

Proposed TennCare Waiver Amendment

**Office of the Governor
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Executive Summary

In the face of unsustainable growth in TennCare expenditures and in an effort to preserve health coverage for hundreds of thousands of Tennesseans, the State of Tennessee submits this proposal to restructure the TennCare program to ensure both financial viability and high quality coverage well into the future.

The TennCare program is at a crossroads. Either it must be fundamentally reformed and reorganized on a path toward sustainability, or it will collapse of its own weight, forcing a return to traditional Medicaid and leaving the uninsured, Medically Eligible, and optional Medicaid beneficiaries to cope on their own.

Tennessee has chosen the path of reform. We are pleased to submit this proposal representing the culmination of a year's worth of work with stakeholders from around the state to preserve this important program.

Policy goals. Tennessee is proposing to amend its current TennCare waiver (No. 11-W-00151/4) to achieve three fundamental policy goals.

- First, we want to be able to retain as many enrollees as possible on the program. Currently, the TennCare program covers 275,000 uninsured and Medically Eligible persons, as well as 124,000 persons in optional Medicaid categories who are not institutionalized and not eligible for Medicare. In the absence of TennCare coverage, the state recognizes that critical health care needs will go unmet. The state further recognizes that there are other individuals not currently enrolled who are also in need of health insurance. To the extent that planned reforms are successful, the state hopes to expand coverage to other needy populations.
- Second, we want to insure that TennCare dollars are better directed toward provision of quality health care for those enrollees. We can promote better quality care through innovations such as disease management programs, increased use of evidence-based medicine, and pharmacy programs that encourage the use of less expensive, therapeutically comparable drugs.
- Third, we want to establish a clear target for the total amount of funds spent each year on TennCare as a proportion of the state's budget. The target we have set is 26% of state revenues.

Tennessee has spent and will continue to spend a sizeable amount on the TennCare program. We are not proposing to reduce spending on TennCare. Rather, we are proposing to change the dynamic from unmanageable increases year after year to increases that are predictable and reasonably proportional to the growth in Tennessee's revenues. We want to be able to balance health care expenditures with spending on other state priorities, such as education, safety, and job training. This waiver amendment represents an effort to sculpt, rather than slash, the program.

We are requesting an implementation date for this amendment of January 1, 2005, although we will sequence the implementation components to match operational readiness. We recognize that it is impossible to foresee every possible change that may

be needed to enable TennCare to achieve its goals, and so we are including in this amendment some suggestions for “fine tuning” the program as we go forward. We also anticipate that we may need to return to the Centers for Medicare and Medicaid Services (CMS) with requests for changes from time to time in order to manage the program appropriately.

Program growth. In 1994, Tennessee embarked on a bold experiment to redesign its Medicaid program to expand coverage to thousands of uninsured and uninsurable Tennesseans through TennCare. The cost of the program has grown rapidly over the years, with no end in sight. Current estimates, assuming moderate recovery of the economy, are that TennCare’s costs could grow by as much as 80 percent by fiscal year 2008.¹

Changes proposed. The major cost containment/quality of care initiative being proposed is a pharmacy program that will focus on use of lowest cost therapeutically comparable drugs. Tennessee plans to initiate a new and rigorous prior authorization process for certain drugs and to take steps to insure that enrollees receive drugs that are most appropriate for their care, as well as most cost effective for the state. In addition, Tennessee seeks approval to be able to categorically exclude from coverage for adults (not children) certain classes of drugs including antihistamines, H2 blockers, and proton pump inhibitors for which functionally comparable and appropriately substitutable drugs are available over-the-counter in non-prescription form. Finally, Tennessee plans to initiate additional retrospective and prospective drug utilization review programs to reduce misuse and overuse of drugs.

Changes in the current distribution of eligibility categories between “TennCare Medicaid” and “TennCare Standard” are also being planned. “TennCare Medicaid” presently includes all Medicaid eligibles. “TennCare Standard” includes all persons who are eligible for TennCare only by virtue of being eligible for the TennCare demonstration project. These persons are referred to as demonstration eligibles.

We are proposing that TennCare Medicaid be limited to mandatory Medicaid eligibles and related categories only. The remaining optional Medicaid categories will be converted to demonstration eligibles and treated as part of the TennCare Standard population, except for purposes of calculating budget neutrality, when they will be treated as Medicaid “hypotheticals” (or Medicaid Eligibility Group 2, as defined in Attachment B of the current Special Terms and Conditions.) As a result of these changes, approximately 70% of the TennCare population will be covered by TennCare Medicaid, and 30% will be covered by TennCare Standard.

We are planning to implement new benefit limits and copays for the TennCare Standard population, although children will be exempt from both benefit limits and copays. The newly defined TennCare Medicaid population will continue to be eligible for all medically necessary covered services and will have no cost-sharing requirements.

Services for which limits are proposed for TennCare Standard are inpatient hospital services, outpatient hospital services, physician services, pharmacy, and lab and X-ray services. Certain vulnerable groups within TennCare Standard will be exempt from

¹ McKinsey & Company, *Achieving a Critical Mission in Difficult Times—TennCare’s Financial Viability, Part 1 of a two-part report*, December 11, 2003, p. 3.

these benefit limits, however. These exempt groups include children and pregnant women, as well as certain persons with disabilities. The end result of these new classifications is that about 80% of the TennCare population will continue to have no limits on access to covered services based on the standard of medical necessity. The one exception is the \$30,000 lifetime limit on inpatient and outpatient substance abuse services for adults.

TennCare Standard members will be required to make copays for certain services. Those with incomes at or above poverty will also be required to pay premiums. We anticipate that premium amounts will rise each year at a rate not to exceed the rate of medical inflation.

With respect to children who participate in TennCare, we do not seek to waive any EPSDT requirements that may be applicable or to remove benefits currently received by TennCare children. Accordingly, no children in any eligibility category will be subject to the categorical exclusion of certain drug classes or to service limits. They will be subject to the new focus on using the lowest cost therapeutically comparable drugs and to the new definition of medical necessity, both in a manner consistent with EPSDT. With respect to our current waiver, CMS has clarified that we are not required to provide demonstration children with EPSDT benefits, and we do not expect this amendment to change that situation or to impose any new mandates. Nevertheless, although we are not required to, we have to date provided full screening, diagnostic, and treatment benefits to the waiver population and plan to continue to do so. In fact, we are proposing to close the gap further between the Medicaid and waiver groups by eliminating existing cost-sharing requirements that apply to approximately 38,000 children in the TennCare Standard population today.

Infrastructure improvements to be made include:

- Implementation of a new disease management program,
- Re-evaluation of the MCO network structure,
- A strengthening of the TennCare organization,
- A new, already enacted but not yet implemented statutory definition of medical necessity,
- Establishment of a more effective fraud and abuse unit and related enforcement mechanisms, and
- Establishment of an Advisory Commission that will make recommendations on an annual basis regarding changes in TennCare that may be needed.

A set of program parameters is proposed for CMS pre-approval to enable the state to quickly make changes to adjust to budget realities. Use of these parameters will enable the state to implement pre-approved modifications to TennCare without having to seek new waivers from the CMS. Adoption of changes within these parameters that would result in program expansion will be undertaken only when there is evidence that the state's budget neutrality cap will not be exceeded. In addition, the state wants to make clear that future amendments to the waiver will be requested from CMS to enable us to adapt to changes that may be needed.

Implementation of the entire proposal will increase the likelihood that a quality-oriented TennCare will remain viable for needy persons in Tennessee. We believe this proposal offers our best chance for preserving a quality focused TennCare program and

maintaining health insurance coverage for optional Medicaid enrollees and hundreds of thousands of uninsured and Medically Eligible Tennesseans.

Achieving the policy goals and reform measures set forth in this application is contingent upon external factors that are beyond the state's control. If, due to these factors, the state is unable to move forward with reform measures, then the state will have no choice but to implement alternative cost savings measures that will necessitate the removal of all or part of the Standard population and optional Medicaid enrollees, or elimination of some or all optional benefits, such as pharmaceuticals, for some or all of the population. We have included a mechanism for the Governor, in the first year after approval, to move to a "fallback plan" designed to control expenditures through more traditional cost-cutting methods, without the need for further CMS approval. (See Chapter 5.) While these choices are unfortunate and unwanted, the state must achieve financial viability in this program so that it can address other pressing needs.

