

TennCare Prescription Drug Costs



**John G. Morgan
Comptroller of the Treasury
Office of Research
December 2002**



STATE OF TENNESSEE

COMPTROLLER OF THE TREASURY

John G. Morgan
Comptroller

STATE CAPITOL
NASHVILLE, TENNESSEE 37243-0264
PHONE (615) 741-2501

December 16, 2002

The Honorable John S. Wilder
Speaker of the Senate
The Honorable Jimmy Naifeh
Speaker of the House of Representatives
And
Members of the General Assembly
State Capitol
Nashville, Tennessee 37243

Ladies and Gentlemen:

Transmitted herewith is a report prepared by the Office of Research concerning prescription drug costs in the TennCare program. The report provides information and recommendations that may be useful to policymakers in considering ways to reduce prescription drug costs in the program while maintaining quality patient care.

Sincerely,

A handwritten signature in cursive script that reads "John G. Morgan".

John G. Morgan
Comptroller of the Treasury

TennCare Prescription Drug Costs



Richard Gurley
Associate Legislative Research Analyst

Ethel R. Detch, Director
Douglas Wright, Assistant Director
Office of Research
505 Deaderick Street, Suite 1700
Nashville, TN 37243-0268
615/401-7911
www.comptroller.state.tn.us/orea/reports

John G. Morgan
Comptroller of the Treasury

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Executive Summary

Rising prescription drug costs in recent years have produced a significant drain on state resources through TennCare and have strained the state's overall health care market. Both national trends and internal program changes have contributed to rising costs in the TennCare program. This report:

- provides a brief history of the pharmacy benefit in the TennCare program;
- analyzes recent trends in prescription drug costs within the program;
- evaluates strategies implemented by Tennessee to control TennCare prescription drug costs in light of initiatives in other states and the private sector; and
- recommends changes in the TennCare prescription drug benefit to make the program more cost-effective.

This report concludes:

Costs in all three areas of prescription drug spending in the TennCare program—the dual-eligible carve-out, the behavioral health carve-out, and managed care organization (MCO) drugs costs—have grown faster than national trend rates in recent years. Pharmacy costs across the country have increased dramatically in recent years. However, costs in the TennCare program have grown faster than national trend rates. Increases above national rates appear to be driven by moving medical drugs for dual-eligible enrollees and behavioral drugs for all enrollees to open formularies and by the impact of the *Grier Consent Decree* on MCO drug costs. Had costs in these areas grown at projected trend rates, TennCare prescription drug costs would have been over \$200 million less in fiscal year 2002. (See pages 7-8.)

The *Grier Consent Decree* creates incentives for MCO behavior that may result in increased costs to the state under capitated arrangements. The *Grier Consent Decree* increased MCO costs through appeal-driven administrative costs, more dispensing fees associated with 14-day supplies, and lower rebates (in percentage terms) for brand drugs dispensed. As a strategic response, MCOs added many drugs to their formularies, significantly increasing average ingredient cost for dispensed drugs. The methodology of the PricewaterhouseCoopers actuarial analysis accounts for this increase and the decrease in dispensing fees brought about by adding drugs to a formulary. However, it does not account for changes in administrative costs and rebates caused by MCO decisions. (See pages 8-9.)

The TennCare pharmacy carve-out lacks prior authorization procedures to control the use of more expensive medications, and the *Grier Consent Decree* has undermined MCO prior authorization requirements. Many private insurance companies and state Medicaid programs use prior authorization requirements to steer recipients to more cost-effective medications. The TennCare pharmacy carve-out lacks significant prior authorization requirements, and the *Grier Consent Decree*, which allows patients to receive 14-day supplies of many nonformulary drugs without prior authorization, has reduced the capacity of MCOs to control costs. (See pages 9-10.)

The TennCare pharmacy carve-out lacks a formulary designed to direct patients to the most cost-effective medications, and differences in MCO formularies undermine

their effectiveness. Private insurance companies and Medicaid programs use formularies—lists of preferred drugs—to direct patients to cost-effective medications. The TennCare pharmacy carve-out lacks a formulary and offers no incentives for the use of less expensive medications. Because of the increased effort required to keep up with multiple formularies, TennCare physicians frequently prescribe drugs not on MCO formularies. (See pages 10-12.)

The TennCare program has not maximized rebates it receives from pharmaceutical manufacturers. Federal law (OBRA 90) requires pharmaceutical manufacturers to offer their “best price” to state Medicaid programs. In fiscal year 2002, OBRA 90 generated rebates of 20.85 percent for the TennCare pharmacy carve-out. However, MCOs do not qualify for these rebates, and the PriceWaterhouseCoopers actuarial analysis underlying MCO capitation rates assumes rebates of only seven percent. Many states have begun using Medicaid preferred drug lists to negotiate “supplemental rebates” above those guaranteed by OBRA 90. Neither the TennCare pharmacy carve-out nor TennCare MCOs receives supplemental rebates. (See pages 12-14.)

The TennCare program will implement a three-tier copayment structure in January 2003, but its structure will differ from standard commercial practice. Private insurance companies generally base three-tier copayments on preferred drug lists. The TennCare Bureau plans to base copayments on whether or not a drug is available in generic form. As a result, the TennCare program will have far fewer drugs in the third tier (higher copay) than most private companies, undermining the copayment structure’s effectiveness in reducing program costs. (See pages 14-16.)

Research is insufficient to predict the impact of copayments on patient health and pharmacy reimbursement rates. Some academic research has suggested that Medicaid recipients forego needed medications when states implement copayments, resulting in poorer health and more costly medical procedures in the long run. Some research has also suggested that many Medicaid recipients refuse to pay copayments but receive prescription drugs nonetheless because of federal law requirements. This practical impact is a cut in pharmacy reimbursements. In both cases, the research is inconclusive. (See pages 16-17.)

TennCare MCOs conduct most drug utilization review (DUR) programs found in the private sector, but the TennCare pharmacy carve-out lacks many of these. Most private insurance companies and MCOs have:

- computer edits to prevent improper prescriptions from being filled;
- step therapy and prior authorization requirements for less expensive drugs; and
- interventions targeting specific pharmacists and/or physicians identified through company data.

The TennCare pharmacy carve-out has many computer edits, but most are “soft” edits that allow payment to go through. The pharmacy carve-out has no step therapy requirements and mandates prior authorization only for growth hormone. Finally, because the state lacks reliable provider-level data, TennDUR, the entity responsible for conducting retrospective drug utilization review for the TennCare pharmacy carve-out, is

unable to develop initiatives targeting specific pharmacists and physicians. (See pages 17-20.)

TennCare MCO contracts require physician and pharmacy lock-ins for abusive users of prescription drugs; the TennCare pharmacy carve-out also has a lock-in program. Lock-in programs require certain patients to receive all their prescriptions from a single physician and/or have those prescriptions filled at a single pharmacy, decreasing the chances of duplicative prescriptions or drug/drug interactions. States generally use lock-in programs for patients who use a large number of prescription drugs or who appear to be abusing some medications. (See page 20.)

TennCare MCOs and the TennCare pharmacy carve-out have procedures to promote the use of lower cost over-the-counter and generic medications when possible. All MCOs and the TennCare pharmacy carve-out cover some over-the-counter medications, such as pain relievers, antihistamines, and antacids. They also use maximum allowable cost (MAC) pricing to promote the use of generic medications. Both strategies can reduce patient reliance on more costly brand drugs. (See pages 20-21.)

Pharmacy payment rates for brand drugs in the TennCare pharmacy carve-out are lower than most Medicaid programs but above payment rates frequently found in the private sector and actual pharmacy costs. The TennCare Bureau pharmacy carve-out uses a reimbursement rate of AWP¹ minus 13 percent for brand-name drugs and a dispensing fee of \$2.50. This pharmacy payment rate is lower than most state Medicaid programs. However, many private insurers use even lower payment rates, and the Office of the Inspector General released a report in September 2002 that concluded actual pharmacy acquisition costs were AWP minus 17.2 percent. (See page 21.)

The TennCare pharmacy carve-out lacks limits on prescription drugs that could produce program savings without adversely affecting patient care. Several states place limits on the number of prescriptions patients can receive through Medicaid programs in a single month or year. Though some of these programs are global limits, others focus only on brand drugs or on specific classes of drugs. The TennCare program has no such limits. (See pages 21-22.)

The TennCare Bureau has established pilot programs in disease management through the TennCare Centers of Excellence, but the potential financial and health impact of these programs is not yet clear. Disease management (DM) programs encourage patients to take necessary steps in the treatment of high cost medical conditions such as asthma, diabetes, and congestive heart failure (CHF). Using funding from the pharmaceutical industry, the TennCare Centers of Excellence will begin DM pilot programs for some major disease states in early 2003. (See pages 22-23.)

The TennCare Bureau has implemented some measures to obtain outside third-party payment for TennCare procedures when appropriate, but alternative procedures could be more efficient. Many Medicaid recipients use other third-party payment sources in addition to Medicaid, usually Medicare or private insurance. As a

¹ Average wholesale price—AWP is a common benchmark in the prescription drug industry, though it is not truly an “average” of any set of prices. Instead, it is the rough equivalent of the “sticker price” in the automobile industry.

payer of last resort, Medicaid should not cover services provided by these entities. The TennCare Bureau has implemented a system that requires payment of prescription drugs through Medicare at the point of sale when appropriate. However, the bureau pays the full cost of drugs for patients with private insurance and contracts with a third party vendor to recoup payment from the private insurer after the sale. (See pages 24-25.)

Many states, including Tennessee, have created discount prescription drug plans for low-income individuals. As drug costs in the private market have escalated, many states have used Medicaid waivers to make prescription drugs more affordable for citizens, particularly the elderly and low-income groups, not included in state Medicaid plans. The Center for Medicare and Medicaid Services (CMS) has approved “Pharmacy Plus” waivers for five states. The benefit for TennCare’s “dual eligible” population is similar to these programs though some states provide benefits to larger populations. (See page 25.)

Recently announced reforms by the TennCare Bureau may not significantly increase the cost-effectiveness of the program. On November 7, 2002, the TennCare Bureau announced plans to develop a single statewide formulary.² From this formulary, the state will negotiate rebates with pharmaceutical companies, and the University of Tennessee College of Pharmacy will serve as the state’s pharmacy benefit manager. It is unclear if the bureau proposal will increase the cost-effectiveness of the TennCare pharmacy benefit. Specific concerns include:

- The TennCare Bureau proposal will allow the state to obtain rebates guaranteed through OBRA 90 for all prescription drugs but is unlikely to provide leverage to negotiate supplemental rebates; (See page 26.)
- The composition of the TennCare Formulary Committee could undermine public confidence in the formulary; (See page 26.)
- The University of Tennessee College of Pharmacy may be unable to provide expertise available from private pharmacy benefit management (PBM) companies but is not subject to potential conflicts of interest prevalent in the PBM industry; (See page 27.)
- The *Grier Consent Decree* may undermine the effectiveness of the TennCare Bureau proposal; (See page 27.) and
- The TennCare proposal does not include the creation of a formulary for behavioral drugs, reducing the amount of savings it will produce. (See page 27.)

Legislative Recommendation

- The General Assembly may wish to create a discount pharmacy program for low-income citizens not eligible for the TennCare program.

Executive Recommendations

- The Office of the Attorney General should seek a revision to the *Grier Consent Decree* to strengthen MCO prior authorization requirements.

² “Single Formulary Targets Prescription Drug Costs in TennCare,” TennCare Bureau press release, November 7, 2002.

- The TennCare Bureau should work toward the implementation of a single statewide formulary.
 - If the TennCare Bureau implements a single statewide formulary, the formulary committee should not include members with a vested interest in creating a formulary that is overly expansive or restrictive.
 - If the TennCare Bureau implements a single statewide formulary, it should make clinical data on formulary and nonformulary medications widely available.
 - If the TennCare Bureau implements a single statewide formulary, it should pursue supplemental manufacturer rebates.
 - If the TennCare Bureau implements a single statewide formulary, it should tie three-tier copayments to that formulary.
- The TennCare Bureau should study the impact of copayments to determine whether or not copayment requirements appear to reduce enrollee use of essential medications.
- The TennCare Bureau should establish regulations that clarify under what circumstances pharmacists can deny service to TennCare Medicaid members who refuse to pay copayments.
- The TennCare Bureau should seek a full-service pharmacy benefits manager (PBM) to administer programs associated with the TennCare pharmacy carve-out.
- The TennCare Bureau should maintain pharmacy and primary care physician lock-ins for enrollees who use large amounts of prescription medication.
- The TennCare Bureau should examine the potential costs and benefits of moving to a full pharmacy carve-out.
- The TennCare Bureau should fully implement point-of-service third-party-liability (TPL) recovery programs.
- The TennCare Bureau, in conjunction with other divisions of the Department of Finance and Administration and other agencies, should explore strategies for reducing drug costs through cooperative efforts among state programs.

Responses to this Report

Response letters from the TennCare Bureau and TennDUR are included as Appendix C and Appendix D. Both letters include information on recent and planned initiatives designed to improve the cost-effectiveness of the TennCare prescription drug benefit.

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Introduction

Rising prescription drug costs in recent years have produced a significant drain on state resources through TennCare and have strained the state's overall health care market. These trends are not unique to Tennessee, and many states have taken or are considering actions meant to curb rising drug costs. In its previous report, *Prescription Drug Costs in Tennessee*, the Office of Research:

- examined underlying causes of rising drug costs in Tennessee and the nation as a whole;
- reviewed steps private organizations and the federal government have taken to curb growth in pharmaceutical spending;
- evaluated methods Tennessee agencies and state employee health plans use to purchase prescription drugs;
- evaluated actions of other states to reduce prescription drug costs; and
- outlined further options for Tennessee to slow drug cost growth in state employee health plans, state wholesale purchases, and the state prescription drug market as a whole.

This report:

- provides a brief history of the pharmacy benefit in the TennCare program;
- analyzes recent trends in prescription drug costs within the program;
- evaluates strategies implemented by Tennessee to control TennCare prescription drug costs in light of initiatives in other states and the private sector; and
- recommends changes in the TennCare prescription drug benefit to make the program more cost-effective.

Methodology

The conclusions reached and recommendations made in this report are based on:

- Interviews of TennCare Bureau staff, staff of TennCare managed care organizations (MCOs), and staff of Affiliated Computer Systems (ACS) and the University of Tennessee Health Science Center responsible for drug utilization review (DUR) in the TennCare program;
- Interviews of Department of Commerce and Insurance, Department of Health, and Office of the Attorney General staff;
- An extensive literature review of research on state Medicaid programs and prescription drug costs;
- Analysis of data from the TennCare Bureau, TennCare MCOs, the Georgia Department of Community Health, the Michigan Department of Community Health, and national sources;
- Interviews of staff affiliated with Medicaid programs in Florida, Georgia, Idaho, Massachusetts, Michigan, Maine, North Carolina, Oklahoma, South Carolina, Texas, and Vermont;
- Interviews of Tennessee physicians and pharmacists;
- Interviews of state and national researchers specializing in health care costs;

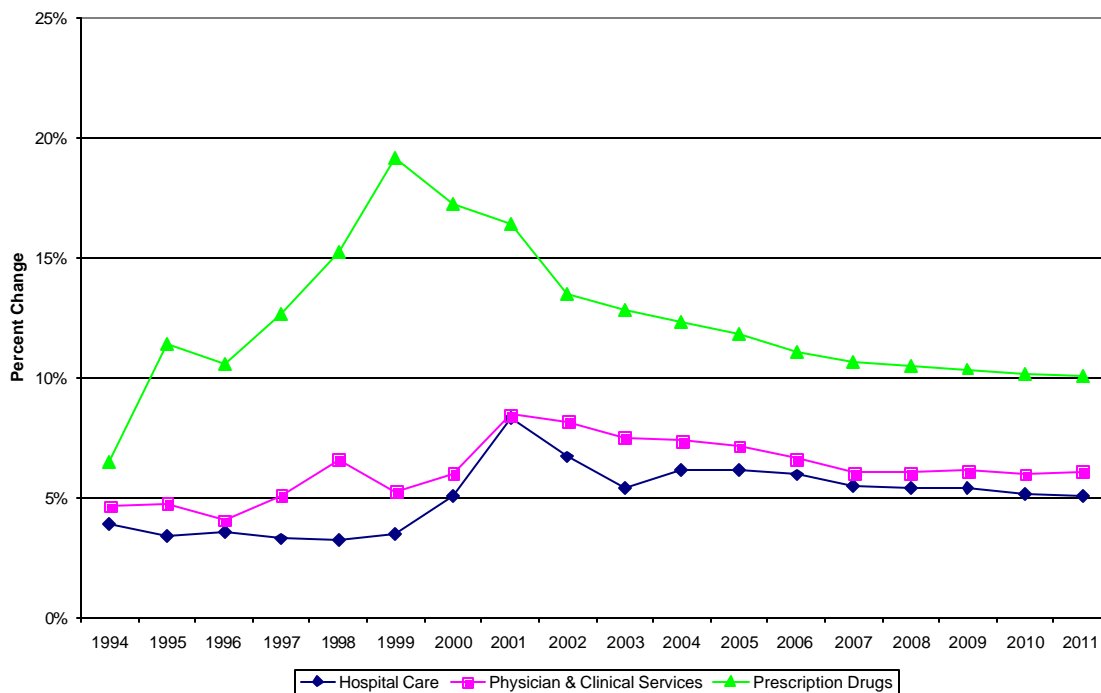
- Interviews of pharmacy benefit management (PBM), disease management (DM), and health care consulting companies;
- Interviews of staff of pharmaceutical companies; and
- Interviews patient and consumer advocates.

