaluation of those drug classes. All information was evaluated according to established evidence methods and in a public forum. These recommendations were given to the Office of Medical Assistance Programs (OMAP) for pricing. OMAP made cost-effective selections for the list.

Vermont

The fiscal year 2002 Budget Act authorized the Department of Prevention, Assistance, Transition, and Health Access (PATH) to establish a pharmacy best practices and cost control program, designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program was to apply to Medicaid beneficiaries and several other state assistance programs (VHAP and VScript). The law mandated the creation of a PDL. The PDL is the key feature in the program. The Drug Utilization Review Board adopted the PDL and it was implemented in March 2002. Non-preferred drugs can still be prescribed if medically necessary.

In the 2002 legislative session Governor Howard Dean, M.D. (D) signed a comprehensive prescription drug bill that affected the expanded Pharmacy Best Practices and Cost Control Program. The PDL can now be used as leverage in

negotiations with pharmaceutical manufacturers for supplemental rebates or drug discount. Drugs used for the treatment of mental illness are exempt from prior authorization. Drugs used by nursing home residents are exempt from the PDL.

West Virginia

A measure enacted in 2002 authorizes the Department of Human services Secretary to enter into supplemental drug rebate agreements with pharmaceutical manufacturers and protects the negotiations from public disclosure.

GENERIC SUBSTITUTION STATE ACTIVITY (2001–2002)

States are employing several methods to encourage generic drug use through [increased] reimbursement rates to pharmacies and lower copayments for generics. Some states have taken it a step further by mandating generic drug substitution. While some states specifically direct the pharmacist to substitute generic [drugs], some have crafted language that will only reimburse based on generic price [or] require prior authorization for brand name prescriptions. Activity regarding increased usage of generic drugs has grown in last few years. To date, 29 states—**Alabama, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, New Hampshire, New Mexico, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Utah, Virginia, West Virginia and Wisconsin**—have legislative or regulatory language that either requires drug substitution under Medicaid (21), limits reimbursement based on the generic drug price (2) or requires prior authorization for brand name drugs (6).

The following state information briefly describes generic substitution state activity for 2001 and 2002.

Connecticut

In June 2002 the state Department of Social Services announced that the Medicaid program will implement a prior authorization process for brand name drugs. Providers will need to seek prior authorization for brand name medications where a generic equivalent exists, if a client requests an early refill of any prescription, and for prescriptions that are billed for greater than $500 for a 30 day supply. The process will be implemented over a four month phase-in period. Medicaid is one of three states programs that this new policy applies. The State Administered General Assistance (SAGA) and ConnPACE are the other two programs.

Idaho

A measure enacted in 2002 directs the Department of Health to develop a process of prior approval when the physician prescribes brand name drugs.

Kentucky

In late 2001 emergency regulations were established to require doctors to obtain prior approval before prescribing brand name [drugs].

Massachusetts

In late 2001 a policy was instituted requiring prior authorization for brand name drugs when a generic drug is available. Prior authorization is granted in case of medical necessity.

Mississippi

A 2002 law prohibits providers from prescribing a brand name drug if a generic drug is available. Pharmacies will only be reimbursed at the generic drug price, if a generic drug is available for the prescription.

New York

A 2002 measure signed into law by Governor George Pataki (R), prohibits reimbursement for a brand name drug when a generic substitute is available. However, the state's commissioner of Health may exempt any brand name drug from this restriction.

Oregon

In 2001 Governor John Kitzhaber (D) signed into law a measure that directs the Department of Human Services (DHS) to adopt a Practitioner-managed Prescription Drug Plan for Medicaid. DHS is prohibited from limiting the use of drugs for mental illness, HIV, AIDS or cancer. The [law] also limits payment of prescription drugs to the price of its generic equivalent. A by-product of the Prescription Drug Plan was the development of a PDL.

Vermont

During the 2001 session, Vermont's generic substitution law was amended to require generic substitution unless the brand name drug is medically necessary or unless the patient agrees to pay for the additional costs.

2002 MEDICAID DRUG COST CONTAINMENT LEGISLATIVE ACTIVITY

So far this year, 11 states—Florida, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Mississippi, New Mexico, Ohio, Vermont and West Virginia—enacted legislation pertaining to PDLs (7), supplemental rebates (6) and generic drug substitution (4).

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Copies of this report have been distributed to the following:

Legislative Audit Committee

The Honorable Tom Craddick, Speaker of the House, Chair
The Honorable David Dewhurst, Lieutenant Governor, Vice Chair
The Honorable Teel Bivins, Senate Finance Committee
The Honorable Bill Ratliff, Senate State Affairs Committee
The Honorable Talmadge Heflin, House Appropriations Committee
The Honorable Ron Wilson, House Ways and Means Committee

Office of the Governor

The Honorable Rick Perry, Governor

Health and Human Services Commission

Mr. Albert Hawkins, Commissioner