Toward that end, we also note that these reforms are calculated to achieve a certain level of savings in the program as compared to current projections. In estimating these savings, we assumed the continuation of the financing mechanisms currently permissible. To the extent that these mechanisms are restricted or eliminated, either now or in the future, within or outside of the waiver, we will need to identify replacement funding so that the overall budgetary impact remains stable. We anticipate that CMS will continue to work with us to maintain current funding levels so that we can avoid the need for other changes to the TennCare demonstration project.

Public Input

In accordance with federal and state requirements regarding the submission of Section 1115 waiver amendments, the state has undertaken the following activities to assure public input into the content of this proposal.

February 2003-late summer 2003

The public discussions concerning TennCare's fiscal challenge to the state budget began in February 2003 through the new Governor's public budget hearings. During discussions with the TennCare Director, the Governor learned of a current state fiscal year overexpenditure of about \$370 million and additional funding requirements of \$700 million for the state fiscal year beginning July 2004. Those discussions, which were widely reported, provided the backdrop for identification of potential administrative changes and benefit reductions, the impetus for efforts to settle several ongoing legal cases, and the incentive for undertaking a new and original effort to examine the state's options regarding TennCare.

During the 2003 legislative session, extensive discussions were held with Tennessee's public policy leadership concerning the importance of TennCare's financial future. The Governor and members of his staff and cabinet also engaged in discussions at public presentations and forums with TennCare stakeholders and, through the print and electronic media, presented ideas for consideration by the public concerning the future of TennCare.

Late summer 2003

McKinsey & Company, an international management consulting firm, was engaged to prepare a review of the financial sustainability of TennCare and to provide suggestions for alternative courses of action if needed. As part of their preparation, they interviewed over 150 stakeholders in the TennCare program—government workers, provider representatives, consumers, business leaders, advocates, etc.—to learn their perspectives on the program's problems and successes.

December 2003 – January 2004

The first McKinsey & Company report, entitled *Achieving a Critical Mission in Difficult Times—TennCare's Financial Viability*, was delivered on December 11, 2003. The report was posted on the Governor's website in a summary form and in its entirety. It was distributed by the Governor's office at a number of briefings held immediately following its release. Participants in the briefings included the media, legislative leadership, representatives of provider groups, the initial funders of the project, and advocates for TennCare enrollees.

The Commissioner of Finance and Administration followed up on the issuance of the report by conducting public meetings in eight separate locations in Tennessee. These locations included:

Nashville (December 15)

Blountville (December 16)
Memphis (December 17)
Knoxville (December 18)
Chattanooga (December 18)
Jackson (January 6)
Cookeville (January 7)
Cleveland (January 20)

February 2004

McKinsey & Company released a second report on February 11, 2004, outlining possible strategies for consideration in addressing the problems identified in the first report. Hard copies of the report were prepared, along with a powerpoint presentation, and used in briefings on February 11 and 12 for the legislative leadership, advocates, providers, Managed Care Organizations participating in TennCare, and the project's funders. The Governor's Office provided a press release concerning the report, and copies of the report and other related material were available on the Governor's website. There was considerable discussion in the electronic and print media.

On February 17, the Governor addressed a joint convention of the Tennessee General Assembly on the topic "Last Chance Strategy to Save TennCare." The speech was broadcast live across the state and posted on the Governor's website. On February 18, and again on February 26, the Governor met with the advocates to discuss the principles and concepts incorporated in his speech. On February 20, the Governor met with children's advocates concerning his proposals and the potential impact these proposals would have on children.

During this time and afterward, members of the Governor's cabinet and senior staff met on several occasions with Congressional staff to solicit comment and input, as well as support, for the TennCare reform proposal. Separately, the Governor has met with members of the Tennessee Congressional delegation to review the structure of the reform proposal and to request their input.

March –August 2004

Several workgroups were formed to develop the details of the waiver amendment request. One of these was the Key Constituent Workgroup. Acting as representatives of the Administration, several members of the Key Constituent Workgroup made available a weekly meeting time for discussion with members of the advocacy community. At the discretion of the advocates, five such meetings were held during this period. Information was provided regarding the state's organizational structure for developing reforms, and input was sought regarding all aspects of the reform effort.

Areas where input was sought and provided included the definition of "disabled," the provision of benefits to children, the practices associated with establishment of a safety net, implementation of the new pharmacy benefit proposals, and changes related to optimizing Managed Care Organizations. The broad-based advocacy community worked collaboratively to assimilate this information into a set of recommendations entitled *A Study to Minimize Harm to TennCare Enrollees while Reforming and Preserving the Fiscal Integrity of the TennCare Program* and presented it to the

Administration. Such information was disseminated to appropriate state workgroups for review and consideration in decision-making processes.

Legislation was introduced in the General Assembly to provide statutory support for the reforms being sought by the Governor. Two separate bills were introduced, one on general programmatic issues and one on fraud and abuse. Each bill was intensively discussed in a number of House and Senate Committee meetings, as well as on the floors of the House and Senate. The TennCare Oversight Committee of the Tennessee General Assembly met on April 19 and heard testimony from physicians, the Tennessee Pharmacy Association, and the Tennessee Medical Association. All of these forums were open to and attended by members of the public. A formal bill-signing ceremony was held for the programmatic bill at the Capitol on May 11. This event received widespread media coverage.

During this time, the Commissioner of Finance and Administration met with the advocates on three separate occasions:

March 20

June 1

June 10

At these meetings, the Commissioner heard general observations from the advocates regarding the status of the Administration's review and consideration of the advocates' input and key issues of interest to the advocates, particularly the definition of the groups to be exempt from benefit limits, the determination of copayments, and premium requirements.

The TennCare Chief Medical Officer held another meeting with advocates on April 7 to discuss the proposed statewide disease management program.

Additional meetings were held between the Commissioner and the Tennessee Hospital Association (THA) and the Tennessee Medical Association (TMA), respectively. The Governor and the Commissioner met jointly with the Board of Directors of TMA on April 15, and THA on April 19.

On June 24, the Governor's proposal as outlined in his earlier speech was presented to the Medical Care Advisory Committee meeting. Members of the committee were asked for input on the proposals.

August 2004 and following

In accordance with Tennessee law, the state is submitting the waiver amendment proposal to the TennCare Oversight Committee of the TennCare General Assembly 30 days prior to submitting the waiver amendment to CMS, and, in compliance with court orders, is submitting the waiver amendment proposal to the Tennessee Justice Center at the same time. Based on public comment received to date, this proposal has changed in several significant ways from the elements of the plan outlined by the Governor in the February speech. Two examples are the definition of disability and the inapplicability to children of eliminating certain drug classes.

Concurrent with and following the required submission to the TennCare Oversight Committee and the Tennessee Justice Center, there will be opportunity for public comment on the waiver amendment proposal. There will be a series of briefings for

TennCare stakeholders and the general public in addition to at least one public meeting with each of three groups—providers, enrollees, and citizens. The waiver amendment proposal will be posted on the Governor’s website, and citizens will be able to obtain copies of the waiver amendment proposal and additional information by downloading copies from the Internet or by requesting them by toll-free telephone, e-mail, or mail. Copies of these documents will also be available at many state offices across Tennessee. Opportunity for direct comment concerning the proposal will be available through the Internet, by toll-free telephone and by mail. Additionally, there will be opportunity for direct comment at the briefings and public meetings.

The state will promulgate rules to govern the revised program. This process will occur through the formal Uniform Administrative Procedures Act, which includes the issuance of public necessity rules, publication in the *Tennessee Administrative Register* of notice of rulemaking, and the conduct of an open public hearing.

Chapter 1: Background

Brief history of current waiver

The initial TennCare waiver began on January 1, 1994. A three-year extension was approved for the period beginning January 1, 1999. A one-year extension of the project was approved for the period of February 1, 2002, through January 31, 2003.