Background

National Drug Expenditures

According to the Center for Medicare and Medicaid Studies (CMS), U.S. spending on prescription drugs grew from \$51.3 billion in 1993 to \$121.8 billion in 2000, a 137 percent increase. In contrast, overall health care spending grew by only 48 percent. As seen in Exhibit 1, CMS projects growth in prescription drug spending to outpace increases in other areas of health care spending for at least the next decade.

Exhibit 1: Annual Health Care Spending Growth



Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Table 2 (<http://www.hcfa.gov/stats/NHE-Proj/proj2001/tables/t2.htm>) and Table 9 (<http://www.hcfa.gov/stats/nhe-oact/tables/t9.htm>).

Third-party payers such as Medicaid or private insurance companies have borne the brunt of these spending increases. Chart 2 shows the average change in national prescription drug spending from 1994 to 2000, and Chart 3 shows spending on prescription drugs as a percent of all health care spending. Out-of-pocket spending includes deductibles and copayments but does not include insurance premiums. Increased prices, increased utilization, or a combination of the two always drives increased spending. Both factors have contributed to rising prescription drug spending.

Exhibit 2: Annual Change in Prescription Drug Spending

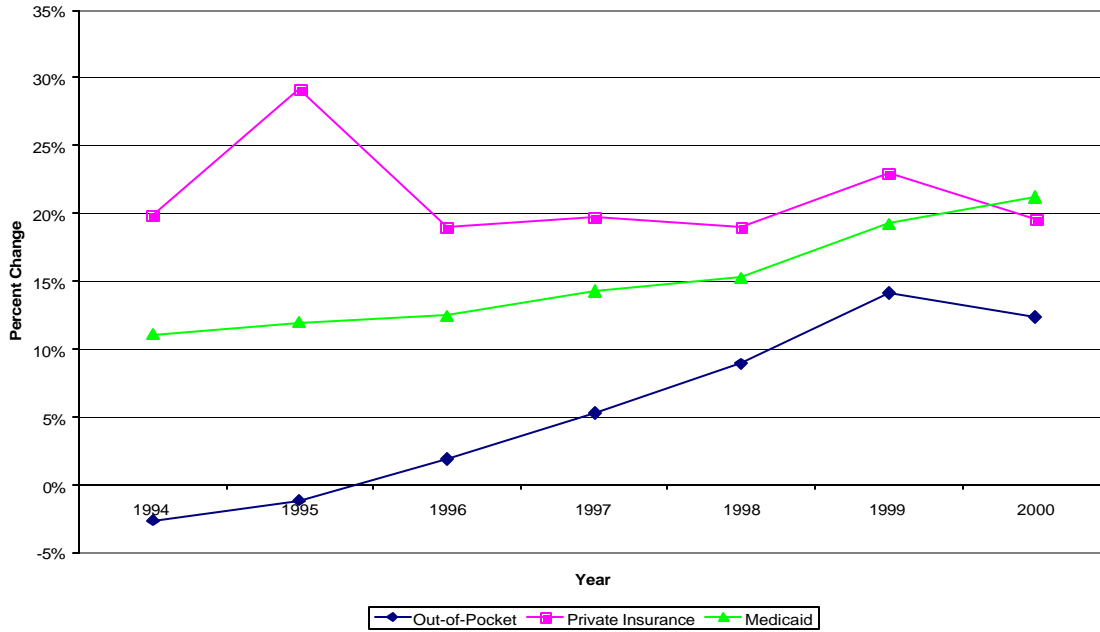
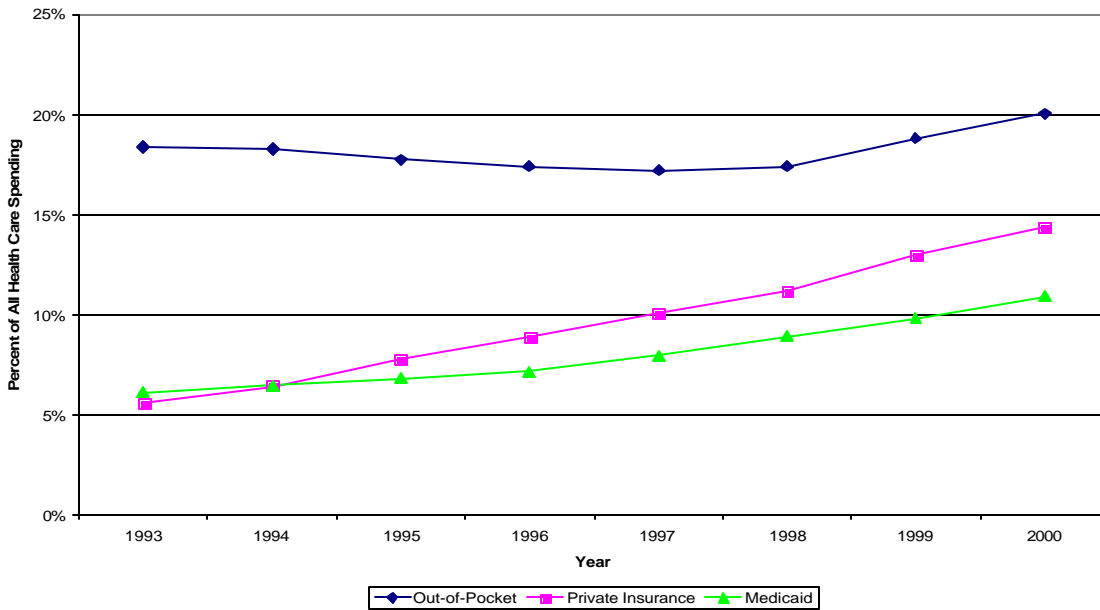


Exhibit 3: Prescription Drugs as a Share of all Health Care Spending



Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Table 9 (<http://www.hcfa.gov/stats/nhe-oact/tables/t9.htm>).

For a more thorough discussion of the forces driving increases in pharmacy spending, see the Office of Research report, *Prescription Drug Costs in Tennessee*.

TennCare Prescription Drug Benefits—A Brief History

On January 1, 1994, the state of Tennessee embarked on an ambitious Medicaid reform program known as TennCare. The state shifted its entire Medicaid population into managed care administered by private managed care organizations (MCOs). Policymakers hoped to parlay savings from this shift to expand coverage to include much of Tennessee's previously uninsured low-income population and those who did not qualify for private insurance because of preexisting medical conditions. By creating TennCare, the state qualified for federal matching funds to provide approximately two thirds of the cost of covering these groups. Despite considerable controversy, TennCare appears to have accomplished its goal, at least nominally. It provides health coverage to approximately 870,000 Medicaid-eligible individuals and 570,000 in TennCare's "waiver" population¹ and spending remains below limits established by the federal government. However, TennCare has endured frequent criticism and experienced financial difficulties. As part of the rehabilitation of Xantus, the State paid over \$46 million state dollars with no federal matching funds as direct provider payments and a loan to Xantus. Rapidly rising costs in recent years have brought the long-term viability of the program into question, and the program is now in a stabilization period meant to reduce the risk faced by MCOs and secure federal funding in the event of cost overruns.

In the original TennCare program design, the TennCare Bureau pays MCOs through capitation payments. MCOs receive these payments each month to provide health services, including prescription drug services, for all patients under their care. Under this model, if MCOs reduce patient use of high cost drugs, they would profit. However, they are at risk if prescription drug costs or other medical costs increased beyond projections. Each MCO has its own formulary, a list of drugs preferred by the MCO. A doctor who wishes to prescribe a nonformulary drug must demonstrate that the medication is medically necessary. Proving medical necessity requires the doctor to demonstrate through medical records that formulary drugs are either ineffective or produce adverse side effects. Though several of the formularies are similar, no two are identical.

The TennCare Bureau contracts with private behavioral health organizations (BHOs) to provide mental health and substance abuse benefits. These benefits include inpatient and outpatient psychiatric and mental health services, substance abuse treatment, mental health case management, and specialized symptom management and crisis services.² They also initially included behavioral health medications. However, MCO doctors retained the authority to prescribe many of these medications. Under this arrangement, BHOs were at risk for higher costs from behavioral drugs but had limited means to manage the use of those drugs since they frequently lacked a contractual relationship with prescribing physicians. The MCOs, in contrast, had no financial incentive to control physicians' prescription of behavioral medications. As new antipsychotic drugs emerged in the mid-1990s and pharmacy costs escalated, the financial health of the BHOs deteriorated.³ In an effort to stem rapidly growing costs, BHOs implemented significant prior authorization and step therapy requirements that

¹ Based on enrollment figures from September 12, 2002.

² "Re-Issue of the Managed Care Contract Provider Risk Agreement between the State of Tennessee Department of Mental Health and Developmental Disabilities and Premier Behavioral Health," TennCare Bureau, <http://www.state.tn.us/tenncare/BHOcont.pdf> (accessed September 1, 2002).

³ Paula Wade, "TennCare Retooling Mental Health Care Plan," *The Commercial Appeal*, July 6, 1998, p. A1.

some doctors and patient advocates felt were inappropriate.⁴ In order to address these challenges, the TennCare Bureau “carved out” the behavioral health pharmacy program on July 1, 1998.⁵ The bureau now covers mental health drugs, both those prescribed by MCO physicians and those prescribed by BHO physicians, on a fee-for-service basis.

A similar contractual problem existed with TennCare’s dual (Medicare/TennCare) eligible population.⁶ MCOs were at risk for the cost of prescription drugs. However, patients’ Medicare physicians frequently did not contract with MCOs, undermining the MCOs’ ability to manage prescribing behavior. On July 1, 2000, the TennCare Bureau carved out pharmacy benefits for its dual enrollees.⁷ Since that time, the TennCare pharmacy carve-out has provided all prescription drugs for the dual population (approximately 230,000 enrollees) and behavioral drugs for all TennCare enrollees. Prescription drug costs for the carve-out were approximately \$676 million in fiscal year 2002 after rebates, about 58 percent of total spending on outpatient prescription drugs in the TennCare program.⁸

By early 2002, several trends undermined the stability of contractual relationships between the state and MCOs. Rapidly escalating pharmacy costs and uncertainty surrounding the reverification process made it difficult to determine appropriate capitation rates for fiscal year 2003. Also, several MCOs had medical loss ratios well over 85 percent, placing the financial health of the plans in jeopardy.⁹ Were those plans to fail, the state could again face significant provider payments from state-only dollars.

In response, the TennCare Bureau moved MCOs into an eighteen month stabilization period beginning July 1, 2002. Under this arrangement, the state rather than the MCOs is at risk for medical expenses including prescription drug costs. If costs exceed projected levels, the state will continue to draw down federal matching funds for those expenses. During the stabilization period, MCOs receive a 9 percent administrative fee for dual Medicare/TennCare enrollees and a 7.25 percent administrative fee for nondual enrollees. Stabilization period contracts require the MCOs to continue cost control programs, temporarily freeze provider reimbursement rates, and provide incentive payments to MCOs that keep medical expenses below targets set by the bureau.¹⁰ Two incentive payment measures, generic drug utilization and third party liability (TPL) recovery rates, relate to prescription drug costs.¹¹ (See page 24 for further discussion of third-party liability.)

Concurrently with the move to the stabilization period, the TennCare Bureau applied for and received approval of a new waiver that includes significant design changes in the program. That waiver became effective July 1, 2002, though it will not be fully implemented until January 1, 2003. Among the most significant changes, the program will differentiate between the Medicaid population and the “waiver population,” (uninsureds and uninsurables).

⁴ Rebecca Ferrar, “TennCare’s Mental Health Wing Revamped, Including Steps on Drugs,” *Knoxville News-Sentinel*, May 22, 1998, p. A4.

⁵ “Important TennCare Drug Information for Pharmacists,” TennCare Bureau, June 27, 2000.

⁶ TennCare’s “dual eligible” population consists of people eligible for both TennCare and Medicare. Because Medicare covers most hospital and physician expenses, TennCare’s primary financial responsibility for these enrollees is prescription drug costs.

⁷ “Important TennCare Drug Information for Pharmacists,” TennCare Bureau, June 27, 2000.

⁸ Correspondence from Darin Gordon, TennCare Bureau, September 20, 2002.

⁹ Manny Martins, TennCare Bureau Director, testimony before the fiscal review committee, August 22, 2002.

¹⁰ Manny Martins, TennCare Bureau Director, testimony before the fiscal review committee, August 22, 2002.

¹¹ Mark Reynolds, TennCare Bureau Director, memorandum to the members of the TennCare Oversight Committee, May 21, 2002.

TennCare-Medicaid will have continuous open enrollment and provide those benefits mandated by federal law. TennCare Standard, which includes the waiver population, will provide fewer benefits and will have only one annual open enrollment period, subject to funding in each year's budget. The waiver also modifies the process for determining if an individual is "medically eligible."¹² The most significant change for the pharmacy benefit will be the implementation of tiered copayments for prescription drugs. (See page 15 for more information on tiered copayments.)

¹² The "medically eligible" population is synonymous with the "uninsurable" population. The change in terminology reflects a move from eligibility determination system based on a declination letter from an insurance company to a points-based system that assesses an individual's insurance risk to determine whether or not he/she qualifies for TennCare as a medically eligible individual.

Analysis and Conclusions

TennCare Drug Expenditure Trends

TennCare has experienced significant increases in drug costs as part of a national trend of rising pharmacy costs. According to the National Institute for Health Care Management, U.S. retail spending on prescription drugs nearly doubled from 1997 to 2002.¹³ This rapid increase in spending was due to increases in the number of prescriptions dispensed, price increases for many prescription drugs, and customer movement from lower-cost to higher-cost medications. Many factors have contributed to these changes, which have impacted the TennCare program as well as the nation as a whole. (For an examination of the factors driving cost increases, see the Office of Research report *Prescription Drug Costs in Tennessee*.)

The TennCare dual and BHO carve-outs have experienced major increases in drug costs above national trend rates. The TennCare Bureau “carved out” the behavioral health pharmacy program on July 1, 1998, moving behavioral drugs from a tightly controlled formulary with significant prior authorization and step therapy requirements to an open formulary that provides access to virtually all medications without those requirements. (See pages 9 and 18 for more information on prior authorization and step therapy.) Since that time, per member per month costs for behavioral health drugs within TennCare have grown faster than national trend rates. Had costs for the BHO pharmacy program grown at national trend rates for prescription drug costs, program costs would have been approximately \$81.5 million less in fiscal year 2002, approximately 27 percent of actual costs.¹⁴ Exhibit 4 shows actual spending on prescription drugs in the TennCare program during fiscal year 2002 after taking into account rebates from pharmaceutical companies.

The TennCare Bureau carved out medical drugs for dual-eligible enrollees on July 1, 2000. As with behavioral drugs, the carve-out eliminated many prior authorization and step therapy requirements that had required physicians to demonstrate higher cost drugs were necessary before patients could receive them. Since the dual medical drugs were carved out, per member per month costs for those drugs have increased well above national trend rates. Had costs for dual-eligible medical drugs grown at national trends for prescription drug costs, pharmacy costs for these drugs would have been over \$64 million less in fiscal year 2002, over 17 percent of actual costs.¹⁵ (See Exhibit 4.)

¹³ National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002.

¹⁴ Office of Research analysis of TennCare Bureau data.

¹⁵ Office of Research analysis of TennCare Bureau data.

Exhibit 4: Actual and Projected TennCare Pharmacy Costs in Fiscal Year 2002

Program	Actual FY02 Cost	Projected Cost at Trend Rate	Cost Difference	Cost Difference as Percent of Actual FY02 Cost
MCO	\$486,654,747	\$431,044,987	\$55,609,760	11.4%
Dual Medical	\$372,005,756	\$307,938,142	\$64,067,614	17.2%
Behavioral	\$304,141,395	\$222,674,294	\$81,467,101	26.8%
Total TennCare	\$1,162,801,898	\$961,657,423	\$201,144,475	17.3%

Note: Comparison national trend rates are for all prescription drug spending. Underlying cost drivers for specific components of the TennCare program might differ from those of national trend rates. All costs are net of manufacturer rebates. Actual FY02 costs for Dual Medical and Behavioral drugs reflect actual rebates of 20.85%. Actual MCO and all projected costs reflect 7% rebates assumed in the PricewaterhouseCoopers actuarial study.

TennCare MCOs have experienced major increases in drug costs above national trend rates, apparently as a result of the Revised Grier Consent Decree. On July 31, 2000, the United States District Court approved the *Revised Grier Consent Decree*. The revised decree went into effect November 1, 2000. MCO contracts with pharmacies require pharmacists to contact physicians if they prescribe drugs not on MCO formularies.¹⁶ Under the *Grier Decree*, if the pharmacist is unable to contact the prescribing physician or if the physician refuses to substitute a formulary drug, the pharmacist must provide a two week supply of the prescribed medication to the patient.¹⁷ Virtually all persons interviewed believe the *Grier Decree* seriously impairs the ability of MCOs to channel patients away from more expensive therapies, and many believe pharmaceutical companies actively encourage TennCare physicians to prescribe nonformulary drugs via *Grier*.

Since the implementation of the *Revised Grier Consent Decree*, generic utilization rates for TennCare MCOs have declined significantly, fueling rapid increases in drug costs. Applied Health Outcomes projected MCO pharmacy costs for the 11 months following the implementation of the *Grier Consent Decree* and compared actual costs to those projections. For January through July 2001, MCO drug costs were 11.4 percent above projected costs. Extrapolating an 11.4 percent cost increase to fiscal year 2002 yields actual costs approximately \$56 million over projected costs.¹⁸ (See Exhibit 4.) However, the Applied Health Outcomes period of analysis ends at July 2001. Many interviewees stated that the *Grier Decree* resulted in continued erosion of MCO formulary compliance throughout fiscal year 2002. If that was the case, the impact of the *Grier Decree* could be significantly higher.

The *Grier Decree* creates incentives for MCO behavior that may result in increased cost to the state in capitated arrangements. Since the implementation of the *Grier Decree*, most MCOs have noted significant increases in the use of nonformulary medications. This has created a three-fold problem for the MCOs. First, working through *Grier* appeals creates an additional administrative burden on MCO staff. Second, because *Grier* covers 14-day supplies rather than 30-day supplies, MCOs must pay two dispensing fees to pharmacies for a month's supply of a medication dispensed through *Grier*. Finally, though MCOs receive sizable rebates on formulary medications, they receive no rebates for nonformulary medications.

¹⁶ Correspondence from Leo Sullivan, TennCare Bureau, Pharmacy Director, August 28, 2002.

¹⁷ *Revised Grier Consent Decree*, Civil Action No. 79-3107, July 31, 2000, § C(14)(a)(iv).

¹⁸ Office of Research analysis of TennCare Bureau data.

Many MCOs have responded to these pressures by placing some previously nonformulary medications on their formularies. Doing so relieves them of the administrative burden of *Grier* appeals for newly added drugs, and reduces dispensing fees associated with those drugs. It also allows them to gain manufacturer rebates for the drugs. On the other hand, newly added formulary drugs are consistently more expensive than those previously on the formulary.

The annual actuarial analysis that serves as the basis for capitation rates relies on prior claims history. Depending on the assumptions employed by actuaries, reductions in dispensing fees and increases in drug costs produced by these changes in MCO behavior would both influence the actuarial analysis. However, since the actuarial analysis assumes administrative costs of 15 percent, it does not adjust for administrative savings garnered from moving drugs into the formulary. The actuarial analysis also maintains an assumption of 7 percent rebates regardless of MCO behavior in adding drugs to their formularies. In both cases, the *Grier Decree* has created a financial incentive for MCOs to add drugs to their formulary even though doing so might result in additional costs to the state through future capitation rates.

Medicaid Cost Containment Mechanisms

Prior Authorization

Prior authorization (PA) requires the prescribing physician to provide additional information and justification to the insurer for certain drugs before the prescription can be filled.¹⁹ Prior authorization is most often used for medications that, though more expensive than other medications, offer little or no clinical benefit to the average patient. A patient can receive the higher cost medication if the health plan grants prior authorization, but the patient's physician must demonstrate that the patient needs the more expensive drug.

Research has shown prior authorization requirements can reduce Medicaid drug costs without increasing costs for other services. For example, Tennessee's Medicaid program began requiring prior authorization for all nongeneric NSAIDs²⁰ in 1989 (prior to TennCare). From 1988 to 1991, expenditures for NSAIDs decreased 53 percent, and there was no corresponding increase in spending for other drugs or associated outpatient and inpatient medical services. Researchers concluded the requirement was "highly cost effective," producing savings of \$12.8 million with administrative expenses of only \$75,000.²¹ Prior authorizations are also frequently used for drugs of abuse to identify health plan members who may be using drugs inappropriately or selling them illegally.

The *Grier Decree* has undermined the effectiveness of MCO prior authorization requirements, increasing the use of more expensive nonformulary medications. All TennCare MCOs have significant prior authorization provisions in place, but many interviewees contended that the *Revised Grier Consent Decree* has undermined the effectiveness of those provisions since doctors can prescribe 14-day supplies of many nonformulary drugs without prior authorization. Many interviewees asserted that doctors routinely ignore prior authorization provisions when writing scripts for nonformulary drugs.

¹⁹ Miriam Basch Scott, "Formulary is Top Pharmacy Benefit Management Tool," *Employee Benefit Plan Review*, January 2001, p. 35.

²⁰ Non-steroidal anti-inflammatory drugs (NSAIDs) are medications which have pain-relieving (analgesic) effects and reduce inflammation when used over a period of time. They are most commonly used in arthritis treatment.

²¹ Walter Smalley, et. al., "Effect of a Prior-Authorization Requirement on the Use of Nonsteroidal Antiinflammatory Drugs by Medicaid Patients," *The New England Journal of Medicine*, June 15, 1995, pp. 1612-1617.

The TennCare Bureau pharmacy carve-out lacks prior authorization procedures to control the use of more expensive medications. TennCare MCOs and Medicaid programs in other states have constructed formularies that channel patients toward more cost effective medication. In order to receive a nonformulary drug, a patient's physician must receive prior authorization from the health plan. The TennCare pharmacy carve-out requires prior approval for growth hormone. However, all other covered drugs are available without prior authorization.

The TennCare Bureau pharmacy carve-out lacks prior authorization procedures designed to control fraud and abuse of prescription drugs. States also use prior authorization provisions to curtail fraud and abuse. In early 2002, North Carolina began requiring prior authorization for Oxycontin, a frequently abused analgesic painkiller. Medicaid payments for the drug decreased by 30 percent in three months. In June, North Carolina authorities arrested 32 people who had "rented" Medicaid cards to drug dealers who used the cards to buy Oxycontin at taxpayer expense.²² Medicaid programs to reduce abuse of prescription drugs can be particularly effective when coupled with state controlled substance monitoring programs. Again, the TennCare pharmacy carve-out requires prior approval for growth hormone, but all other covered drugs are available without prior authorization.

Formularies

Federal law (OBRA 93) allows states to establish formularies that exclude drugs that do not offer a "significant, clinically meaningful therapeutic advantage" over other drugs included in the formulary and still participate in the federal rebate program. Drugs not included on state formularies must be available through prior authorization. Prior authorization programs allow prescribing physicians to request coverage of nonformulary drugs from state Medicaid agencies or contracted MCOs. OBRA 93 requires agencies to respond within 24 hours of a doctor's request for coverage. Pharmacies must provide 72-hour supplies of drugs in emergency situations while agencies process the request.²³

Many states have obtained or are seeking Medicaid waivers that allow them to use drug cost as a more explicit factor in creating formularies. Florida and Michigan, as the first states to pursue this strategy, have received the most national attention for their efforts. Both states require pharmaceutical manufacturers to offer the Medicaid programs additional discounts in order to be included on formularies. Michigan created an extensive list of "best-in-class" drugs based on clinical data. These drugs are available without prior authorization. In order to avoid prior authorization requirements, manufacturers of other drugs must cut prices to those offered by the lowest priced best-in-class drug in each class.²⁴ State officials estimate the resulting preferred drug list (PDL) will save the fee-for-service program \$45 million in fiscal year 2003, about 7 percent of program costs. State officials expect to save another \$36 million by implementing the same PDL for the state's managed care plans.²⁵ Michigan has also made its formulary available through ePocrates, a widely used software package that allows doctors to

²² Lois Nilsen, "Prior Authorization Fights Medicaid Fraud; Oxycontin Use Down Thirty Percent," North Carolina Department of Health and Human Services, July 1, 2002.

²³ 42 USC 1396r-8(d)(4).

²⁴ Russell Gold, Scott Hensley, and Andrew Caffrey, "Industry Headache: States Square off against Drug Firms in Crusade on Prices," *Wall Street Journal*, December 7, 2001, p. A1.

²⁵ Correspondence from Dave Viele, Michigan Department of Community Health, Deputy Director for Budget and Finance Administration, October 28, 2002.

access information on prescription drugs through a handheld computer.²⁶ CMS approved a waiver that allows Florida to exclude drugs from its formulary if the manufacturer does not offer “supplemental” rebates in addition to those guaranteed by OBRA 90. These drugs are still available through prior authorization.²⁷ (See page 13 for more information on programs in Florida and Michigan.)

The Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit against the U.S. Department of Health and Human Services in June to halt the implementation of formularies in Florida, Michigan, and other states. The suit charges that the Michigan formulary “restricts access to medicines for America’s most vulnerable patients.”²⁸

Proponents of formularies counter that the drug lists are therapeutically sound, offering patients ready access to all clinically appropriate medications. Patients still have access to drugs not on the lists if their doctors can offer evidence that the drugs are medically necessary. The case is pending in New York’s Federal District Court.²⁹ PhRMA has also sued Florida in federal court and Michigan in state court. Both cases are under appeal.³⁰ Along with Michigan and Florida, Illinois, Louisiana, Minnesota, New Mexico, North Carolina, Oregon, Vermont, and West Virginia have developed preferred drug lists based around prior authorization requirements or are in the process of developing such lists.³¹

Some critics of formularies have contended that restrictive formularies drive up overall health care costs. Duke University researchers compared states with restrictive Medicaid formularies to those without such formularies. The researchers found physician and hospital expenses in formulary states decreased when they removed their formularies.³² A study in *The American Journal of Managed Care* that included both Medicaid and private HMOs found plans with high formulary restrictions also had high utilization rates for physician and hospital services.³³ However, critics of the study noted that its authors failed to establish a baseline of comparison for costs and utilization patterns.³⁴ Without such a baseline, there is no way to determine how formulary practices influenced utilization of health services.

The TennCare pharmacy carve-out lacks a formulary designed to direct patients to the most cost-effective medications . The TennCare pharmacy carve-out has a negative formulary, a list of drugs that are not covered by the program. However, the formulary

²⁶ Interview with Dave Viele, Michigan Department of Community Health, Deputy Director for Budget and Finance Administration, October 17, 2002.

²⁷ Andy Schneider and Linda Elam, “Medicaid: Purchasing Prescription Drugs,” *Kaiser Commission on Medicaid and the Uninsured*, January 2002, pp. 5-6.

²⁸ Robert Pear, “Drug Industry Sues over Limiting Medicaid Costs,” *The New York Times*, July 2, 2002.

²⁹ Robert Pear, “Drug Industry Sues over Limiting Medicaid Costs,” *The New York Times*, July 2, 2002.

³⁰ Joan Rose, “One Judge Upholds Florida’s Cost-Cutting Tactics; Another Slams Michigan’s,” *Medical Economics*, March 8, 2002, p. 19.

³¹ Richard Cauchi, *Medicaid Survival Kit: 7. Pharmaceuticals*, National Conference of State Legislatures, May 2002, p. 7-6; “Louisiana Medicaid Pharmaceutical and Therapeutics Committee,” Louisiana Department of Health and Hospitals, <http://www.dhh.state.la.us/MEDICAID/P&TCommittee/index.htm> (accessed July 11, 2002); Debbie Crane and Lois Nilsen, “Prescription Drug Savings Plan Announced for NC Medicaid,” North Carolina Department of Health and Human Services, May 30, 2002; National Conference of State Legislatures, “2002 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” July 10, 2002, <http://www.ncsl.org/programs/health/drugdisc02.htm> (accessed July 17, 2002).

³² William Moore, Karen Gutermuth, and Etienne Pracht, “Systemwide Effects of Medicaid Retrospective Drug Utilization Review Programs,” *Journal of Health Politics, Policy, and Law*, August 2000, pp. 653-688.

³³ Susan Horn, et. al., “Intended and Unintended Consequences of HMO Cost-Containment Strategies: Results from the Managed Care Outcomes Project,” *The American Journal of Managed Care*, March 1996.

³⁴ “Study Questions Efficacy of Formularies in Cutting Costs,” *Managed Care*, April 1996.

contains only drug classes specifically excluded under federal law.³⁵ It does not differentiate between drugs within a class. Traditional formularies exclude some drugs from most drug classes, choosing to cover only those drugs that are most cost-effective.

Differences in MCO formularies undermine their effectiveness. Health care researchers have found that doctors are less likely to prescribe formulary drugs when they must negotiate multiple formulas for different health plans.³⁶ Numerous interviewees commented that doctors have to deal with many different formularies for both their TennCare patients and those under private insurance plans. As a result, they are less likely to follow MCO formularies.

Rebates

Companies in many industries offer discounts to large purchasers of services. Pharmaceutical companies offer discounts to insurance plans in the form of rebates. Generally, insurance plans that purchase more drugs can receive greater percentage rebates from manufacturers. Insurance companies and pharmacy benefit managers (PBMs) take rebates into account when constructing formularies. Within a given drug class, MCOs will generally include drugs whose companies offer the lowest post-rebate price.

The federal Omnibus Budget Reconciliation Act of 1990 (OBRA 90) included several features relating to Medicaid prescription drug benefits. The most significant of these is OBRA 90's "best price" feature. The law requires drug manufacturers to enter a rebate agreement with the Health Care Finance Administration (HCFA—now CMS, the Center for Medicare and Medicaid Services) in order to have their products covered by Medicaid.³⁷ These agreements mandate that the companies provide rebates to state Medicaid plans sufficient to reduce drug prices to the "best price" available to commercial, nonprofit, or most other government purchasers.³⁸ In exchange, state Medicaid plans must provide coverage for these drugs with only limited restrictions.³⁹ They may, however, exclude drugs that fall under any of the following categories:

- Anorexia, weight loss, or weight gain drugs,
- Fertility drugs,
- Cosmetic or hair growth drugs,
- Drugs to treat cough and cold symptoms,
- Smoking cessation drugs,
- Vitamins and mineral products,
- Barbituates, and
- Benzodiazepines (selected anti-depressants).⁴⁰

³⁵ Anorexia, weight loss, or weight gain drugs; fertility drugs; cosmetic or hair growth drugs; drugs to treat cough and cold symptoms; and smoking cessation drugs.