A new waiver was submitted to CMS in February 2002. This waiver was subsequently approved for a five-year period beginning on July 1, 2002. In the new waiver, TennCare was divided into two programs, TennCare Medicaid for Medicaid eligibles and TennCare Standard for demonstration eligibles. (Demonstration eligibles are those who are eligible for TennCare only because of the Section 1115(a) waiver.) A third program, TennCare Assist, which was to be a premium assistance program for low-income persons, was proposed and approved, but not implemented.

During the first year of the new waiver that began on July 1, 2002, the state attempted to reverify the eligibility of every demonstration enrollee, using new criteria spelled out in the waiver. This process resulted in a shift to TennCare Medicaid of many demonstration enrollees who were found to meet Medicaid eligibility standards. This process also resulted in the disenrollment from TennCare of those people found to be no longer eligible for any category in the program.

One purpose of splitting TennCare into TennCare Medicaid and TennCare Standard was to offer a different benefit package to each group. The projected implementation date for the benefit changes was January 1, 2003, but was subsequently put on hold indefinitely as part of the overall review of the program by the current Administration, which entered office in January 2003. The benefits currently being offered to enrollees in both TennCare Medicaid and TennCare Standard are the same benefits that were available to them prior to July 1, 2002.

Consent Decrees and Agreed Orders

Both before and after the creation of TennCare, several lawsuits were filed against the state related to its Medicaid program. These lawsuits resulted in consent decrees or agreed orders which in many instances imposed additional requirements for the state above and beyond what is required by federal law or the Centers for Medicare and Medicaid Services in the TennCare waiver. A primary example of this is that the state cannot implement a standard prior authorization program for pharmacy benefits. Meeting the requirements of these consent decrees has resulted in added costs to the TennCare program.

The primary cases in which consent decrees and agreed orders have been entered are the following:

- *John B. v. Goetz*, which deals with the requirements for the Medicaid Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program in Tennessee.
- *Rosen v. Commissioner of Finance and Administration*, which deals with requirements related to due process rights for persons applying for TennCare or being disenrolled from TennCare.

- *Grier v. Goetz*, which addresses due process requirements related to denials, reductions, suspensions, terminations, or delays in service delivery.

The state maintains its commitment to honoring the provisions of these consent decrees unless and until they are modified or reversed. Changes in the consent decrees will be required to fully implement this reform proposal. However, if the state is unsuccessful in obtaining necessary judicial relief in order to implement reform, then the state may need to seek reductions in eligibility and benefits in order to meet its budgetary requirements. Such fallback actions are discussed in this application in Chapter 5.

TennCare's financial situation

In the late summer of 2003 Governor Phil Bredesen worked with a group of stakeholders to commission an independent study of the financial viability of TennCare. The stakeholders who provided the financial and administrative support for this study were BlueCross/BlueShield of Tennessee, Hospital Corporation of America, the Tennessee Farm Bureau, Vanderbilt University, and 22 other hospitals acting through the Tennessee Hospital Association. The study was conducted by McKinsey & Company, an international management consulting firm.

The study, which was completed in December 2003, reached the following conclusion:

Our assessment is that, even with current and planned improvement efforts and solid program management, TennCare as it is constructed today will not be financially viable. Without additional reform, the program is projected to become so costly by fiscal year 2008 the state will find it difficult, if not impossible, to both support TennCare and meet its obligations in other critical state programs. TennCare's costs could grow by as much as 80 percent by fiscal year 2008, and its cost growth could represent more than 80 percent of new state revenues in each of the 4 years leading up to that date.²

McKinsey & Company projected that the future growth in TennCare spending would come from many sources, but three areas would likely account for almost 80% of the growth.³ The projected percent of total program growth attributed to these three program areas is as follows:

- Pharmacy—56%
- Professional services—14%
- Outpatient services—8%

McKinsey & Company identified enrollment growth as the fourth key driver of TennCare costs in the coming years.⁴ It is closely correlated with general economic conditions, particularly for those in the traditional Medicaid population.

Tennessee has three major goals with respect to the future of the TennCare program. We want to preserve the program for the 275,000 non-Medicaid uninsured and Medically

² McKinsey & Company, *Achieving a Critical Mission in Difficult Times—TennCare's Financial Viability, Part 1 of a two-part report*, December 11, 2003, p. 3.

³ *Ibid.*, p. 27.

⁴ *Ibid.*, pp. 31-32.

Eligible individuals now enrolled, as well as the 124,000 persons in optional Medicaid categories who are not institutionalized and not eligible for Medicare. We want to be sure that our enrollees get quality health care. And we want to keep growth in program spending at a predictable percentage of the state's total revenues so that we can balance provision of health care for needy citizens with provision of services to address other critical needs, such as education, public safety, and job creation.

The only solution appears to be instituting reforms that will lower the rate of growth in spending, while also addressing quality of care issues. A lower growth rate for Tennessee will, of course, mean a reduction in cost increases for the federal government. For every state dollar saved by reforming TennCare, the federal government will save nearly two dollars.

Governor's plan for reform

On February 11, 2004, McKinsey published the second part of its report, which described a set of 25 potential initiatives for controlling costs in TennCare. Five different combinations of those initiatives were developed as illustrative approaches for consideration. The McKinsey Reports, both Part 1 and Part 2, were widely distributed and discussed by stakeholders throughout Tennessee. They were posted on the Governor's website to facilitate widespread availability.

On February 17, 2004, the Governor presented his TennCare reform plan to the Tennessee General Assembly. He stated that he wanted to preserve the TennCare program for the people it serves, and that he did not wish to simply return to Medicaid. However, he emphasized that fundamental changes would be needed if the program is to continue. He listed four key principles underlying his proposals:

- Fix the problem; don't pass it off.
- Protect children, pregnant women, and the disabled.
- Eliminate fraud and abuse.
- Provide benefits we can afford.

Immediately after the Governor's speech, the Commissioner of Finance and Administration began a process called "TennCare Transformation." The purpose of this process was to develop plans for implementing the broad themes laid out by the Governor. Several subteams were formed to develop individual pieces of the transformation process. These subteams included:

- Key constituent relations
- Change communications
- Actuarial support
- Legal/regulatory/waiver strategy
- MCO optimization
- Benefits, coverage, and enrollment
- Pharmacy
- Care management
- Organization
- Existing program management

The kickoff meeting of the entire TennCare Transformation Team was held on March 4, 2004. Governor Bredesen addressed the group and provided them with their charge. The meeting was attended by several dozen team members, primarily state employees. An intense meeting schedule was developed for all the subteams, as well as the core group of team leaders, with each team responsible for preparing and implementing detailed workplans. Representatives of the Department of Finance and Administration closely monitored the activities of the teams and recorded progress.

In addition to the team activities, the Governor's office worked with legislative leaders to enact legislation that would provide statutory support for the reforms being sought. Two legislative acts were passed. One dealt with programmatic details such as cost controls, care management, and the TennCare Advisory Commission. The second act dealt with fraud and abuse. It created an Office of TennCare Inspector General, and it also added new penalties for fraud committed by both enrollees and providers. The program bill was passed overwhelmingly by the General Assembly on May 6, 2004, and approved by Governor Bredesen on May 17, 2004. The fraud and abuse bill was passed overwhelmingly by the House of Representatives on May 6, 2004, and by the Senate on May 13, 2004, and approved by Governor Bredesen on May 28, 2004.

Chapter 2: Proposed New Components

The new components outlined in this proposed waiver amendment are the result of work performed by Governor Bredesen and the entire TennCare Transformation Team. Implementation of some of these strategies will require waivers of Medicaid statutes and regulations beyond those already approved for the current waiver. Other changes will require modifications of existing waivers and/or authority to receive federal financial participation for costs not otherwise matchable. Some changes can be implemented without any modifications. A summary of additional waiver requests and clarifications is included in Chapter 4.

Each component contains three parts. First, we have described what is included in the current approved waiver on the topic. Second, we have discussed the adequacy of the current waiver for addressing the changes proposed by the Governor. And third, we have listed the specific actions we are proposing.