³⁶ Michael Stein, Alastair Wood, and Theodore Pincus, "Implementation of Multiple Outpatient Formularies: Undesirable Effects," *Clinical Pharmacology and Therapeutics*, January 1997, pp. 1-7.

³⁷ 42 USC 1396r-8(a)(1).

³⁸ 42 USC 1396r-8(c). "Best price" provisions do not include prices paid by the Department of Veterans Affairs, state homes, the Public Health Service, or certain types of public clinics; prices charged under the Federal Supply Schedule; prices used by state pharmaceutical assistance programs; and depot prices and single award contract prices.

³⁹ 42 USC 1396r-8(d).

⁴⁰ 42 USC 1396r-8(d)(2).

The actuarial analysis that serves as the basis for TennCare MCO capitation rates assumes MCOs receive much smaller rebates than those guaranteed through OBRA 90. OBRA 90 rebates are designed to produce savings for the federal and state governments, and federal law specifically states that “covered outpatient drugs dispensed by health maintenance organizations” do not qualify for OBRA 90 rebates.⁴¹ In fiscal year 2002, the TennCare pharmacy carve-out obtained rebates of approximately 20.85 percent of initial drug costs through OBRA 90.⁴² In contrast, the PricewaterhouseCoopers actuarial analysis used as the basis for MCO capitation rates assumed MCOs receive 7 percent rebates.⁴³ Increasing the rebate assumption for MCO drugs from 7 percent to 20.85 percent would have produced over \$72 million in program savings in fiscal year 2002.

Several interviewees believe the average MCO rebate is significantly higher than seven percent, though no interviewee suggested MCO rebates approach 20 percent. Because rebate agreements include strict confidentiality clauses, the exact amount of MCO rebates is uncertain. Even if an average of 7 percent across MCOs is accurate, the rebate level of individual MCOs likely varies considerably. Rebates on brand-name drugs are generally much higher than those for generic drugs. As utilization has shifted from generic drugs to brand products since the *Grier Consent Decree* went into effect, several MCOs have noted a significant increase in rebates. Concurrently, MCOs have noted a decreased capacity to negotiate rebates with pharmaceutical companies because many companies feel that *Grier* creates an environment where MCOs will purchase their products whether or not those products are on MCO preferred drug lists. During the 18-month stabilization period, MCO rebates will accrue to the state, providing a more thorough picture of rebate levels and dynamics.

The TennCare pharmacy carve-out receives rebates guaranteed through OBRA 90 but does not seek or receive supplemental rebates beyond those. Though OBRA 90 guarantees state Medicaid programs will receive the “best price” available to all private sector and most government entities, it does not prohibit states from pursuing and receiving even higher rebates from pharmaceutical companies. Eleven states have passed legislation in the past two years to facilitate the collection of “supplemental rebates” beyond those guaranteed by OBRA 90.⁴⁴

The Florida law requires a total rebate of 25.1 percent (including OBRA 90 rebate and supplemental rebate) for most brand drugs in order to be considered for inclusion in the state’s preferred drug list (PDL). The state constructed its PDL from those drugs based on the most cost-effective drugs in each therapeutic category. Florida officials stated the state’s Medicaid program saved approximately \$100 million in fiscal year 2002 through supplemental rebates and its preferred drug list.⁴⁵

The Michigan Medicaid program created a pharmacy and therapeutics committee composed of prominent medical practitioners from the state. This committee determined the two most

⁴¹ 42 USC 1396r-8(j).

⁴² Data provided by Sybil Creekmore, TennCare Bureau, accounting manager.

⁴³ Correspondence from Martin Staehlin, PricewaterhouseCoopers, June 7, 2002.

⁴⁴ Florida, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, New Mexico, Ohio, and West Virginia. “Medicaid Prescription Drug Laws and Strategies, 2001-2002,” National Conference of State Legislatures, July 10, 2002, <http://www.ncsl.org/programs/health/medicaidrx.htm> (accessed July 17, 2002).

⁴⁵ Telephone interview with Jerry Wells, Florida Agency for Health Care Administration, Medicaid Pharmacy Program Manager, June 13, 2002.

effective medications from every therapeutic class. The state then created a preferred drug list based around these “reference drugs.” In order to be included on the state preferred drug list, other drugs must cost no more than the lowest cost reference drug in each class. In many cases, pharmaceutical companies must offer supplemental rebates beyond those guaranteed by OBRA 90 to reduce their products’ prices below those of the reference drugs. Michigan officials estimate shifting its fee-for-service plans to a preferred drug list with supplemental rebates produces savings of \$900,000 a week, roughly \$45 million a year. The state plans to carve out pharmacy benefits from its HMO plans this fiscal year, moving those plans to a single preferred drug list with supplemental rebates. State officials project this shift will save approximately \$36 million.⁴⁶

The TennCare dual (Medicare/TennCare) eligibles carve-out and behavioral drug carve-out both qualify for OBRA 90 rebates. Carve-out rebates were approximately 20.85 percent of initial drug costs in fiscal year 2002. The TennCare Bureau does not pursue or collect supplemental rebates.

Copayments

In recent years, commercial insurance plans have increasingly relied on three-tier copayment structures to influence prescription drug use. Most of these plans base copayments on a preferred drug list (PDL) developed by the insurance company or its pharmacy benefits manager. The lowest tier copay is for generic drugs, the second tier includes preferred brand-name drugs, and the third tier consists of nonpreferred brand drugs. Many medications are remarkably similar to other medications. In these cases, insurance plans will generally place the least expensive medications in the second tier and place medications that cost more but offer little or no health benefit in the third tier.⁴⁷

The 1982 federal Tax Equity and Fiscal Responsibility Act (TEFRA) clarified states’ authority to charge “nominal” copayments for Medicaid services. Nominal pharmacy Medicaid recipients copayments for enrollees cannot exceed \$3 per script,⁴⁸ an amount that has not changed since 1973.⁴⁹ However, several states have obtained waivers that allow them to charge copayments of up to \$5 per script.⁵⁰ Federal law prohibits prescription copayments for the following groups in the absence of a Medicaid waiver:

- Children under 18;
- Those in inpatient medical facilities; and
- Hospice care recipients;⁵¹ and
- Categorically needy enrolled in HMOs.⁵²

⁴⁶ Interview with Dave Viele, Michigan Department of Community Health, Deputy Director for Budget and Finance Administration, October 17, 2002.

⁴⁷ Tennessee Comptroller of the Treasury, *Prescription Drug Costs in Tennessee*, Office of Research, November 2002, p. 22-23.

⁴⁸ Bruce Stuart and Christopher Zacker, “Who Bears the Burden of Medicaid Drug Copayment Policies?” *Health Affairs*, March/April 1999, p. 202.

⁴⁹ Department of Health and Human Services, Health Care Financing Administration, 48 CFR 5730(I)(C)(1), February 8, 1983,

⁵⁰ Richard Cauchi, *Medicaid Survival Kit: 7. Pharmaceuticals*, National Conference of State Legislatures, May 2002, p. 7-10.

⁵¹ 42 USC 1396o(b)(2).

⁵² Department of Health and Human Services, Health Care Financing Administration, 48 CFR 5730, February 8, 1983.

Federal law also prohibits copayments in the following circumstances:

- If the drug is for a medical emergency;
- If the drug is a pregnancy-related expense for an expectant mother; and
- If the drug is for family-planning purposes.⁵³

In 2000, 28 states imposed some type of copayment for Medicaid prescription drug benefits.⁵⁴ Most were flat copayments for each script. However, many states have implemented tiered copayments. In 2000, five states used tiered copayments based on whether a drug was generic or brand name. Eight states used tiered copayments based on drug cost.⁵⁵ However, copayments in Medicaid programs are so low—typically \$3 per script or less—that they are much less effective in driving market share than prior authorization requirements.

TennCare will move to a three-tier copayment structure in January 2003, but its structure will differ from standard commercial practice. The new TennCare waiver includes a three-tier copayment schedule shown in Exhibit 5. These copayments will go into effect January 1, 2003. The lowest tier includes generic medications. The second tier consists of brand-name drugs with no generic equivalents (single-source). The third tier includes only brand-name drugs with generic equivalents (multi-source).⁵⁶ Standard commercial insurance plans also use a three-tier copayment structure. Like the TennCare structure, the lowest tier includes generic drugs. However, unlike the TennCare structure, these plans use a preferred drug list (PDL). Companies place those medications from each class that appear to be most cost-effective on a PDL. Drugs on the PDL require a second tier copay. Those medications that cost more but offer little therapeutic benefit are placed on the third tier. Thus, the TennCare structure places many drugs on the second tier that are third-tier drugs on most commercial plans.

Exhibit 5: TennCare Copayment Levels

	Generic	Single-Source Brand	Multi-Source Brand
TennCare Medicaid	\$1	\$1	\$5
TennCare Standard below Poverty	\$1	\$3	\$15
TennCare Standard above Poverty	\$5	\$15	\$25

Source: John Tighe, Deputy to the Governor for Health Policy, memo to the House Finance Committees, June 13, 2002.

The TennCare pharmacy carve-out and TennCare MCOs use Maximum Allowable Cost (MAC) pricing for drugs that have generics available on the market. A TennCare carve-out MAC price is the highest price that the bureau or an MCO will pay for a certain drug. For example, the MAC price for fluoxetine, the active ingredient in the antidepressant Prozac, is 88.5 cents for a 20 mg tablet. When a TennCare enrollee presents a prescription for fluoxetine to a pharmacist, the pharmacist is free to dispense any A-rated brand or generic version of 20 mg fluoxetine tablets. However, TennCare will not pay more than 88.5 cents a tablet for the script. Thus, pharmacies already almost always dispense generic forms of medication when

⁵³ 42 USC 1396o(b)(2).

⁵⁴ Richard Cauchi, *Medicaid Survival Kit: 7. Pharmaceuticals*, National Conference of State Legislatures, May 2002, p. 7-10.

⁵⁵ Richard Cauchi, *Medicaid Survival Kit: 7. Pharmaceuticals*, National Conference of State Legislatures, May 2002, p. 7-10.

⁵⁶ John Tighe, Deputy to the Governor for Health Policy, memo to the House Finance Committees, June 13, 2002.

possible. Because of this, very few TennCare enrollees will likely pay third-tier copayments under the existing framework.

Copayments may reduce Medicaid recipients' use of medically necessary drugs and lead to adverse health events and higher physician and hospital costs. Some interviewees have expressed concern that TennCare recipients may choose to discontinue their use of some prescription drugs when faced with copayments. Several noted the potential for TennCare enrollees to continue using drugs that produce immediate noticeable benefits (allergy and heartburn medications, for example) and drop drugs that are of greater long-term importance. At least one MCO has examined the possibility of paying patient copayments for essential medications.

A large body of research has examined the potential for Medicaid copayments to reduce recipients' use of medication. Most studies found that Medicaid copayments reduced consumption of all drugs, including those essential to preventing and treating major conditions. As a result, recipients' health status declined and their increased use of physician and hospital services offset savings in drug costs. However, the vast majority of this research relies on data from the early 1980s.⁵⁷ Since that time federal poverty thresholds have more than doubled while Medicaid copayment limits have remained constant.⁵⁸ Thus, the current impact of Medicaid copayments on prescription drug use is probably less than these studies indicate.

The only recently published domestic research used survey data of senior citizens enrolled in both Medicare and Medicaid in 1992. The study found Medicaid enrollees in noncopay states filled 24.6 prescriptions a year versus 19.6 prescriptions in states with Medicaid copayments. The researchers concluded most of the difference (3.4 prescriptions) was due to copayment policies. They noted that respondents made some out-of-pocket payment for 68 percent of prescriptions in copay states and 26 percent of prescriptions in noncopay states, an indication that many recipients in all states were buying a significant portion of their drugs outside of Medicaid. The study did not contain any evidence that copayments had different impacts on major therapy and minor therapy medications.⁵⁹

Provisions of federal law allow Medicaid recipients to avoid paying copayments. Federal law prohibits providers from denying care or services to Medicaid recipients who are unable to pay copayments.⁶⁰ The legal burden for this determination rests with providers. That is, a pharmacist must show that a customer is able and unwilling to pay a copayment in order to deny service; the customer does not have to demonstrate an inability to pay to receive a prescription without paying. Critics have contended that this feature allows Medicaid recipients to avoid copayments even if they are able to pay them. Federal regulation requires

⁵⁷ For example: Stephen Soumerai, et. al., "Payment Restrictions for Prescription Drugs under Medicaid: Effects on Therapy, Cost, and Equity," *New England Journal of Medicine*, August 27, 1987, pp. 550-556; Stephen Soumerai, et. al., "Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia," *New England Journal of Medicine*, September 8, 1994, pp.650-655; C. Reeder and A. Nelson, "The Differential Impact of Copayment on Drug Use in a Medicaid Population," *Inquiry*, Winter 1985, pp. 396-403.

⁵⁸ U.S. Census Bureau, *Historical Poverty Tables*, "Table 1. Weighted Average Poverty Thresholds for Families of Specified Size: 1959 to 2000," <http://www.census.gov/hhes/poverty/histpov/hstpov1.html> (accessed August 29, 2002).

⁵⁹ Bruce Stuart and Christopher Zacker, "Who Bears the Burden of Medicaid Drug Copayment Policies?" *Health Affairs*, March/April 1999, pp. 201-212.

⁶⁰ 42 USC 1396o(e).

states to establish procedures whereby providers can determine whether or not recipients are able to pay.⁶¹ In practice, effective procedures are virtually impossible to create, and many states including Tennessee have established that, for purposes of federal law, if a Medicaid recipient claims to be unable to pay a copayment, that person is unable to pay.⁶²

Some pharmacy advocates have suggested states reimburse providers for unpaid copayments. The federal government does not offer federal financial participation for such payments, so they must be made entirely from state dollars.⁶³ As a result, states generally do not reimburse pharmacies for unpaid copayments, and the amounts owed pharmacies by recipients translate into direct reductions in pharmacy revenues. Research has consistently found that Medicaid recipients fail to pay copays but has produced mixed results on the extent of to which nonpayment occurs. One study found that Medicaid recipients claim to pay copayments for only 70 percent of their Medicaid prescriptions.⁶⁴ A 1998 survey of pharmacists in Maryland, Pennsylvania, and West Virginia found that just over half waived at least one Medicaid copayment in an average week. However, 49 percent of respondents indicated they collected over 99 percent of Medicaid copayments, and 94 percent stated they received copayments for over 90 percent prescriptions.⁶⁵

Drug Utilization Review

Federal law requires both prospective and retrospective drug utilization review (DUR) for all Medicaid programs.⁶⁶ The TennCare DUR Advisory Board is responsible for developing policies for DUR programs. (See Appendix B for a list of committee members and DUR providers for the TennCare carve-out.) Along with claims processing services, Affiliated Computer Services (ACS) provides prospective DUR for the TennCare BHO/dual eligibles drug carve-out. TennDUR, an entity at the University of Tennessee Health Science Center, provides retrospective DUR services.

TennCare MCOs conduct many DUR practices found in the private sector. All MCOs contract with pharmacy benefit managers (PBMs) for claims processing services. These PBMs have computer edits in place to indicate if a prescription should not be filled. For example, if a prescription appears to duplicate another prescription the patient has already received or may produce an interaction with another medication, the PBM's computer system will send a message to the pharmacist. Edits generally cover instances of:

- Therapeutic or ingredient duplication;
- Drug/drug or drug/allergy interaction;
- Low or high dose;
- Age, sex, and pregnancy alerts;
- Excessive duration; or

⁶¹ Department of Health and Human Services, Health Care Financing Administration, 50 CFR 23009, May 30, 1985.

⁶² Correspondence from Leo Sullivan, TennCare Bureau Pharmacy Director, October 8, 2002.

⁶³ Department of Health and Human Services, Health Care Financing Administration, 50 CFR 23009, May 30, 1985.

⁶⁴ Bruce Stuart and Christopher Zacker, "Who Bears the Burden of Medicaid Drug Copayment Policies?" *Health Affairs*, March/April 1999, p. 210.

⁶⁵ Cheryl Fahlman, Bruce Stuart, and Christopher Zacker, "Community Pharmacist Knowledge and Behavior in Collecting Drug Copayments from Medicaid Recipients," *American Journal of Health-System Pharmacy*, March 1, 2001, pp. 389-395.

⁶⁶ 42 U.S.C. 1396r-8(g).

- Nonformulary medication.

Many of these edits are “hard” edits, meaning the PBM will not provide reimbursement for the drug if it is not covered. Edits are one form of prospective DUR. Prior authorization requirements are also an example of prospective DUR. Another example is step therapy or “fail first” requirements, which requires physicians to prescribe older, less expensive drugs first. Patients may only receive the newer, costlier medication if those interventions fail. In 2000, 11 of 43 states responding to a national survey had “fail first” requirements for some classes of drugs.⁶⁷

MCOs also conduct retrospective DUR. Virtually all MCOs profile physicians to analyze their prescribing patterns. Some conduct “counter-detailing,” visits with physicians to encourage them to use formulary medications. Some have considered offering incentive payments to physicians to promote formulary compliance. Other retrospective DUR initiatives directly target health concerns rather than drug costs. John Deere Health, for example, does an annual data run to see if patients suffering from congestive heart failure (CHF) are taking beta blockers and ACE inhibitors, relatively inexpensive medications that have demonstrated major health benefits for CHF patients. If the patients are not taking the medications, John Deere contacts their physicians to determine why.⁶⁸

Current prospective DUR practices for the TennCare pharmacy carve-out are less extensive than those found in the private sector and in many state Medicaid program, increasing the likelihood of inappropriate use of medication. The TennCare Bureau contracts with Affiliated Computer Systems (ACS) to provide claims processing services for the TennCare pharmacy carve-out. Individual pharmacists, after consulting information provided by the ACS computer network, conduct prospective DUR at the point of sale. The claims processing system includes numerous computer edits to indicate if a prescription should not be filled. However, virtually all of these edits are “soft” edits, edits that post information on the pharmacy computer screen but allow payment to go through if the pharmacist choosing to disregard the message.⁶⁹ Pharmacies have the ability to suppress these messages within their software so the dispensing pharmacists never see them.⁷⁰ Some interviewees suggested that many pharmacies suppress these messages to reduce the workload for pharmacists and protect them from liability for potential interactions, though the Tennessee Board of Pharmacy has not documented any such instances.⁷¹

The carve-out lacks most of the more extensive prospective DUR provisions found in the private sector and many Medicaid plans. Neither the bureau nor ACS has constructed a formulary for the carve-out. Medicaid formularies generally require prior authorization for nonformulary drugs. The carve-out does not require step therapy for any drugs.

Current retrospective DUR practices for the TennCare pharmacy carve-out fail to meet standards set by federal law, increasing the likelihood of inappropriate use of

⁶⁷ Andy Schneider and Linda Elam, “Medicaid: Purchasing Prescription Drugs,” *Kaiser Commission on Medicaid and the Uninsured*, January 2002, p. 14.

⁶⁸ Telephone interview with Jim Utt, Regional Pharmacy Director, John Deere Health, May 23, 2002.

⁶⁹ “ProDUR Edits,” TennCare Bureau.

⁷⁰ Telephone interview with Jerry Dubberly, Director of Clinical Services, Affiliated Computer Systems, June 10, 2002.

⁷¹ Correspondence from Kendall Lynch, Department of Commerce and Insurance, Tennessee Board of Pharmacy Director, September 26, 2002.

medication. Federal law requires Medicaid programs to conduct retrospective DUR “for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.”⁷² Federal law further requires retrospective DUR to “provide for active and ongoing educational outreach programs” that include “written, oral, or electronic reminders containing...suggested changes in prescribing or dispensing practices,” “use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention,” and “intensified review or monitoring of selected prescribers or dispensers.”⁷³ Retrospective DUR typically involves an analysis of prescription drug data followed by letters, phone calls, or office visits targeted toward specific doctors or pharmacists who may be prescribing unnecessary or less cost-effective medications. A study of the Wisconsin Medicaid program found that sending letters to physicians and pharmacists significantly reduced inappropriate prescriptions for dipyridamole, a drug used to prevent blood clots.⁷⁴ A separate study of retrospective DUR programs in seven states found the programs significantly reduced drug costs without raising other health costs.⁷⁵ Most private insurance companies today rely on phone calls or face-to-face meetings with practitioners. However, fewer than half of states responding to a 2000 survey “address the diagnostic appropriateness of beneficiaries’ medications, track prescription use by disease or focus on high cost enrollees” in their DUR programs.⁷⁶

TennDUR, an entity at the UT Health Science Center, is responsible for carrying out retrospective DUR. The state’s DUR Advisory Board comprised of health practitioners from across the state oversees TennDUR’s actions. (Members of the DUR Advisory Board are listed in Appendix B.) TennDUR currently has three primary areas of focus: developing a web site with extensive county-level utilization data,⁷⁷ analyzing the impact of variation in drug therapy and other factors on patient outcomes, and responding to specific research requests by the TennCare Bureau. TennDUR intends to offer programs to constituent groups such as the Tennessee Medical Association, the Tennessee Nursing Association, and the Tennessee Pharmacists Association for use in their postgraduate educational programs.⁷⁸

Until recently, TennDUR has lacked reliable recent patient-level data that would allow it to identify specific physicians and pharmacists for intervention as required by federal law. On July 1, 2002 TennCare began requiring all pharmacy claims submissions to include the prescribing physician’s DEA number. TennDUR staff are working to use this data to create a more current and extensive database including prescribing and dispensing information. If successful, they hope to send data to providers comparing them to provider trends on a county or even a zip code level. This data could also be used to identify physicians to receive educational materials.

⁷² 42 U.S.C. 1396r-8(g)(2)(B).

⁷³ 42 U.S.C. 1396r-8(g)(2)(D), 42 U.S.C. 1396r-8(g)(3)(C)(iii).

⁷⁴ Theodore Collins, et.al. “A Controlled Letter Intervention to Change Prescribing Behavior: Results of a Dual-Targeted Approach,” *Health Services Research*, October 1997, pp. 471-489.

⁷⁵ William Moore, Karen Gutermuth, and Etienne Pracht, “Systemwide Effects of Medicaid Retrospective Drug Utilization Review Programs,” *Journal of Health Politics, Policy, and Law*, August 2000, pp. 653-688.

⁷⁶ Kaiser Commission on Medicaid and the Uninsured, “Policy Brief—Medicaid and the Prescription Drug Benefit,” September 2002, p. 23.

⁷⁷ www.utmem.edu/TennDUR/

⁷⁸ Correspondence from Walter Fitzgerald, TennDUR program director, December 5, 2002.

TennCare MCO contracts require physician and pharmacy lock-ins for abusive users of prescription drugs; the TennCare pharmacy carve-out also has a lock-in program.

Another type of retrospective DUR intervention is a physician or pharmacy lock-in. These programs require certain patients to receive all their prescriptions from a single physician and/or have those prescriptions filled at a single pharmacy, decreasing the chances of duplicative prescriptions or drug/drug interactions. States generally use lock-in programs for patients who use a large number of prescription drugs or who appear to be abusing some medications.

Current TennCare MCO contracts mandate both physician and pharmacy lock-ins for “abusive utilizers of pharmacy services.”⁷⁹ TennCare guidelines require lock-in programs for both the MCOs and the pharmacy carve-out to identify enrollees who abuse or overutilize prescription drugs and restrict them to a single prescribing physician and single pharmacy under most circumstances.⁸⁰ The bureau has not released criteria it will use to determine which enrollees must enter lock-ins.

Promotion of Low-Cost Substitutes

TennCare MCOs and the TennCare pharmacy carve-out have procedures to promote the use of lower cost over-the-counter medications when possible. Over-the-counter (OTC) and generic medications often provide cost-effective alternatives to more expensive brand medications. All MCOs cover some over-the-counter medications, such as pain relievers, antihistamines, and antacids. Over-the-counter versions of these drugs are generally much less expensive than prescription drugs in the same class. The TennCare pharmacy carve-out also covers a number of common OTC drugs.⁸¹

The TennCare pharmacy carve-out uses MAC prices to encourage the use of generic medications when possible. Maximum allowable cost (MAC) prices are the highest prices insurers will pay for certain drugs. The U.S. Department of Health and Human Services (HHS) sets MAC prices called federal upper limit (FUL) prices for many multisource drugs, drugs available in generic form. Medicaid programs may pay pharmacies more or less than the FUL. However, states cannot spend more for all FUL drugs in the aggregate than those drugs would have cost under FUL prices.⁸² Research from the Office of the Inspector General has found that the Department of Human Services had not established FUL prices for 104 of the 200 most prescribed multisource drugs. Furthermore, FUL prices are often still well above actual pharmacy costs.⁸³

MCOs set their own MAC prices without regard to FUL prices. The TennCare pharmacy carve-out, like most state Medicaid programs, sets its own maximum allowable cost (MAC) limits for many frequently prescribed generic drugs that do not have FUL prices. It also establishes its own MAC prices for some drugs with FUL prices that are closer to actual market levels. Some interviewees have commented that the bureau sometimes fails to respond quickly to market shifts such as significant price drops when setting MAC limits. However,

⁷⁹ *Amended and Restated Contractor Risk Agreement*, TennCare Bureau, July 1, 2001, <http://www.state.tn.us/tenncare/MCOCRA.pdf> (accessed November 4, 2002), 2-3.j.4.

⁸⁰ “TennCare Pharmacy Programs Lock-In Guidelines,” TennCare Bureau, October 11, 2002.

⁸¹ TennCare Pharmacy Program Over-The-Counter Drug Formulary, February 2001.

⁸² 42 USC 1396r-8(e)(4).

⁸³ Janet Rehnquist, *Medicaid Pharmacy—Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products*, Department of Health and Human Services, Office of the Inspector General, September 2002, A-06-02-00041, p. 8.

this does not appear to be the case. The Office of Research examined MAC prices for 19 frequently prescribed behavioral health drugs available as generics and the 16 generic drugs most frequently prescribed for the TennCare dual population, comparing MAC prices for the TennCare pharmacy carve-out to those in the Michigan and Georgia Medicaid plans, both of which use full-service private PBMs to reduce drug costs. Tennessee has MAC prices in effect for 32 of the 35 drugs. Georgia has MAC prices for 33, and Michigan has MAC prices for 31. TennCare MAC prices for medical drugs were only slightly higher than MAC prices found in those states, and TennCare's MAC prices for behavioral drugs were significantly lower.⁸⁴

Pharmacy Payment Reductions

Pharmacy payment rates for brand drugs in the TennCare pharmacy carve-out are lower than most Medicaid programs but above payment rates frequently found in the private sector and actual pharmacy costs. When pharmacies fill prescriptions for health plans, they receive two forms of payment: reimbursements for the drug costs and dispensing fees for pharmacy services. (For a more thorough discussion of pharmacy payments, see the Office of Research report *Prescription Drug Costs in Tennessee*.) Medicaid programs generally use reimbursement rates of average wholesale price (AWP) minus some percent for brand-name drugs with no generic equivalent. The TennCare Bureau pharmacy carve-out uses a reimbursement rate of AWP minus 13 percent for brand-name drugs and a dispensing fee of \$2.50.⁸⁵ These payment rates are among the lowest for Medicaid programs.⁸⁶ However, private sector health insurers often pay lower reimbursement rates and dispensing fees.

Partly in response to an August 2001 report by the Office of the Inspector General (OIG), several states have cut reimbursement rates or considered such cuts.⁸⁷ However, many people criticized the methodology in that report, and OIG conducted a more thorough analysis published in September 2002. In this analysis, OIG broke down reimbursement rates more thoroughly than the previous analysis. The study found retail pharmacies had an average acquisition cost of AWP minus 17.2 percent for single-source brand drugs (drugs with no generic equivalent).⁸⁸ This is probably a much more accurate representation of actual pharmacy costs because most Medicaid programs, including TennCare, establish restrictive MAC price limits on drugs with generic versions available.

Prescription Limits

The TennCare pharmacy carve-out lacks limits on prescription drugs that could produce program savings without adversely affecting patient care. In 2001, 12 of 43 states responding to a national survey had monthly or annual limits on the number of prescriptions or certain types of prescriptions patients may obtain through Medicaid.⁸⁹ Most states allow patients to exceed these limits if their physician demonstrates the medical necessity of the additional medication. Several interviewees felt this requirement places an

⁸⁴ Office of Research analysis of Georgia, Michigan, and Tennessee data.

⁸⁵ Correspondence from Leo Sullivan, Pharmacy Director, Tennessee Department of Health, Bureau of TennCare, May 24, 2002.

⁸⁶ Kaiser Commission on Medicaid and the Uninsured, "Policy Brief—Medicaid: Purchasing Prescription Drugs," January 2002, Table 7 and Table 8.

⁸⁷ "Medicaid Plans Target Prescription Drug Costs," *Drug Store News*, February 18, 2002, p. 1; "Drugstores Threaten to End Medicaid Service," *New York Times*, March 12, 2002, p. A16.

⁸⁸ Department of Health and Human Services, Office of the Inspector General, "Medicaid Pharmacy—Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products," September 2002, A-06-02-00041.

⁸⁹ Andy Schneider and Linda Elam, "Medicaid: Purchasing Prescription Drugs," *Kaiser Commission on Medicaid and the Uninsured*, January 2002, pp. 9-10.

undue burden on physicians and, in cases where physicians do not follow through quickly, may result in patients not receiving needed medication.

Some states have more refined programs. In February 1992, Florida began paying for only one antiulcer medication at a time and set limits for refills. A year after the program was announced, prescription rates and costs for the affected drugs fell by a third. Most importantly, these decreases did not result in increased hospitalizations for ulcers.⁹⁰ Florida now limits Medicaid patients to six brand drugs a month. There are no limits on generic medications and patients can receive more brand medications if their physicians demonstrate medical necessity.⁹¹

Disease Management

The TennCare Bureau has established pilot programs in disease management through the TennCare Centers of Excellence, but the potential financial and health impact of these programs is not yet clear. Disease management (DM) programs have received increasing attention in recent years as a means of improving the quality of care and reducing health care costs though they may (and often do) result in increased drug costs. The Disease Management Association of America defines DM as “a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant.”⁹² Though the scope and nature of DM programs varies considerably, all work to ensure that patients are taking necessary steps in the treatment of their conditions. They work best for high cost medical conditions such as asthma, diabetes, and congestive heart failure (CHF).

Though Florida now generally requires brand companies to offer supplemental rebates for their drugs to be included on the state’s Medicaid formulary, the state allows them to provide disease management services instead if those programs will produce the same level of net savings for the state. The state has entered contracts with two companies—Pfizer and Bristol-Myers Squibb—to provide DM services. The Pfizer contract, promising \$33 million in savings over two years, is the largest disease management contract in Medicaid history.⁹³ If savings from DM programs do not materialize, pharmaceutical companies have agreed to pay Florida the difference between actual savings and those in the contract. Both companies paid Florida for fiscal year 2002 because their DM programs, not fully implemented that year, had not yet produced any measurable savings. Despite this, the disease management contracts placed a tremendous administrative burden on the state, requiring Medicaid officials to compare many competing and overlapping proposals, all of which require complicated mathematical models to validate actual program savings.

Louisiana has recently contracted with Health Alliance for disease management programs in diabetes and asthma.⁹⁴ In July, Eli Lilly entered a partnership with the state of Colorado to

⁹⁰ David Cromwell, et. al. “Can Restrictions on Reimbursement for Anti-Ulcer Drugs Decrease Medicaid Pharmacy Costs without Increasing Hospitalization?” *Health Services Research*, February 1999, pp. 1593-1610.

⁹¹ Telephone interview with Jerry Wells, Florida Agency for Health Care Administration, Medicaid Pharmacy Program Manager, June 13, 2002.

⁹² Disease Management Association of America, “Definition of DM,” <http://www.dmaa.org/definition.html> (accessed August 15, 2002).

⁹³ Christopher Swope, “Treating Medicaid,” *Governing*, July 2002, pp. 24-25.