Component 1: Covered Populations, Benefits, and Cost-Sharing

Provisions of current TennCare waiver

TennCare Medicaid and TennCare Standard. The current waiver divides all enrollees into two groups: TennCare Medicaid and TennCare Standard. All Medicaid eligibles are included in TennCare Medicaid. All demonstration eligibles, meaning persons who are eligible for TennCare under the terms of the waiver (or “demonstration”), are included in TennCare Standard.

Open and closed enrollment. Medicaid eligibles can, of course, enroll at any time. In addition, our current waiver allows us to offer continuous enrollment to Medically Eligible persons with incomes below poverty.

New uninsured persons, as well as new Medically Eligible persons with incomes at or above poverty, may enroll in TennCare only during designated open enrollment periods. As many as two open enrollment periods may be held each year, depending upon the availability of funding from the General Assembly. Income limits for uninsured people can be set at any level up to 200% of poverty and can vary within that limit for subpopulations such as adults and children. There has been no open enrollment for uninsured persons since the new waiver began on July 1, 2002.

Tennessee has had an IMD (Institutions for Mental Diseases) waiver since January 1994. That waiver is scheduled to phase out in June 2007, which will affect coverage for persons aged 21-65 who are residing in those institutions.

Benefits. The current waiver describes four sets of benefits:

- A benefit package for Medicaid children;
- A benefit package for Medicaid adults;

- A benefit package for people in TennCare Standard;
- A pharmacy-only package for “grandfathered” TennCare/Medicare dual eligibles⁵.

The separate benefit packages have not been implemented. Covered benefits continue to be available as medically necessary to all enrollees.

The current waiver has a limitation of \$30,000 in lifetime benefits for inpatient and outpatient substance abuse treatment services for adults. The previous waiver had this same limit, but it was waived for adults with Severe and/or Persistent Mental Illness (SPMI). Because of the inability to implement the new benefits in the current waiver which has been discussed elsewhere in this application, the limitation continues to be waived for adults with SPMI.

Cost-sharing. There are no cost-sharing requirements for TennCare Medicaid eligibles. TennCare Standard enrollees with incomes at or above poverty are required to pay premiums, as well as copays on certain services (inpatient, outpatient, physician, vision, dental, home health care, pharmacy, and speech therapy). TennCare Standard enrollees with incomes below poverty are required to pay copays on pharmacy services.⁶ Denial of pharmacy services is permitted for TennCare Standard enrollees who do not make their copays.⁷

The current waiver has two Out-of-Pocket (OOP) Maximums for TennCare Standard. There is an overall OOP maximum for persons with copay responsibilities, which is \$1,000 for individuals and \$2,000 for families with incomes between 100% and 199% of poverty. For persons with incomes at or above 200% of poverty, the OOP maximum is \$2,000 for individuals and \$4,000 for families. In addition, there is a pharmacy individual OOP maximum, which is \$150 per month.

“Waiver duals” (people who are in the grandfathered group eligible for TennCare and Medicare but not Medicaid as of December 31, 2001) were to be eligible for pharmacy services only, effective January 1, 2003.⁸ A separate pharmacy-only premium was approved for this group.

MCO choice. The currently approved waiver envisioned that enrollees would have the opportunity to change MCOs at the same time that they present themselves for renewal of their eligibility. They can also change MCOs through the appeals process. Attachment II-E of the approved Operational Protocol provides medical hardship criteria that may be used when enrollees wish to change MCOs.

⁵ “Grandfathered” TennCare/Medicare duals are persons who were enrolled in TennCare and Medicare but not Medicaid on December 31, 2001, and who have remained continuously eligible in this category. This is a category that was “grandfathered” from the previous waiver. No new individuals are being enrolled.

⁶ These separate pharmacy copays have not been implemented.

⁷ This provision has not been implemented.

⁸ This provision has not been implemented. On May 22, 2003, the state requested CMS to remove the limitation of “pharmacy-only” services for this population. No decision has been provided to the state.

Adequacy of current TennCare waiver

Simply dividing the TennCare population into Medicaid eligibles and non-Medicaid eligibles and defining benefits accordingly does not allow us to tailor benefits and provide sufficient protection to certain groups who need it—namely, children, pregnant women, and individuals with disabilities. Fairness dictates that copays and premiums should be spread more evenly across as much of the TennCare population as possible. We also believe it is appropriate to ask demonstration eligibles, even people in vulnerable populations, to share in the cost of their care.

One problem that has been experienced is the delivery of methadone services as part of the inpatient and outpatient substance abuse benefit. The state has experienced difficulty in that few methadone clinics have been willing to contract with the BHOs. This problem has resulted in the state's having to make direct payments to enrollees who have received methadone clinic services. In the Appropriations Bill of 2003, the Tennessee General Assembly indicated its intent that "no payments shall be made to patients" receiving methadone treatment.⁹ This is a situation which cannot be allowed to continue.

Proposed actions

TennCare Medicaid and TennCare Standard. First, we are seeking approval to regroup TennCare enrollees in the TennCare Medicaid and TennCare Standard programs mentioned above. In this proposal, TennCare Medicaid will be limited to mandatory Medicaid eligibles and certain closely related categories.¹⁰ Optional Medicaid enrollees will be moved to the demonstration population and enrolled in TennCare Standard. (Removal of these persons from the current Medicaid population will be accomplished through amendments to Tennessee's Title XIX State Plan.)

The revised demonstration populations are as follows:

- **Demonstration Population 1: Uninsured individuals with incomes below 200% of poverty.** This group is currently in the demonstration population with an income limit of 200% of poverty. New members of the group may enroll only during announced periods of open enrollment, although individuals who are losing Medicaid eligibility and who are otherwise eligible for this category may join this category at the time they leave Medicaid. (These people are called "Medicaid rollovers.") The current number of individuals enrolled in Demonstration Population 1 as of June 2004 is approximately 169,000.

⁹ Public Chapter 356 of the Public Acts of 2003, Section 10, Item 36(3).

¹⁰ For administrative simplicity, we have included with the mandatory Medicaid population those Medicaid categories that are optional but closely related to mandatory categories, such as TANF extends from 12-18 months and PLIS women and infants between 133% and 185% poverty. All Medicaid institutionalized individuals are also included.

- **Demonstration Population 2: Uninsured individuals who have been determined to be Medically Eligible.** This group is currently in the demonstration population. New members of the group with incomes below poverty can enroll at any time. New members of the group with incomes at or above poverty may enroll only during announced periods of open enrollment, although individuals who are losing Medicaid eligibility and who are otherwise eligible for this category may join this category at the time they leave Medicaid. (These people are called “Medicaid rollovers.”) The current number of individuals enrolled in Demonstration Population 2 as of June 2004 is approximately 106,000. (This figure includes persons in the grandfathered “waiver dual” category.)
- **Demonstration Population 3: Individuals who meet the criteria for the Medically Needy category who are neither institutionalized nor dually eligible for Medicaid and Medicare.** At present this group is enrolled as an optional Medicaid category. The current number of individuals enrolled in Demonstration Population 3 as of June 2004 is approximately 123,000.
- **Demonstration Population 4: Uninsured women under age 65 who have been screened by a CDC site and found to need treatment for breast and/or cervical cancer.** At present this group is enrolled as an optional Medicaid category. The current number of individuals enrolled in Demonstration Population 4 as of June 2004 is 537.

We wish to clarify that the individuals in Demonstration Populations 3 and 4 will continue to be treated as “hypotheticals” for the purpose of calculating budget neutrality. They will be categorized as Medicaid Eligibility Group 2, as MEGs are defined in Attachment C of the current Special Terms and Conditions of the waiver.

It is Tennessee’s wish to separate the Medically Needy category into institutionalized and non-institutionalized populations. The institutionalized population will remain in the Medicaid group, as will the Medically Needy who are dually eligible for Medicare and Medicaid, and the non-institutionalized, non-dually eligible population will move to TennCare Standard.

Table 1 shows the proposed the proposed new composition of TennCare Medicaid. Table 2 shows the proposed new composition of TennCare Standard.

Table 1
Composition of TennCare Medicaid in the New Waiver Amendment

Note: The number of people in each category is unduplicated from top to bottom. That means that an individual on SSI who is dually eligible for Medicare and Medicaid, as an example, will be counted in the Dual Eligible category (which comes first) and not the SSI category (which comes later). Numbers are current as of June 2004.

	Children under age 21	Adults	Total
Medically Needy persons who are institutionalized and/or dually eligible for Medicare and Medicaid	32	36,341	36,373
Non-Medically Needy persons who are institutionalized and/or dually eligible for Medicare and Medicaid	805	167,413	168,218
SSI (non-institutionalized, non dual eligibles)	43,886	104,217	148,103
TANF/Categorical Medicaid Only, including 18 months extended Medicaid	258,379	112,549	370,928
PLIS pregnant women to 185% poverty (includes presumptive eligibles); infants to age 1 to 185% poverty, children 1-6, 133% poverty, children 6-19, 100% poverty (includes DCS children)	196,568	11,440	208,008
Other	27	773	800
TOTAL	499,697	432,733	932,430
Total TennCare population	618,772	712,500	1,331,272
Percent of the total TennCare population that is eligible for TennCare Medicaid	81%	61%	70%

Note: TANF = Temporary Aid to Needy Families. PLIS = Poverty Level Income Standard. SSI = Supplemental Security Income. "Institutionalized" individuals include those who are enrolled in HCBS waivers who, but for the HCBS waiver, would require institutional placement.

Table 2
Composition of TennCare Standard in the New Waiver Amendment

Note: The number of people in each category is unduplicated. That means that an individual who qualifies as both an Uninsured and a Medically Eligible, as an example, will be counted in the Uninsured category (which comes first) and not the Medically Eligible category (which comes later). Shaded categories are those that are presently included in TennCare Medicaid. Numbers are current as of June 2004.

	Children under 21	Adults	Total
Non-institutionalized Medically Needy who are Aged, Blind, and Disabled AND are not also eligible for Medicare	3	10,011	10,014
Non-institutionalized Medically Needy who are in a category other than Aged, Blind, and Disabled AND are not also eligible for Medicare	63,144	49,854	112,998
Women needing treatment for breast and/or cervical cancer	0	537	537
Uninsured	54,350	146,997	201,347
Medically eligible	1,578	72,368	73,946
TOTAL	119,068	279,767	398,842
Total TennCare population	618,772	712,500	1,331,272
Percent of the total TennCare population that is eligible for TennCare Standard	19%	39%	30%

We are seeking to withdraw the provision of the current waiver that calls for a pharmacy-only program for grandfathered TennCare/Medicare duals. This program was never implemented.

Regarding coverage of methadone clinic services, it is our intent to remove this benefit from the TennCare program effective January 1, 2005, if methadone clinics remain unwilling to contract with the BHOs. As stated earlier, the Tennessee General Assembly has stated its intent that the practice of paying enrollees directly for the care they have received in methadone clinics must end. If we are unable to deliver this service through BHO providers, then we plan to remove it as a covered benefit. Whether or not methadone clinic services remain covered, however, we are proposing to implement the provision in the current waiver to limit inpatient and outpatient substance abuse benefits for all adults.

And finally, we would like to request a limited continuation of the IMD waiver that is due to expire on June 30, 2007. Under this more limited waiver, Tennessee would be able to continue to cover care provided to IMD residents *outside* of the institution, but the IMD services themselves would not be covered. Should the more limited waiver not be granted, we plan to implement a "suspension of benefits" policy whereby IMD patients are not disenrolled from TennCare but only suspended during the time they are in an IMD.

Open and closed enrollment. We are seeking the ability to offer different types of enrollment periods for different demonstration populations. Open enrollment for persons in Demonstration Population 1 and for persons with incomes above poverty in Demonstration Population 2 will continue to occur as described in the current waiver. We want to offer continuous enrollment for persons in Demonstration Populations 3 and 4 (see above), since these individuals presently have the opportunity to enroll at any time under Medicaid.

Enrollee choice of MCOs. With respect to assuring enrollee choice of MCOs, we plan to return to the annual ballot arrangement that was used in the first years of TennCare. Rather than allowing enrollees to change throughout the year, we will have a single ballot period when they can change. The ballot period will be held in the fall in order to allow all changes to be complete by January 1. We will still have an appeals process for hardship circumstances, but we expect that this process will be much more limited than it is currently. The first ballot period under the new waiver will be held in the fall of 2005.

Benefits. There will continue to be no benefit limits for medically necessary covered services offered to the core TennCare Medicaid population. However, for the new TennCare Standard population, we are proposing to organize the benefit packages differently from the manner in which they are outlined in the approved waiver. We want to have some benefit limits for certain persons in TennCare Standard, but we want to exempt three groups: namely, children under age 21, pregnant women, and persons with disabilities.¹¹ Services in excess of these benefit limits will not be considered to be covered TennCare services.

In the Governor's February speech to the General Assembly, he proposed a definition of disabled that would have exempted from benefit limits those persons who qualified for Supplemental Security Income (SSI). After considerable consultation and public input, the number of persons who would be exempted from benefit limits was expanded to include the following:

- Persons with Supplemental Security Income (SSI);
- Persons eligible for Medicaid Medically Needy as Aged, Blind, or Disabled;
- Persons who are receiving Medicaid institutional services;
- Persons who are receiving Medicaid Home and Community Based Services Waiver (HCBS) services;
- Persons eligible for a mandatory or optional Medicaid category (even if those categories are moved to the demonstration population) who are receiving Supplemental Security Disability Income (SSDI).

For non-exempt persons in the TennCare Standard population, the following benefit limits would apply:

- Inpatient hospitalizations—45 days per enrollee per year
- Physician outpatient services—10 visits per year
- Hospital outpatient services—8 visits per enrollee per year

¹¹ The "disabled" in the demonstration population includes Medically Needy individuals in the aged, blind, or disabled category, as well as Medically Needy and Breast/Cervical Cancer enrollees who receive Supplemental Security Disability Income (SSDI).

- Lab and X-ray—10 occasions per enrollee per year
- Pharmacy—6 prescriptions per enrollee per month

Again after public consultation and input, the decision was made that the non-pharmacy benefit limits described above will not apply to behavioral health services, such as acute inpatient psychiatric inpatient hospitalization or psychological counseling.

Prior to implementation of the benefit reductions, we will identify a short-list of encounter types and products that will not count toward the above limits, including, for example, most chemotherapy and radiation treatments for cancer patients.

In addition, we wish to clarify that the benefits package we are providing to the TennCare Standard population subject to these benefit limits does not include coverage of any services provided pending allowable factual appeals of the application of benefit limits or the denial of services for failure to make copays or premiums. Enrollees who bring successful appeals will be retroactively covered for any services provided while the appeal was pending.

We estimate that, at most, 20% of the TennCare population will be subject to benefit limits. See Table 3 below.

Table 3
Enrollees with Benefit Limits in TennCare Standard

Note: Numbers below are overstated, since they include pregnant women and persons receiving SSDI payments. Pregnant women in any of the categories listed below will be moved to an exempt status at the time TennCare learns of their pregnancy. Persons enrolled in either the Medically Needy category or the category for Women with Breast or Cervical category who are identified as being recipients of SSDI payments will be moved to exempt status at the time TennCare learns of their SSDI status.

Categories with Benefit Limits	Numbers
Non-institutionalized MN adults who are not categorized as aged, blind, or disabled OR dually eligible for Medicaid and Medicare	49,854
Women needing treatment for breast and/or cervical cancer	537
Uninsured adults	114,385
Medically eligible adults	66,770
Medically eligible adults with Medicare	38,210
TOTAL	269,756
Total TennCare population	1,331,272
Percent of total TennCare population with benefit limits	20%

At a point in the future when the disease management initiative discussed as Component 3 (see below) is viable, Tennessee may wish to re-visit benefit limits for

those enrolled in disease management who are receiving evidence-based medical treatment. Many of the individuals participating in disease management will be exempt from benefit limits by virtue of their eligibility category. However, for those participants who are subject to benefit limits, we think it may make sense over time, as disease management and evidence-based medicine approaches are put in place, to tailor benefit limits in accordance with evidence-based medicine guidelines for particular diseases or disease categories in order to improve health outcomes and to better manage the overall cost of delivering care.