⁹⁴ “Voluntary Asthma & Diabetes Disease Management Program,” Louisiana Department of Health and Hospitals, <http://www.dhh.state.la.us/MEDICAID/Health%20Alliance%20Info%20Sheet.htm> (accessed October 14, 2002).

provide disease management services for diabetes patients and those with both schizophrenia and other conditions in the state's Medicaid program.⁹⁵

MCOs receive payment through a capitated payment structure, creating an incentive to implement DM programs that will reduce patient costs in the long run. However, high patient turnover rates among MCOs undermine this incentive. MCOs have little financial reason to invest in DM programs for their patients if they expect those patients to leave their MCO after a short period of time.

The pharmacy carve out administered by the TennCare Bureau does not include any disease management programs. However, the bureau has begun an initiative called the TennCare Centers of Excellence that will produce disease management programs for the bureau. The initiative is funded entirely by pharmaceutical companies. Steering committees comprised of specialists from across Tennessee evaluate proposals for each disease state from sponsoring companies. The asthma and diabetes steering committees have already evaluated proposals for those diseases, and sponsors will implement the proposals in 2003. The Lilly proposal for diabetes, for example, will provide patient education and provider support for 30 to 50 patients in West Tennessee. The company will provide diabetes patients with educational materials, self care diaries, and meal planning guides.⁹⁶

Private Pharmacy Benefit Management

Many state Medicaid programs have contracted with private pharmacy benefit managers (PBMs) to provide pharmacy services in a more cost-effective manner. These include both local and national PBMs. Georgia's contract with a national PBM has precipitated a number of changes in the administration of the state's Medicaid program, and contacted staff feel these changes have produced meaningful savings.⁹⁷ Michigan has used a national PBM to implement its preferred drug list and garner supplemental rebates. Maine has chosen to contract with GHS, a local pharmacy benefit manager, to facilitate the implementation cost control measures and research into other steps the state could take to control costs. In fiscal year 2001, Maine expanded the number of drugs requiring prior authorization, implemented more aggressive MAC pricing, and implemented an electronic cost avoidance system for third-party liability. These steps produced savings of almost \$20 million that year.⁹⁸

MCOs in conjunction with affiliated PBMs perform most cost control functions provided by private pharmacy benefit managers in other states' Medicaid pharmacy programs. The extent of private PBM involvement with MCOs varies considerably. All TennCare MCOs contract with private PBMs for claims processing and prospective DUR through automated computer systems. Some also use private PBMs in developing a formulary and negotiating rebates with pharmaceutical manufacturers. Others conduct these services on their own. MCOs generally conduct their own retrospective DUR, using data gleaned from PBM files to target initiatives at specific patients and providers.

⁹⁵ "Eli Lilly and Company Partners with the State of Colorado to Help Patients and Control Medicaid Costs," *AFX News Limited*, July 19, 2002.

⁹⁶ Eli Lilly and Company, "Answers for TennCare Diabetes Center of Excellence: Offering of Diabetes Management Solutions and Support for TennCare Bureau," presentation to TennCare Centers of Excellence Steering Committee.

⁹⁷ Telephone interview with Lori Garner, Georgia Department of Community Health Pharmacy Director, May 29, 2002.

⁹⁸ Telephone interview with Jude Walsh, Maine Bureau of Medical Services, Director of Quality Improvement, June 3, 2002.

The TennCare Bureau’s contract with Affiliated Computer Services does not include many cost control measures found in other states’ Medicaid pharmacy benefit manager contracts. The TennCare Bureau contracts with Affiliated Computer Systems (ACS) to provide claims processing services for the TennCare pharmacy carve-out. Individual pharmacists, after consulting information provided by the ACS computer network, conduct prospective DUR at the point of sale. Several interviewees have commented that ACS effectively processes claims. However, ACS does not perform many of the services often provided by private PBMs to state Medicaid programs. These include:

- Retrospective drug utilization review (DUR);
- Determination of maximum allowable cost (MAC) limits for drugs available in generic form;
- Provision, where applicable, of mail-order prescription benefits;
- Crafting of targeted prescription limits; and
- Formulary construction, including prior authorization and step therapy requirements.

TennDUR, an entity at the UT Health Science Center provides retrospective DUR services for the TennCare pharmacy carve-out. However, it often takes several months before an initial claim for a prescription drug becomes a final claim in the TennDUR database.⁹⁹ Therefore, the data do not provide a sound basis for targeted interventions at the physician, patient, or pharmacist level. The TennCare Bureau sets MAC limits for drugs available in generic form.

Cost Avoidance for Third-Party Liability

The TennCare Bureau has implemented some measures to obtain outside third-party payment for TennCare procedures when appropriate, but alternative procedures could be more efficient. Many Medicaid recipients use other third-party payment sources in addition to Medicaid, usually Medicare or private insurance. As a payer of last resort, Medicaid should not cover services provided by these entities. Federal law allows states to require Medicaid recipients eligible for private group health plans to enroll in those plans.¹⁰⁰ Federal law requires states to “take all reasonable measures to ascertain the legal liability of third parties.”¹⁰¹

Medicare covers a limited number of prescription drugs. A significant minority of Medicaid recipients also have some type of private insurance as well. Private insurance plans typically require members to pay substantial copayments for prescription drugs. Many pharmacy computer billing systems now have “split billing” capacity, the ability to charge multiple entities for a single purchase. In this case, the pharmacy would charge a private insurance plan for the cost of the drug minus the plan’s copay and charge Medicaid for the copayment. However, some Medicaid recipients never notify pharmacists that they carry private insurance, and Medicaid programs pay the full cost of the recipient’s drugs.

The current MCO contracts include third-party liability recovery rates as a performance measure used in calculating variable administrative fees (incentive payments).¹⁰² The bureau is updating computer payment programs to ensure TennCare does not pay for drugs covered

⁹⁹ Interview with Walter Fitzgerald, TennDur Project Director, June 18, 2002.

¹⁰⁰ 42 U.S.C. 1396e(a).

¹⁰¹ 42 U.S.C. 1396a(a)(25)(A).

¹⁰² *Amended and Restated Contractor Risk Agreement*, “Amendment Number 2,” TennCare Bureau, July 1, 2002, 3-10.h.2(f), p. 33-35.

by Medicare.¹⁰³ The Bureau uses a “pay-and-chase” system to recoup payments from private insurers of TennCare recipients. In this system, the Bureau pays for prescribed drugs and authorizes a private company, PCG, to seek and obtain required payments from private insurance companies on behalf of the state. The state pays its contractor 6.75 percent of recovered claims. This is an additional state cost, and in many instances this incentive may not be sufficient to motivate aggressive recovery. A point-of-service system that split bills between private insurance plans and TennCare would be more efficient, but obtaining reliable up-to-date information on private insurance enrollments is difficult. The Bureau plans to begin a pilot program in the future to determine if a point-of-service third-party billing system could work.¹⁰⁴

Discount Programs for Special Populations

Many states, including Tennessee, have created discount prescription drug plans for low-income individuals. As drug costs in the private market have escalated, many states have used Medicaid waivers to make prescription drugs more affordable for citizens, particularly the elderly and low-income groups, not included in state Medicaid plans. The Center for Medicare and Medicaid Services (CMS) has approved “Pharmacy Plus” waivers for five states. These waivers allow states to draw down federal matching funds to provide prescription drug benefits to low-income qualified Medicare beneficiaries who are not eligible for Medicaid. All five programs include some combination of enrollment fees, copayments, and annual maximums.¹⁰⁵ The benefits of these programs and the populations served by them are similar to those provided for TennCare’s non-Medicaid dual-eligible population, approximately 50,000 enrollees. Under this program, many Medicare enrollees below 200 percent of the federal poverty level can receive prescription drugs at reduced cost.¹⁰⁶

These approaches provide a traditional prescription drug benefit with fixed copayments. Other states have created programs that allow enrollees to purchase drugs at Medicaid prices obtained through OBRA 90’s best price provisions. Maine’s Healthy Maine Prescriptions program is the most prominent example. In June 2001, the U.S. Court of Appeals struck down a similar program in Vermont, ruling that rebates from Medicaid best-price provisions are designed to accrue to federal and state governments, not to purchasers of prescription drugs. As a shield against a similar ruling, Maine subsidizes the program with about \$20 million state funds a year. PhRMA has filed suit, and the case is pending at the Court of Appeals level. In May, 2002, the court refused a request to halt the program until a decision is rendered.¹⁰⁷ Maryland, New Hampshire, South Carolina, and Vermont have applied for federal waivers to create similar programs.¹⁰⁸

¹⁰³ Interview with Leo Sullivan, Bureau of TennCare, Pharmacy Director, June 4, 2002.

¹⁰⁴ Interview with Leo Sullivan, Bureau of TennCare, Pharmacy Director, June 4, 2002.

¹⁰⁵ Jennifer Ryan, “Pharmacy Plus Waivers: Incrementalism at Work,” George Washington University, National Health Policy Forum, NHPF Forum Session Meeting Announcement, November 19, 2002.

¹⁰⁶ Based on September 2002 enrollment data.

¹⁰⁷ Bart Jansen, “Federal Official Gives Maine Rx a Boost,” *Portland Press Herald*, June 1, 2002.

¹⁰⁸ National Conference of State Legislatures, “Prescription Drug Laws in Maine,” April 18, 2002, <http://www.ncsl.org/programs/health/pharm-me.htm> (accessed May 17, 2002).

Recent Developments

On November 7, 2002, the TennCare Bureau announced plans to develop a single statewide formulary.¹⁰⁹ The proposal calls for the University of Tennessee College of Pharmacy to develop a core formulary. A TennCare Formulary Committee appointed by the director of the TennCare Bureau will then make modifications and deliver a final formulary to the Bureau. Upon implementation, the University of Tennessee College of Pharmacy will serve as the TennCare Bureau's pharmacy benefit manager (PBM). TennCare MCOs will continue to contract with current PBM partners, but all rebates will flow directly to the state. The Bureau will negotiate rebates directly with manufacturers after the statewide formulary has been determined.

The TennCare Bureau proposal will allow the state to obtain rebates guaranteed through OBRA 90 for all prescription drugs but is unlikely to provide leverage to negotiate supplemental rebates. Because the state is at risk for prescription drug expenditures during the stabilization period, federal law allows the state to receive rebates through OBRA 90 for drugs formerly ineligible for OBRA 90 rebates. The proposal requires rebates at least equal to those guaranteed by OBRA 90, reiterating the requirements of federal law. The proposal directs the bureau to negotiate rebates for all drugs on the single statewide formulary. In the private sector and in other state Medicaid programs pursuing supplemental rebates, pharmaceutical companies must agree to offer rebates in order to have their products included on formularies. If the TennCare Bureau determines specific drugs to be included on a single state formulary prior to rebate negotiations, pharmaceutical companies will have no financial incentive to offer supplemental rebates, and the bureau will not likely obtain rebates beyond those guaranteed by OBRA 90.

The composition of the TennCare Formulary Committee could undermine public confidence in the formulary. Formularies (also known as preferred drug lists or PDLs) can have a marginal or significant impact on prescription drug costs depending on how many drugs are included. More limited formularies can produce sizable savings. However, as stated earlier, overly restrictive formularies can impede patient access to needed drugs and increase other medical costs. Ideally, a formulary should include drugs that produce meaningful health benefits for many patients; nonformulary drugs will still be available with prior authorization. The Bureau has not publicly defined the composition of the Formulary Committee. A Formulary Committee comprised of members with a vested interest in increasing the availability of prescription drugs could produce a formulary that is too expansive and fails to significantly reduce costs. In contrast, a committee with members who have a financial interest in reducing drug costs could create a formulary that is too restrictive.

The University of Tennessee College of Pharmacy may lack expertise available from private pharmacy benefit management (PBM) companies but is not subject to potential conflicts of interest prevalent in the PBM industry. The TennCare Bureau plans to use the University of Tennessee College of Pharmacy to perform some functions typically performed by private PBMs. The Bureau has yet to clearly define the college's specific role. Officials interviewed in other states frequently cited initiatives generated by private PBMs contracting with their states as sources of savings. No other state has contracted with a college of pharmacy to provide a full slate of PBM services, and the University of Tennessee has little

¹⁰⁹ "Single Formulary Targets Prescription Drug Costs in TennCare," TennCare Bureau press release, November 7, 2002.

experience providing some common PBM services. Alternately, critics of private PBMs have noted that they rely on pharmaceutical companies for a significant portion of their revenue and may have financial incentives to direct plan members to more costly medications. The University of Tennessee would not be subject to the same financial pressures.

The *Grier Consent Decree* may undermine the effectiveness of the TennCare Bureau proposal. The TennCare Bureau's proposal calls for pharmacists to dispense 5-day supplies of prescribed nonformulary medications while a prior authorization (PA) request is processed if the prescribing physician cannot be contacted or refuses to alter the script to a formulary medication. The *Grier Consent Decree* requires 14-day supplies of nonformulary medications in such cases. If the Bureau does not achieve a successful renegotiation of the *Grier Decree*, that provision could undermine a single statewide formulary as it has MCO formularies. Federal statute requires 72-hour (3-day) supplies of nonformulary medications while PA requests are processed. Though moving from 14-day to 5-day supplies should produce significant savings, reducing initial nonformulary supplies to 72 hours would likely produce even greater savings.

The TennCare proposal does not include the creation of a formulary for behavioral drugs, reducing the amount of savings it will produce. Behavioral drugs accounted for over \$300 million in spending through the TennCare program in fiscal year 2002, roughly one-fourth of total spending on prescription drugs through TennCare. Spending on behavioral drugs has increased dramatically since the TennCare Bureau carved out the behavioral pharmacy benefit and moved it to an open formulary. Returning behavioral drugs to a closed formulary would likely produce significant savings for the TennCare program. However, the current bureau proposal would create a formulary only for medical drugs.

Recommendations

Legislative Recommendations

The General Assembly may wish to create a discount pharmacy program for low-income citizens not eligible for the TennCare program. Prescription drug costs have risen rapidly in recent years, straining the budgets of many low-income households without private insurance. A discount pharmacy program could reduce this strain. If the General Assembly chose to fold a discount pharmacy program into the TennCare program, the state could leverage federal funding and federally-mandated rebates to reduce state costs. The General Assembly could also require member enrollment fees and copayments to reduce state costs. Finally, if the state chose to implement a single formulary for the TennCare program, using the same formulary for a discount pharmacy program would make it eligible for significant supplemental manufacturer rebates and, by increasing the total population under the formulary, could potentially increase rebates for the TennCare program as a whole.

Administrative Recommendations

The Office of the Attorney General should seek a revision to the *Grier Consent Decree*. The *Grier Consent Decree* has eroded the ability of TennCare MCOs to control prescription of nonformulary medications. The *Grier Decree* increased MCO pharmacy costs approximately 11.4 percent, resulting in costs of over \$55 million in fiscal year 2002. There is no evidence that this increase in costs produced any measurable health benefit for TennCare enrollees.

The TennCare Bureau should work toward the implementation of a single statewide formulary. TennCare physicians have frequently complained that multiple formularies contribute to the TennCare “hassle factor.” Research has shown that multiple formularies reduce formulary compliance. A single statewide formulary would reduce the administrative burden on physicians, decrease the number of appeals for nonformulary drugs, and place the state in a position to negotiate supplemental rebates from pharmaceutical manufacturers for the TennCare program. Such a formulary should include all drug categories within the TennCare program.

If the TennCare Bureau implements a single statewide formulary, the formulary committee should not include members with a vested interest in creating a formulary that is overly expansive or restrictive. A formulary committee must possess clinical expertise but cannot contain members who would have a financial interest in restricting the formulary. Likewise, it should not contain members who have an interest in expanding the formulary. Representatives of the pharmaceutical industry, for example, should not be included on a formulary committee.

If the TennCare Bureau implements a single statewide formulary, it should make clinical data on formulary and nonformulary medications widely available. The primary basis for a sound formulary must be clinical data. Cost factors should be a secondary concern. Making the data used to make formulary decisions available on the internet and in print form would increase confidence in the appropriateness of a formulary.