Cost-sharing and premiums. All TennCare Medicaid enrollees will continue to be exempt from premium and copay responsibilities. The optional Medicaid enrollees, other than children, who will be reclassified as demonstration eligibles for the TennCare Standard population will no longer be exempt from premiums or copays, however.

Rather than having copays just for those with incomes at or above poverty, we are proposing copays for TennCare Standard enrollees at all income levels. Table 4 shows the proposed sliding scale-arrangements.

Table 4
Proposed Copays¹² for Enrollees in TennCare Standard

Service	Enrollees at or below 49% poverty	Enrollees between 50% and 99% poverty	Enrollees between 100% and 299% poverty	Enrollees at or above 300% poverty
Inpatient hospital (per admission)	\$30	\$50	\$100	\$250
Outpatient services (per visit)				
--Non specialist	\$1	\$10	\$20	\$30
--Specialist/OP	\$3	\$15	\$25	\$40
hospital service				
--ER visit that does not lead to admission	\$10	\$20	\$40	\$60
Pharmacy ¹³				
--A-drugs*	\$1	\$3	\$5	\$10
--B-drugs*	\$2	\$7	\$10	\$20
--C-drugs*	\$3	\$10	\$15	\$40
Other (per visit)				
--Speech therapy/PT/OT outside of a home health visit	\$1	\$10	\$15	\$20

**If the categorization of drugs as A-drugs, B-drugs, and C-drugs is not complete by the time of implementation, we will define these categories, for copay purposes, as follows:*

Copay that is usually for Category A = All generics

¹² Providers may deny services to individuals who do not make their required copays.

¹³ No copays for family planning prescriptions.

Copay that is usually for Category B = Brand names currently on the Preferred Drug List (PDL) for categories reviewed; brand names for categories NOT reviewed for the PDL to date (e.g., behavioral health drugs and others)
Copay that is usually for Category C = Brand names currently not on the PDL for categories reviewed

In the interest of simplicity, we are requesting to remove the current Out-of-Pocket (OOP) maximums.

In addition, we are seeking approval to extend the provision in the current waiver allowing denial of pharmacy services to individuals who do not make their required copays. We propose to permit denial of any service requiring a copay to enrollees with copay obligations who fail to make their copays. No mandatory Medicaid eligibles will have copay responsibilities, and therefore this policy will not result in denial of services to any TennCare Medicaid enrollees.

Premiums have remained at the same level since 2000. We are proposing to reset the premiums to be more in line with the rate of medical inflation. Although using the medical inflation rate for the period from 2000-2004 would mean an increase of 24%¹⁴ in premiums, we are proposing a more modest increase. The proposed new premium arrangements are shown in Table 5. It is our intent to adjust the premiums in future years annually by a rate not to exceed the rate of medical inflation. We will continue to require premiums only of TennCare Standard enrollees with incomes at or above poverty. As in the past, we intend to disenroll TennCare Standard enrollees (after appropriate notice) who have failed to pay their premiums. The eligibility criteria for this population includes payment of premiums.

**Table 5
Proposed Monthly Premiums for Enrollees in TennCare Standard**

Income Levels	Medicaid	TennCare Standard Individual	TennCare Standard Family
Below 100% poverty	---	---	---
100%-149% poverty	---	\$24	\$48
150%-199% poverty	---	\$42	\$84
200%-249% poverty	---	\$120	\$300
250%-299% poverty	---	\$180	\$450
300%-349% poverty	---	\$240	\$600
350%-399% poverty	---	\$300	\$750
400%-499% poverty	---	\$420	\$1050
500%-599% poverty	---	\$540	\$1350
600% poverty and above	---	\$660	\$1650

¹⁴ Since the 2004 calendar year is not yet complete, we are using for 2004 the compound annual growth rate (CAGR) from 2000-2003.

Notice and appeal rights. Tennessee complies with federal requirements relating to notice, appeal, and continuation of benefits to the extent applicable to TennCare enrollees. In order to administer the new benefit limits and premium and cost-sharing provisions effectively, however, Tennessee is seeking assurances that the state may limit TennCare Standard enrollees' ability to appeal the application of benefit limits, copayments or premiums and denials of service or coverage related to nonpayment of copays or premiums to factual disputes only. Thus, only appeals challenging whether in fact a benefit limit was reached or applicable, or whether in fact a copay/premium was paid will be permitted. Appeals challenging (i) the implementation of the benefit limit, copayment or premium structure or (ii) service or coverage denials in particular circumstances (e.g., contending that a particular service was necessary notwithstanding the benefit limit or failure to make copayments/premiums) will not be permitted. Tennessee will not provide coverage for any services rendered during the pendency of such an appeal because such services are not part of the TennCare Standard benefit package. Tennessee will provide retroactive coverage of any such services in the event such an appeal is successful.

Tennessee intends to provide proper notification of benefit limits and the consequences of failures to make copayments/premiums prior to implementation of these policies. However, enrollees will not be given notice that they are nearing a benefit limit or after they have reached a benefit limit. Nor will the state or MCO provide any form of notice upon service denials based on exceeding a benefit limit or nonpayment of copayments.

These adjustments in Tennessee's notice, appeals, and continuation of benefit policies are intended to avoid unnecessary costs of frivolous appeals that could otherwise be spent on actual services for enrollees. Challenges to underlying TennCare policies on benefits limits and copayments/premiums that are couched as appeals of individual service denials are not an efficient use of TennCare resources. This approach is consistent with federal regulations applicable to the Medicaid population, which explicitly preclude appeal rights when "the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients" (42 CFR § 431.220(b)).

Component 2: Pharmacy Benefit

Provisions of current TennCare waiver

Prescription drugs are covered as medically necessary, with DESI, LTE, and IRS¹⁵ drugs excluded. For TennCare Standard, copays of \$5 for generic drugs or refills and \$15 for brand names or refills are required.¹⁶ Providers have the discretion to refuse pharmacy services to individuals who are unwilling or unable to make their pharmacy copays, although this provision has not been implemented.

¹⁵ DESI, LTE, and IRS drugs are all designations for drugs which have not been proven to be effective.

¹⁶ These copays have not been implemented. Tennessee is continuing to use the pre-July 2002 copays, which are \$5 for TennCare Standard members with incomes between 100% and 200% poverty and \$10 for TennCare Standard members with incomes at or above 200% poverty.

A separate pharmacy-only program, which has not been implemented, is outlined for persons in the grandfathered TennCare/Medicare dual eligible group.¹⁷ There is a separate pharmacy-only premium required for these individuals.

Compliance with statutory limitations on coverage restrictions for outpatient drugs was waived so as to permit managed care contractors to establish drug formularies based on cost, therapeutic comparability, and clinical efficacy.

At present TennCare covers some over-the-counter drugs in certain situations.

Adequacy of current TennCare waiver

Pharmacy is the key driver of growth in TennCare spending. It has been documented that Tennessee citizens (not just those on TennCare) use more prescriptions per person than citizens in any other state.¹⁸ McKinsey & Company estimates that pharmacy costs will drive nearly 60% of the total growth in TennCare through fiscal year 2008, based on existing trends.¹⁹

There is a significant opportunity to reduce the rate of growth of pharmaceutical spending and to improve the quality of care for this population through a set of initiatives that manage both the unit costs and the utilization of pharmaceuticals. An expanded waiver will permit implementation of a comprehensive, statewide initiative designed to restrict unnecessary coverage of costly drugs that have no significant advantage for beneficiaries in terms of therapeutic advantage or clinical efficacy.

Pharmaceutical prices vary widely, with large differences between branded drugs and generic drugs. TennCare's average cost for branded drugs is \$63 per prescription, while its average cost per generic drug is \$18. In recent years, there has been a significant number of patent expirations of brand name drugs, and as a result, there are generic alternatives available in many therapeutic categories. Given this situation, there is significant opportunity to manage costs while maintaining quality through programs that encourage the use of the lowest cost clinically appropriate drug within a therapeutic category.