If the TennCare Bureau implements a single statewide formulary, it should pursue supplemental manufacturer rebates. The TennCare pharmacy carve-out already receives federally-mandated rebates that ensure prices equal to the “best price” available in the private

sector. Several states have used formularies to obtain additional rebates. In order to secure positions on state preferred drug lists, manufacturers must offer supplemental rebates on top of those already guaranteed by federal law. The TennCare Bureau will need to negotiate supplemental rebates prior to establishing a final single formulary to produce significant savings.

If the TennCare Bureau implements a single statewide formulary, it should tie three-tier copayments to that formulary. The existing TennCare copayment structure differs from that used in commercial practice. Furthermore, copay requirements that do not match prior authorization requirements could confuse plan members. Ideally, a copayment structure should reinforce a formulary.

The TennCare Bureau should study the impact of copayments to determine whether or not copayment requirements appear to reduce enrollee use of essential medications.

Research from the 1980s suggests that Medicaid copayments reduce enrollees' use of both essential and nonessential medications. However, it is unclear whether or not copayments will have the same effect now. The TennCare Bureau may wish to utilize expertise at the University of Tennessee Health Science Center to conduct a study to analyze this issue. If copayments appear to reduce use of essential medications, the bureau should consider removing copayment requirements for essential major-therapy medications.

The TennCare Bureau should establish regulations that clarify under what circumstances pharmacists can deny service to TennCare Medicaid members who refuse to pay copayments. Federal law requires pharmacies to provide service to Medicaid enrollees who are unable to pay copayments, and federal regulations require states to establish rules that allow pharmacies to determine which enrollees are unable to pay. Tennessee has yet to formally craft such rules.

The TennCare Bureau should seek a full-service pharmacy benefits manager (PBM) to administer programs associated with the TennCare pharmacy carve-out. The TennCare Bureau has a contract with Affiliated Computer Systems (ACS) to provide PBM services for the TennCare pharmacy carve-out. However, this contract does not include many services PBMs often provide. The TennCare Bureau performs some of these services itself; no party currently provides others. Ideally, a PBM for the TennCare pharmacy carve-out would:

- Assist the bureau in creating a formulary, including automated prior authorization (PA) and step therapy requirements;
- Facilitate both prospective and retrospective drug utilization review (DUR) to promote appropriate use of prescription medications;
- Assist the bureau in establishing maximum allowable cost (MAC) limits for medications available in generic form;
- Assist the bureau in establishing pharmacy payment rates and maintaining an adequate retail pharmacy network;
- Explore the impact of targeted prescription limits;
- Explore the feasibility of mail order pharmacy service for specific drug classes and specific member populations;
- Assist the bureau in developing pharmacy lock-in procedures and implementing pharmacy lock-ins; and
- Propose and evaluate other strategies to improve patient outcomes and reduce costs through the appropriate use of prescription drugs.

The TennCare Bureau should maintain pharmacy and primary care physician lock-ins for enrollees who use large amounts of prescription medication. As the use of prescription drugs increases, so does the risk for adverse reactions, patient abuse, and therapeutic duplication. Requiring those who use many prescription drugs to receive their prescriptions from a single physician and have them filled at a single pharmacy can reduce these risks.

The TennCare Bureau should examine the potential costs and benefits of moving to a full pharmacy carve-out. Some states have chosen to carve out pharmacy benefits from Medicaid managed care plans. Doing so facilitates the implementation of a single statewide formulary and allows the state to collect both federally-mandated and supplemental Medicaid rebates from pharmaceutical companies. However, it also removes the direct incentive for managed care organizations to control prescription drug utilization. If the TennCare program moves to a full pharmacy carve-out, it will likely need to implement financial incentives for MCOs to control physician prescribing patterns.

The TennCare Bureau should fully implement point-of-service third-party-liability (TPL) recovery programs. The TennCare Bureau has implemented point-of-service TPL recovery for Medicare enrollees that deny payment of drugs from TennCare if they are covered by Medicare. The bureau has also implemented a pay-and-chase TPL recovery system in which the Bureau pays for prescription drugs for enrollees with private insurance and requires reimbursement from private insurance companies for their share of the cost. This method results in a payment lag of many months. Furthermore, the state pays its contractor 6.75 percent of recovered claims. This is an additional state cost, and in many instances this incentive may not be sufficient to motivate aggressive recovery.

The TennCare Bureau, in conjunction with other divisions of the Department of Finance and Administration and other agencies, should explore strategies for reducing drug costs through cooperative efforts among state programs. Many states have examined the potential for reducing drug costs through pooling the purchasing power of state Medicaid programs, state employee health plans, and state wholesale purchases. Such strategies are difficult to implement. However, using a common formulary, for example, could increase rebates from pharmaceutical manufacturers in all areas. The state could also potentially achieve greater economies of scale or negotiating leverage when entering contracts with pharmacy benefit managers or pharmacies.

Appendices

Appendix A: Organizations/Persons Interviewed in Conjunction with this Report

AARP

Brian McGuire, Tennessee State Office Legislative Director

Affiliated Computer Services (ACS)

Jerry Dubberly, Director of Clinical Services

Jennifer Carpenter, Clinical Services Manager

American Healthways

Peter McCann, Vice President for Development

Aventis Pharmaceuticals

Walter Gose, Senior Regional Manager, State Government Relations

Blue Cross/Blue Shield of Tennessee

Steven Coulter, Senior Vice President and Chief Medical Officer

Dan Barnett, Senior Medical Director for Medical Risk Management

Terry Shea, Director of Pharmacy Management

Robert "Ned" Giles, Regional Pharmacy Director

David Locke, Director of Government Relations

Eckerd Pharmacy

Les Jones, full-time practicing pharmacist

Bruce McKinnon, full-time practicing pharmacist

Eli Lilly and Company

Butch Benson, Account Manager

Express Scripts

Emilio Tiele, Director of Government Programs, National Employer Division

Rick Dillon, Managed Care Division Sales Director

First Health Services Corporation

Bruce Edgren, Senior Director of Clinical Program Development

Thomas Graves, Vice President of Sales

Scott Allocco, Vice President of Business Development

Florida Agency for Health Care Administration

Jerry Wells, Medicaid Pharmacy Program Manager

Georgia Department of Community Health

Lori Garner, Pharmacy Director

Healthcare Enhancement Systems, Inc.

Robert Osburn, President

Idaho Division of Medicaid

Tammy Eady, Pharmacy Services Specialist
Gayle Gray, Graduate Research Analyst

John Deere Health

James Utt, Regional Pharmacy Manager
Bill Strozyk, Regional Pharmacy Manager

Maine Bureau of Medical Services

Jude Walsh, Director of Quality Improvement

Managed Care Pharmacy Solutions

Sonya King, Pharmacy Benefit Specialist

Massachusetts Alliance for State Pharmaceutical Buying

Brian Putnam, Procurement Manager

Massachusetts Office of Finance and Administration, Fiscal Affairs Division

Jennifer Rubino, Fiscal Policy Analyst

Memphis Managed Care

Edna Willingham, Director of Medical Management
Jamie Patterson, Vice President for Medical Management
Mark Stephens, Pharmacy Director

Mercer Human Resources Consulting

Paul Berger, Principal
Dave Hollis, Principal

Merck and Company

Glen Belemjian, National Account Executive

Michigan Department of Community Health

Dave Viele, Deputy Director for Budget and Finance Administration

National Association of Boards of Pharmacy

Melissa Madagan, Professional Affairs Director

National Institute for Health Care Management

Steve Findlay, Director of Research

National Legislative Association on Prescription Drug Prices

Cheryl Rivers, Executive Director

North Carolina Department of Health and Human Services, Division of Medical Assistance

Sharman Leinwand, Pharmacy Program Manager

Office of Vermont Health Access
Ann Rugg, Managed Care Senior Administrator

Oklahoma Health Care Authority
Nancy Nesser, Director of Pharmacy Service

OmniCare Health Plan
Bruce Triebel, Pharmacy Administrator

PricewaterhouseCoopers
Sandra Hunt, Partner
Martin Staehlin, Director
Jill Stockard, Manager

Schaller Anderson of Tennessee
Deidra Dorsey, Executive Director
Bob Swiekhart, Associate Medical Director
Bob Atkins, Associate Medical Director
Joseph Howard, Director of Health Program Design
Kim Seay, Director of Medical Policy
Lori Hoenig, Director of Policy & Procedures/Change Management
Omari Winbush, Director of Regulatory Affairs
Steve Miller, Pharmacy Director
Michael Colangelo, Statistician

Scrip Solutions
Recie Bomar, President
Phonzie Brown, Vice President of Sales
Daniel Colucci, Director of Sales and Marketing Operations

South Carolina Department of Health and Human Services
James Assey, Pharmacy Director

TennCare Bureau
Manny Martins, Director
Leo Sullivan, Pharmacy Director
Jeff Stockard, Associate Pharmacy Director

TennCare Centers of Excellence
Terri Jerkins, Endocrine Steering Committee member and full-time practicing
physician

Tennessee Citizen Action
Eric Cole, Director

Tennessee Department of Commerce and Insurance
Scott White, Deputy Commissioner
Kendall Lynch, Director of the Tennessee Board of Pharmacy

Tennessee Department of Correction
Fred Hix, Assistant Commissioner for Administration

Tennessee Department of Finance and Administration, Division of Insurance Administration
Richard Chapman, Director
John Anderson, Assistant Director
Keith Athow, Benefit Claims Analyst

Tennessee Department of General Services
Phil Campbell, Purchasing Supervisor

Tennessee Department of Health
Judy Eads, Assistant Commissioner, Bureau of Health Licensure and Regulation
Katie Garman, Appropriate Antibiotic Use Coordinator

Tennessee Department of Mental Health
Liz Ledbetter, Criminal Justice Mental Health Liaison

Tennessee General Assembly
Rep. Gene Caldwell, retired physician and chair of TennCare Oversight Committee
Rep. David Shepard, pharmacist
Sen. Randy McNally, pharmacist

Tennessee Health Care Campaign
Tony Garr, Executive Director

Tennessee Justice Center
Gordon Bonnyman, Managing Attorney

Tennessee Medical Association
Richard Lane, Regional Vice President and full-time practicing physician
Fred Ralston, TennCare Reform Task Force Chairman and full-time practicing
physician

Tennessee Office of the Attorney General
Michael Bassham, Assistant Attorney General

Tennessee Pharmacists Association
Baeteena Black, Executive Director
Roger Davis, Associate Executive Director

Texas Health and Human Services Commission

Bob Harriss, Consultant (former manager of the Texas Medicaid Vendor
Drug Program)

Curtis Birch, Texas Medicaid Program, Director of Drug Utilization Review

University of Memphis, Fogelman College of Business and Economics

Cyril Chang, Professor of Economics

University of Tennessee, County Technical Assistance Service

Terry Hazard, Criminal Justice Consultant

University of Tennessee, Health Science Center

David Mirvis, Director of the Center for Health Services Research

Teresa Waters, Associate Director for Research of the Center for Health Services
Research

Dick Gourley, College of Pharmacy, Dean

Naseem Amarshi, College of Pharmacy, Director of the Drug Information Center

Walter Fitzgerald, College of Pharmacy, Professor of Pharmacy Practice and
TennDUR Project Director

Richard Faris, College of Pharmacy, Assistant Professor

James Bailey, College of Medicine, Chief of the Division of General Internal
Medicine and TennDUR Medical Review Officer

U.S. Food and Drug Administration

Gordon Johnson, retired Deputy Director, Office of Generic Drugs

West Virginia Public Employees Insurance Agency

Tom Susman, Director

Xantus Healthplan of Tennessee

John Gore, Chief of the Healthplan

Wendy Macleod, Medical Director

Appendix B: TennCare Drug Utilization Review Program

TennCare Drug Utilization Review Program July 2002-June 2003

TennCare DUR Advisory Board

J. Sloan Manning, M.D., Chair
Family Practice
1112 Union Avenue
Memphis, TN 38104
Work: 901-448-1899
Fax: 901-523-7681
jmmanning@utm.edu

Butch Benson, D.Ph.
1310 Mulberry Court
Murfreesboro, TN 37130
Work: 615-594-3169
Fax: 615-867-5058
Benson_Ned_Jr@Lilly.com

Christi Capers, Pharm.D.
Clinical Education Consultant
Pfizer, Inc.
4043 Farmingham Woods Drive
Hermitage, TN 37076-4405
Work: 615-885-4641
Fax: 615-885-5446
Voice: 1-800-233-7241, ext 78329
christi.capers@pfizer.com

Diane Crutchfield, D.Ph.
1223 Eaglenest Lane
Knoxville, TN 37922
Work: 865-966-0844
Fax: 865-966-0329
dcrutchfield@tds.net

Roger L. Davis, Pharm.D.
226 Capitol Boulevard, Suite 810
Nashville, TN 37219
Work: 615-256-3023
Fax: 615-255-3528
rld@tnpharm.org

Martha Drannon, Pharm.D.
Frayser Family Counseling Center
Pharmacy
2150 Whitney Avenue
Memphis, TN 38127
Work: 901-353-5440
Fax: 901-353-5464
tdrannon@midsouth.rr.com

Don Hazelwood, D.Ph.
HealthCare Pharmacy
3100 South First Street
Milan, TN 38358
Work: 731-686-7411
Fax: 731-686-2166
hcepharm@iswt.com

Connie J. Holladay, M.D.
6432 River Tide Drive
Memphis, TN 38120
Work: 901-821-0235
Fax: 901-821-0235
Pager: 901-447-4987
choll92095@aol.com

Mack A. Land, M.D.
5210 Poplar Avenue, Suite 200
Memphis, TN 38119
Work: 901-685-3490
Fax: 901-685-3499

David Shepard, Pharm.D., B.C.P.P.
Dickson Apothecary East
104 Highway 70 East
Dickson, TN 37055
Work: 615-446-5585
Fax: 615-446-7770
dashepo@aol.com

Daniel D. Sumrok, M.D.
Family Practice
22700 Highway 22
McKenzie, TN 38201
Home: 731-352-8033
Work: 731-352-0603
Fax: 731-352-0185
drshiloh@aeneas.net

TennCare Bureau

H. Leo Sullivan, D.Ph.
Pharmacy Director
Bureau of TennCare
729 Church Street
Nashville, TN 37247-6501
Work: 615-741-0213
Fax: 615-741-0882
leo.sullivan@state.tn.us

Jeff Stockard, D.Ph.
Associate Pharmacy Director
Bureau of TennCare
729 Church Street
Nashville, TN 37247-6501
Work: 615-532-3107
Fax: 615-741-0882
Jeff.Stockard@state.tn.us

ACS (ProDUR Provider)

Jennifer Carpenter, Pharm.D.
Clinical Services Manager
Consultec, LLC
9040 Roswell Road, Suite 700
Atlanta, Georgia 30350-1892
Work: 1-800-358-2381, Ext. 6685
Fax: 770-641-9938
Jennifer_Carpenter@consultec-inc.com

TennDUR (RetroDUR Provider)

James E. Bailey, M.D., M.P.H., F.A.C.P.
TennDUR Medical Review Officer
Doctor's Office Building
66 North Pauline, Suite 633
Memphis, TN 38104
Work: 901-448-5186
Work: 901-545-7196
Fax: 901-545-6704
Pager: 901-777-9077
jebailey@utm.edu

Walter Fitzgerald, Jr., D.Ph., M.S., J.D.
TennDUR Project Director
847 Monroe Avenue, Suite 208
Memphis, TN 38163
Work: 901-448-2351
Fax: 901-448-1221
Mobile: 901-218-6776
wfitzgerald@utm.edu

Appendix C: Response from the TennCare Bureau



STATE OF TENNESSEE
BUREAU OF TENNCARE
DEPARTMENT OF HEALTH
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

December 12, 2002

John C. Morgan
Comptroller of the Treasury
State Capitol
Nashville, Tennessee 37243-0260

Dear John:

Thank you for forwarding me a draft copy of the "TennCare Prescription Drug Costs" report prepared by your office and for requesting our review of the draft document. I would like to respond by clarifying some minor inaccuracies within the report and then describing some of the initiatives underway at TennCare that address some of the concerns highlighted in the draft report.