Taking advantage of this opportunity could mean requiring the use of a generic drug, such as the use of generic ACE inhibitors to treat hypertension. Or it could mean allowing the use of the lowest cost branded drug, such as the use of a brand-name statin to aggressively lower cholesterol if there are specific conditions where that is absolutely appropriate, such as with a patient who has already suffered a heart attack. TennCare's current generic drug utilization by prescription in its top ten drug classes has been less

¹⁷ "Grandfathered" TennCare/Medicare duals are persons who were enrolled in TennCare and Medicare but not Medicaid on December 31, 2001, and who have remained continuously eligible in this category. This is a category that was "grandfathered" from the previous waiver. No new individuals are being enrolled.

¹⁸ McKinsey & Company, *Achieving a Critical Mission in Difficult Times—TennCare's Financial Viability, Part 1 of a two-part report*, December 11, 2003, p. 30, quoting the Kaiser Family Foundation, Verispan Scott-Levin Source™ Prescription Audit: Special Data Request, 2003. See also Alan Sagar and Deborah Socolar, "Poorer, Sicker States Face Heavier Drug Cost Burdens," Boston University School of Public Health, July 14, 2004.

¹⁹ *Ibid.*, p. 29.

than 50%. Programs in the commercial world have been able to increase generic drug utilization to over 75% without adversely affecting clinical outcomes.

In addition to this strategy, we plan to implement a set of initiatives to manage the utilization of pharmaceuticals. More aggressive use of prospective and retrospective drug utilization review programs is planned in order to encourage the proper use of pharmaceuticals, to prevent adverse effects, and to improve the overall quality of care.

Proposed actions

The goal of the proposed changes is to reduce pharmacy costs while ensuring quality. We want to make better use of a preferred drug list and a formulary to accomplish these goals. While the state recognizes that certain of the reforms it intends to implement pursuant to this waiver request, as described below, would not be consistent with the provisions of consent decrees that currently bind the state, we would anticipate obtaining modifications of those consent decree provisions prior to implementing the affected reforms.

It is our proposal to establish three drug groupings to achieve a balance of clinical and financial benefits. A Pharmacy and Therapeutics (“P&T”) Committee meeting the description at Section 1927(d)(4)(A) of the Social Security Act will make recommendations regarding the therapeutic comparability of drugs to be included on the formulary and recommend clinical guidelines. TennCare will review these recommendations but is ultimately responsible for the final decisions on the formulary and for grouping drugs into A, B, and C categories based on clinical efficacy, side effect profile, and cost considerations.

Drug groupings are as follows:

A-drugs Preferred drugs which could be dispensed without prior authorization. Included in this category would be therapeutically safe and effective but relatively low cost pharmaceutical products as well as generic drugs and drugs for which there is no therapeutically comparable alternative available at lower cost. Under this option, one or two drugs per therapeutic class—representing the least expensive alternative(s) among therapeutically comparable pharmaceutical products—would be designated as “preferred.” If there were several drugs within the therapeutic class that were the same cost, more than two drugs could be in the A-category. In some drug classes, there may be no A-drug for a particular group; for example, where all drugs in a therapeutic class uniformly require preauthorization in order to assure utilization consistent with health and safety considerations.

B-drugs Drugs that are therapeutically comparable to and yet higher-cost than alternatives in the “preferred” category, but for which there are nevertheless some set of clinical scenarios that may make their prescription and use appropriate in lieu of a “preferred” product in some limited number of cases. These drugs would be included on the state’s formulary, but unlike “preferred” products would require prior authorization in advance of any

covered use by TennCare beneficiaries. The prior authorization process would be designed to insure that the drugs are used in accordance with explicit clinical criteria and indications. For example, a high potency statin might be designated as a B-drug based on a detailed clinical guideline that outlined the clinical scenarios for which a lower-potency statin should be the first alternative and the scenarios for which a higher-potency statin is appropriate. In some circumstances, there may be classes of drugs composed only of products that are in the B-drug category, because the P&T Committee recommends that these drugs should be reserved for specific narrowly defined clinical scenarios: e.g., the use of Cox-2 inhibitors for patients with a high risk of gastric problems.

C-drugs **All drugs not explicitly designated as A or B drugs.** These drugs would be excluded from the state's formulary and considered "non-formulary." They would not be covered except in very rare, unique, and/or novel clinical scenarios pursuant to a very stringent exceptions process, in which prior authorization for a covered use of the drug may be afforded based on demonstration in the individual case of medical necessity as defined by the state, e.g., documented significant side effects to drugs in the A and B categories.

As a broad statement of policy, we intend to stop coverage of all over-the-counter drugs, as permitted by law.

We will also exclude from coverage certain classes of drugs for which functionally comparable and appropriately substitutable drugs are available over-the-counter in non-prescription form. In particular, approval is being sought to eliminate the coverage for adults of both prescription and over-the-counter forms of antihistamines (i.e., both sedating and non-sedating antihistamines) and gastric acid reduction drugs; i.e., H2 blockers and proton pump inhibitors. TennCare will continue to cover these prescription drugs for children.

Elimination of coverage of these few drug classes will achieve substantial programmatic savings, enabling TennCare to more effectively direct available funds to therapies and services that are more frequently necessary to treat potentially disabling or life-threatening conditions, and are likely to have a greater impact on the preservation and enhancement of the long-term health of the TennCare beneficiary population as a whole. It is unlikely that these new coverage restrictions will have significant negative effects on the health of the beneficiary population, given the ready availability of over-the-counter medications that are effective in the management of virtually all of the conditions for which the prescription forms of these drugs are utilized.

Since these categories of drugs have been available over-the-counter, several managed care companies and pharmacy benefit managers in the private sector have adopted similar restrictions on coverage of these types of drugs and encouraged over-the-counter use for a variety of conditions, including unlabeled conditions.²⁰ For example, in October 2003, Aetna Inc. stopped covering prescription omeprazole sold in a 20 milligram dose for the majority of members in its drug plans, steering them instead to

²⁰ Med Ad News. Prilosec enters the nonprescription heartburn market with a bang, pushing aside prescription drugs, November 2003.

Prilosec OTC.²¹ Commercial plans have been doing this because formulation of Prilosec OTC contains the same chemical omeprazole that is in generic formulations of omeprazole and in the prescription form of Prilosec. Bioavailability of OTC Prilosec is also similar to Rx Prilosec.²² A similar situation exists with the OTC antihistamines; i.e., the formulation of Claritin OTC contains the same chemical loratadine that is in the prescription form of Claritin.²³ As a result, many commercial plans have stopped covering Claritin, and encouraged OTC use instead.²⁴

The state recognizes that full implementation of these proposals may require modification of one or more provisions of currently effective federal district court consent decrees. In the event that the state is unsuccessful in obtaining any requisite modifications of those decrees, it may be necessary to achieve needed cost savings through alternative means, which might include (among other reductions) elimination of outpatient pharmacy coverage for the demonstration population, further reduction of the number of covered prescriptions for all TennCare beneficiaries, or possibly amendment of the State Plan to eliminate the optional outpatient pharmacy benefit from the TennCare program altogether for some or all TennCare enrollees. Although the state is hopeful that there will be no need to pursue any of these options, we wish to emphasize at this time that the state may later seek additional approvals on an expedited basis in order to enable further reductions to be implemented, such as, if necessary, elimination of all coverage of outpatient pharmacy benefits currently available to the demonstration population, or possibly to an even broader segment of current TennCare enrollees.²⁵

As already stated, it is our intent to impose a limit of six prescriptions per month for all enrollees not designated as exempt. We will require copays for prescription drugs from enrollees in TennCare Standard, although we plan to exempt children from this requirement. Pharmacy copays are shown in Table 4.

We also plan to enhance our prospective and retrospective drug utilization programs, targeted in areas where there is evidence of overuse and potential misuse, such as the use of narcotics, anti-psychotics, and polypharmacy. Some of these programs will involve patient counseling and provider profiling programs. In addition, we plan to implement initiatives to better manage the cost and utilization of “medical” pharmaceuticals including injectables and biologics.