The draft report addresses at several different locations challenges or shortcomings associated with retrospective and prospective drug utilization review (DUR), preferred drug lists (PDL), OBRA 1990 drug rebates and supplemental rebates, maximum allowable cost (MAC) reimbursement for generic drugs, the current pharmacy benefits manager (PBM) contract with Consultec (ACS), copy rules and lock-in policies.

TennCare has a contract with the University of Tennessee's College of Pharmacy to manage the TennCare DUR Board and perform the retrospective DUR responsibilities required by OBRA 1990. During the past year, at the request of TennCare, the leadership of the UT team has been changed to improve the depth and quality of their work under this contract. On July 1, 2002 TennCare began requiring all pharmacy claims submissions for the MCOs and the pharmacy carve-outs to contain the prescribing physician's DEA number. While this system has not been in place long enough to assist UT's physician intervention efforts associated with retro-DUR, it is a vast improvement over the multiple physician identifier systems that were in place prior to July. The point-of-service (POS) pharmacy claims processing system provided by Consultec (ACS) contains hard edits in its prospective DUR program that deny pharmacy claims for early refills and excessive doses of medications. A multitude of soft edits provide information to the pharmacist regarding drug-drug interactions, therapeutic duplication interactions, drug-disease contraindications, drug-allergy interactions, pregnancy contraindications and many other therapeutic considerations. These edits are "soft" to allow the dispensing pharmacist to exercise their professional judgment in these cases and input personal knowledge about a patient's history.

We receive edit reports from Consultec each month that identify the number of these edits encountered by pharmacists and the action taken by the pharmacist. In many cases the pharmacist reverses the claim upon reviewing the interaction or contraindication edits.

TennCare has aggressively pursued drug rebates from pharmaceutical manufacturers, pursuant to OBRA 1990, since the inception of the Medicaid Drug Rebate program in 1991. To date, TennCare has collected ninety-nine percent of all billed rebates, a feat unrivaled across the country. The move by other states to supplemental rebates has been successful in collecting about a five percent increase in rebates, but not without expensive legal challenges from the pharmaceutical industry. Supplemental rebates must be coupled with preferred drug lists (PDLs) and prior approval systems that threaten to exclude certain drugs from coverage in order to leverage the additional rebates. The full impact of a supplemental rebate in the TennCare environment cannot be realized until we have been successful in our attempt to modify the *Grier* Consent Decree, established and implemented a single statewide drug formulary, assembled a seamless prior approval unit, performed intensive physician education programs surrounding formulary compliance and combined all of the pharmaceutical purchasing power of the state.

Tennessee was the first state in the country to utilize the MAC pricing system for generic drugs and was the model for the federal government's Federal Upper Limits (FUL) program. It is important to understand the process that occurs when a brand name drug loses its patent, allowing generic competition to enter the marketplace. In most instances, immediately after a brand drug loses its patent, a single generic manufacturer will have exclusive rights on the generic version for some six to nine months. During this period of time the generic version has no competition and the cost will be only slightly lower than the brand name version. A program like TennCare must be vigilant during this period of time when, net of rebates, the brand name drug is much cheaper than the generic. Once multiple generic companies develop and introduce their generic versions of that drug, the price drops precipitously, and then TennCare will impose a state MAC, usually far in advance of the CMS FUL. The MAC price should be set at a level that encourages pharmacists to seek generic substitution approval from the prescriber.

Due to the confinements of the *Grier* Consent Decree, when TennCare issued an RFP for a pharmacy claims processor to process claims for the two drug carve-outs (behavioral health drugs and the pharmacy benefit for dual eligible members), the decision was made to secure only pharmacy claims processing and management reporting, not a full PBM. Prior to the implementation of the Consultec (ACS) contract, TennCare was paying a PBM fifty-six (56) cents for each transaction and twelve (12) dollars for each prior approval, regardless of the outcome. This traditional PBM did no other management activities in exchange for these high transaction fees. We now pay Consultec only nine (9) cents per paid or denied claim, we do not pay for voided, adjusted or reversed claims. A recent independent review of this contract with Consultec (ACS) praised the contract as very cost-effective.

TennCare has promulgated and distributed to the provider community the final rules concerning pharmacy copays for TennCare members that will go into effect on January 1, 2003.

TennCare has also developed pharmacy lock-in policy guidelines for the MCOs to use when they recognize or identify abusive pharmacy utilization patterns by TennCare members. Each MCO is

required to perform lock-in processes in these instances and submit their policies and procedures to TennCare for approval. The TennCare pharmacy carve-out program managed by the TennCare Bureau is also running abusive pattern queries that will be used to lock-in members to specific pharmacies to control inappropriate behavior.

One of the major challenges facing management of the TennCare and MCO pharmacy programs is the Revised *Grier* Consent Decree. Since my return to TennCare, I have worked with TennCare staff, our Office of General Counsel, the Attorney General's office and our attorneys at Covington and Burling in Washington, D.C. to formulate a compelling legal argument to present to the federal court in order to modify the pharmacy provisions of *Grier*. While we have not yet received a decision from the court on our request to modify *Grier*, I remain optimistic that our arguments to the court will be successful. Two different firms, PricewaterhouseCoopers (PWC) and Applied Health outcomes (AHO) have independently studied the fiscal impact of *Grier* on the TennCare and MCO pharmacy programs, arriving at the same basic conclusion. The pharmacy provisions of *Grier* have had a \$50 million per year impact on pharmacy costs. That \$50 million does not include MCO costs for processing pharmacy appeals (about 8,000 per month at fifty dollars apiece), the state's costs associated with the TennCare Solutions Unit, the costs incurred by our Office of General Counsel associated with the appeals process, the cost increases of the pharmacy carve-outs related to opening the formulary due to *Grier*, the contract with Schaller Anderson or any other of the ancillary costs associated with compliance with *Grier*.

TennCare is also pursuing other pharmacy program initiatives designed improve the quality of care for TennCare members while reducing pharmacy expenditures. These initiatives include the development of an RFP for a vendor to perform fraud, waste and abuse detection and elimination. The contractor will be required to perform desk and onsite audits of every participating pharmacy every year. They will also audit claims processors. While this effort will focus on pharmacy providers, the contractor will undoubtedly encounter problems with the activity of other provider types as well as members. In these instances the contractor will be required to work with TennCare, the Medicaid Fraud Unit of the TBI, TennCare's Quality Assurance Unit and the TennCare Program Integrity Unit. The contractor will not only identify and eliminate these cases of fraud, waste and abuse, but also provide TennCare with cleaner, more accurate pharmacy data.

Another RFP under development will secure the services of a contractor who has expertise in identifying and predicting adverse drug events in the TennCare patient population. This contractor will scrub historical and current TennCare encounter data in order to predict the hospitalizations and emergency room usage associated with inappropriate or duplicative drug therapy before it occurs. Once cases are identified, then the contractor will perform the necessary interventions to prevent the adverse event from occurring. This process will reduce not only hospital and emergency room costs associated with adverse drug events, but also reduce pharmacy expenditures.

The development of the single statewide drug formulary is another initiative underway at TennCare. The implementation date for this change is scheduled for April 1, 2003. The single statewide drug formulary will:

- Reduce delays in filling prescriptions for TennCare members

- Assure consistent member access to covered medications
- Simplify the prescriber's TennCare practice
- Increase physician participation in the TennCare program
- Reduce hassle factors for both physician and pharmacist providers such as prior approval telephone calls and additional paperwork
- Reduce unnecessary *Grier* pharmacy appeals and associated administrative costs
- Maximize the state's buying power and increase pharmaceutical manufacturer rebates during the stabilization plan time period
- Reduce the number of *Grier* reimbursement appeals
- Increase formulary compliance
- Reduction of physician office overhead costs
- Simplification of rebate invoicing and contracting between TennCare and the pharmaceutical manufacturers

The six PBMs for the nine TennCare MCOs are currently negotiating rebate contracts with the pharmaceutical manufacturers that net the MCOs about five percent of their drug spend. By consolidating these different formularies into a single one, TennCare can contract directly with the manufacturers and increase the rebates to over twenty percent. During the stabilization time period, a fifteen percent increase in the rebates collected by TennCare for the \$1 billion pharmacy programs of the MCOs translates into \$150 million worth of savings.

The single statewide drug formulary will not only include the pharmacy benefit for the members of the nine TennCare MCOs, but also the dual eligible members in the TennCare carve-out. The TennCare Bureau has analyzed the expenditures for the behavioral health drugs and we expect to follow a similar process used to develop the single statewide drug formulary to decrease expenditures for those drugs as well.

Members of the TennCare Bureau staff have recently met with officials in West Virginia to explore their multi-state pharmacy program that combines the purchasing power of five state employee pharmacy benefit plans. The development of the single statewide drug formulary will put Tennessee in a position to take West Virginia's ideas to the next level, that is, adding not only all of the state's pharmacy purchasing to a buying pool, but also incorporating the \$2 billion power of the TennCare pharmacy budget.

I hope this information is helpful. If you need additional information or would like to discuss any of the proposed pharmacy improvements, feel free to contact me.

Sincerely,


Manny Martins
Deputy Commissioner

MM:HLS:ds

Appendix D: Response from TennDUR



Office for TennCare Drug Utilization Review
26 South Dunlap, Suite 202
Memphis, TN 38163
901-448-2358 • Fax 901-448-3701

5 December 2002

VIA TELEFACSIMILE
(615) 554-9427

DATE RECEIVED

DEC 11 2002

Richard K. Gurley
Associate Legislative Research Analyst
Offices of Research and Education Accountability
Comptroller of the Treasury
Suite 1700 – James K. Polk Building
505 Deaderick Street
Nashville, TN 37243-0268

**OFFICES OF
RESEARCH & EDUCATION
ACCOUNTABILITY**

Re: Report on TennCare

Dear Mr. Gurley:

It was a pleasure speaking with you today, and I appreciate your taking time from your schedule to again visit with me about the TennDUR Program. As we discussed today and on previous occasions, your understanding of the federal law requirements for retrospective drug use review are accurate. Due to the existing structure of the TennCare program, the focus of the TennDUR Program related to these federal law requirements is upon the TennCare beneficiaries who (1) have Medicare coverage in addition to having TennCare coverage (dual-eligible beneficiaries) or who (2) are enrolled in a Behavioral Health Organization.

I am pleased that you have been able to speak directly with Dr. Jim Bailey, our Medical Review Officer, and gain his insight into the TennDUR program. Since you already have his comments I will not repeat them here, except to add that I agree with the points that he has shared with you.

Since my assuming the position of TennDUR Program Director in January of this year, Dr. Bailey and other experienced staff, together with Dr. Leo Sullivan, have been extremely helpful in educating me as to the many and varied aspects of this Program. In addition, I have gained input and ideas from constituent groups across Tennessee, as well as from the American Drug Utilization Review Society (ADURS) and other similar national organizations.

Based upon all of the information that we have acquired, a number of new initiatives directed at accomplishing the federal law requirements for retrospective drug use review have been planned and are in the early stages of implementation. These initiatives relate directly to the primary focus areas that you identified from your conversation with Dr. Bailey, but in some cases, extend beyond these areas.

Richard K. Gurley
5 December 2002
Page Two

As I shared with you today (and as shared with you previously by Dr. Bailey), due to the quality of the TennCare data it is difficult to engage in specific, targeted interventions related to prescribing practices, particularly at the level of the individual prescriber.

Because of the limitations presented by the quality of the TennCare data, we are conducting more global evaluations. One example of this is to compare quality of care and patient outcomes, based on established performance measures, between counties throughout Tennessee and between the Managed Care Organizations (MCOs). Based upon these differences we are developing educational programming to offer to appropriate parties in the county or at the MCO where it appears that educational programming can be beneficial to improving quality of care and patient outcomes.

As another example (and in an effort to support the TennCare Centers of Excellence initiative), we are examining the level of quality and outcomes being achieved in the treatment of certain disease states. To demonstrate, we have identified that TennCare beneficiaries with certain disease states and medical conditions are being undertreated with drug therapy. This becomes a concern where the peer-reviewed medical literature indicates that placing such beneficiaries on appropriate drug therapy will cause reduction in other health care costs incurred by the TennCare program, including physician office visits, emergency department visits and hospitalizations. For such disease states and medical conditions, we are developing educational programs that, while not targeted specifically at any one or more prescribers, can be delivered by the TennDUR Program staff and other individuals to all prescribers and other health care professionals involved in managing such disease states and medical conditions. The programming will be offered through traditional methods, such as live seminars, and through newer methods, such as through our recently launched TennDUR Program Website. We are also looking at other opportunities to use the website, such as for electronic newsletter posting.

To overcome the limitations of the data, we are working to develop educational programming that does not rely specifically on the data. To demonstrate, we will be actively offering programs to constituent groups, such as the Tennessee Medical Association, Tennessee Nursing Association and Tennessee Pharmacists Association, for use in their postgraduate educational programs. These programs will also be offered to health profession education programs in Tennessee. For example, each year the University of Tennessee College of Pharmacy conducts what is called the "Fall Therapeutics Series" in Knoxville, Nashville and Memphis. I have offered to Dr. Glen Farr, the College of Pharmacy Assistant Dean for Continuing Education, the participation of the TennDUR Program in this Series. While the exact presentation title and which TennDUR Program staff member will be available to speak at each location in the Series have not been confirmed, the purpose will be to share with pharmacists the results of our most recent evaluations of drug utilization and other resources that we are making available to them. But perhaps most importantly, we will share with them ways, based upon the results of our evaluations, that pharmacists may actively contribute to improving the drug utilization of all TennCare beneficiaries.

Richard K. Gurley
5 December 2002
Page Three

Finally, we are working diligently to overcome the limitations associated with the TennCare database. As I mentioned today, I was in Nashville yesterday meeting with clinical pharmacists and representatives from the Center for Health Improvement at Vanderbilt University. This was a very productive meeting in generating ideas as to how we can build computer programs that will allow us to obtain data with a greater degree of reliability and validity, with the goal of being able to identify needs for education at the individual prescriber level.

As Dr. Bailey indicated, we also respond to various requests from the Bureau of TennCare. Since you and I initiated our discussions, one such request in which we have become quite invested is the development of the "statewide" single formulary for the TennCare Program. We are pleased to have the opportunity to participate in development of this formulary, and we view this formulary as providing many opportunities for continued expansion of our activities. To demonstrate, our ability to examine drug utilization beyond the dual-eligible and BHO TennCare beneficiaries has not been practical because of each MCO having its own formulary. We are optimistic regarding the potential to conduct more drug utilization review work upon implementation of the formulary, which we believe will also assist in providing a higher quality database for our research efforts.

All of the above said, we continue to conduct and report on traditional retrospective drug use review activities, most notably the evaluation of patient care in relation to established performance standards. Two very significant patient care evaluations in the areas of hypertension and diabetes have just been completed by Dr. Bailey and our staff. The results of these evaluations will be presented at our quarterly TennDUR Board meeting in Jackson, Tennessee on 13 December 2002. Certainly, we invite you to attend this meeting, and we will forward to you (under separate cover) information about the agenda and location for the meeting.

Again, on behalf of the TennDUR Program staff, I appreciate this opportunity to share information with you. Thank you for the privilege of participating in your efforts, and please let me know if you have any questions or would like additional information.

Sincerely,



Walter L. Fitzgerald, Jr., B.S.Pharm., M.S., J.D.
Program Director

cc: Jim Bailey, M.D., M.P.H., Medical Review Officer, TennDUR Program
Leo Sullivan, D.Ph., Pharmacy Director, Bureau of TennCare
Dick Gourley, Pharm.D., Dean, University of Tennessee College of Pharmacy

Offices of Research and Education Accountability Staff

Director

◆Ethel Detch

Assistant Director (Research)

◆Douglas Wright

Assistant Director (Education Accountability)

Jason Walton

Principal Legislative Research Analysts

Phil Doss

◆Kim Potts

Senior Legislative Research Analysts

Denise Denton

Margaret Rose

Greg Spradley

Emily Wilson

Associate Legislative Research Analysts

Bonnie Adamson

Brian Doss

◆Richard Gurley

Russell Moore

Alisa Palmisano

Melissa Jo Smith

Karen Tolbert

Legislative Research Intern

Bintou Njie

Executive Secretary

◆Sherrill Murrell

◆indicates staff who assisted with this project