²¹ Sarah Ellison, Prilosec OTC: P&G’s Blitz in New Drug Foray. Wall Street Journal, September 12, 2003.

²² http://www.prilosec.com/hcp/hcp_overthecounter.jsp -- graph bioavailability of Prilosec OTC compared to RxPrilosec.

²³ OTC Claritin, Medical Letter, January 6, 2003.

²⁴ Med Ad News. Manufacturers resist efforts to switch prescription drugs over-the-counter as they try to increase sales in a declining antihistamine market. October 2003.

²⁵ In the state’s view, no waiver of applicable statutory provisions is necessary in order to authorize the elimination of outpatient pharmacy coverage for the demonstration population. Nevertheless, to the extent that waiver of provisions referenced in Chapter 4 of this document under the heading of “Exceptions to Medicaid Requirements for the Demonstration Population” may be deemed to be required in order to enable the state to take such action, we would request such approval from the Secretary as may be required in order to implement any further coverage or benefit reductions that may need to be implemented in the future.

We are also considering use of the federal 340B drug discount program to improve pharmacy services and lower drug costs for certain segments of the TennCare population, such as those who are taking a higher number of maintenance medications or who fall within certain disease groups such as asthma, diabetes, chronic obstructive pulmonary disease, and other chronic conditions. Tennessee may conduct a competitive procurement and contract with one or more 340B facilities participating in the 340B program, including disproportionate share hospitals, Federally Qualified Health Centers (FQHCs), and FQHC look-alikes. The contract would require the successful proposer to provide or manage care provided to the target population using techniques such as disease management, case management, and/or telemedicine and to provide pharmacy services either through a mail-order program or a network of retail pharmacies under contract with the 340B entity. Where the contract requires disease management services, this strategy would be integrated and coordinated, for target populations, with the disease management program outlined in Component 3 below.

Finally, we are proposing to remove from the waiver the approved pharmacy-only program for grandfathered TennCare/Medicare duals, since this has never been implemented.

Component 3: Care Management

Provisions of current TennCare waiver

There is no mention of a disease management program in the current waiver. Disease management is currently provided by some MCOs, but disease management efforts are limited in scope and not comprehensive.

Although the current waiver does not contain provisions related to disease management, several of the MCOs have implemented disease management initiatives as part of their medical management activities. Targeted conditions for these disease management programs have included asthma, heart disease, and diabetes. Most TennCare disease management activities in Tennessee were implemented as pilot projects and funded outside the TennCare program by Applied Health Outcomes. Results of these activities have not been measured at the present time.

Adequacy of current TennCare waiver

To the extent that no specific waivers are required to implement a voluntary disease management program, the current waiver is adequate. However, Tennessee is interested in pursuing changes to standardize and expand the use of disease management services in TennCare.

Disease management is a concept that makes a great deal of sense in TennCare. Fifteen percent of TennCare enrollees account for approximately 75 percent of program costs, and four percent of enrollees account for approximately 43 percent of program

costs.²⁶ In addition, many high cost enrollees have multiple diagnoses and chronic conditions, and 40 to 50 percent of this group continues to be high cost users in a subsequent year.²⁷ To control the rising costs associated with these groups, Tennessee plans to implement disease management strategies more widely.

Proposed actions

We are proposing to implement a multi-faceted and innovative disease management program in phases over time to improve the health outcomes and reduce overall costs of caring for enrollees with certain high cost diseases. In the initial phase, TennCare will contract with a vendor to provide both expert clinical and technical support to the physicians and practitioners treating enrollees with certain identifiable diseases and by providing educational interventions to assist patients in managing their diseases more effectively. Expert clinical and technical support will include:

- distribution of evidence-based practice guidelines;
- development of collaborative practice models to include physicians, support service providers and managed care organizations;
- process and outcomes measurement, evaluation, and management; and
- implementation of a routine reporting/feedback loop which may include communication with the enrollee, the physician, the health plan, and ancillary providers and practice profiling.

Patient educational interventions will include primary prevention, behavior modification programs and compliance/surveillance.

The initial eligibility group to be targeted is likely to be SSI adults (age 21 and older) who are not dually eligible for Medicare and who are not institutionalized. Members of this group identified for disease management will automatically be included in the program unless they opt out.

Currently, it is anticipated that enrollees not in the initial eligibility group will be considered for inclusion in the common chronic diseases group on an opt-in basis if they meet criteria established by the disease management vendor and are recommended by TennCare.

Diseases and conditions to be included in this program will likely include the following, plus any additional diseases or conditions selected by the disease management vendor:

- Diabetes mellitus
- Congestive heart failure
- Coronary artery disease
- Asthma
- Chronic obstructive lung disease
- Schizophrenia
- Bipolar disorder
- Major depression

²⁶ McKinsey & Company, *Achieving a Critical Mission in Difficult Times—Illustrative Strategic Options for TennCare, Part 2 of a two part report*, February 11, 2004, p. 29.

²⁷ *Ibid.*, pp. 29-30.

We envision complex case management of selected rare diseases and conditions. In addition, a 24/7 nurse information line for participants in the disease management program and their caregivers is anticipated.

The state plans to contract with a disease management vendor to deliver the program. Potential proposers will be asked to provide disease management of the above diseases as well as others where there could be improved clinical outcomes in the selected disabled population. The disease management vendor must integrate its services with the Managed Care Organizations, Behavioral Health Organizations, and pharmacy benefit manager serving TennCare enrollees. It is possible that an MCO may bid on the contract and become the disease management vendor. This integration will ensure that the services offered by those entities are not duplicated but enhanced by the program. The current plan envisions that the vendor will be asked to guarantee its fees and some portion of potential savings. The Bureau will ensure that there is no duplication in costs and/or effort by the MCOs and the disease management vendors.

Future programs targeted for implementation include:

- Contracting with a vendor/physician/provider to provide comprehensive care management of the institutionalized dually eligible enrollee. The vendor would work to reduce hospital readmissions and complications for institutionalized individuals resulting in improved quality of life and reduced costs.
- Contracting with vendors, hospitals or providers to improve the care and timely discharge of premature neonates. The vendor would be expected to provide intensive caregiver training and discharge planning to facilitate timely discharge of the neonate and prevent costly readmissions.
- Contracting with an outside vendor to improve quality and optimize utilization of advanced imaging. The vendor would provide prior authorization and real-time consultation on selection of the most appropriate advanced imaging procedures in the outpatient setting.
- Development of innovative provider-led care management initiatives that promote evidence-based medicine. Tennessee is considering implementation of a number of initiatives that could promote evidence-based medicine through a state-funded, independent, evidence-based medicine group with members from the payor, provider, consumer and academic communities. This group would be responsible for implementation and oversight of practice guidelines, collecting and analyzing outcomes data and reviewing the impact of new technology on quality and cost. Outcomes data from TennCare, Medicare, and commercial payors would be included.

Component 4: Advisory Commission

Provisions of current TennCare waiver

The current waiver calls for an advisory board to be appointed by the Governor and comprised of 12-15 individuals who are health care and business leaders, providers, and consumers. TennCare and the Tennessee Department of Commerce and Insurance are responsible for presenting to the board every three months an update on TennCare

compliance with statutory and contractual requirements, including but not limited to prompt payment of claims and provider network adequacy (including arrangements to insure the provision of essential services).

The waiver also includes certain provisions for use in expanding or contracting the program. Flexibility was established on use of open enrollment periods (no more than two per year) and income thresholds for the demonstration population of uninsured persons (maximum of 200% poverty, with the possibility of using different income levels for subpopulations such as children and adults). The decision to hold an open enrollment period and the decision regarding income levels to be used in an open enrollment period were to be made by the General Assembly each year through legislative appropriations.

Adequacy of current TennCare waiver

The advisory board mentioned above has a limited role, and there is additional flexibility needed to manage the program effectively within available resources. The board does not focus on financial viability, which is a need under the new proposal.

Proposed actions

Tennessee plans to establish a TennCare Advisory Commission in accordance with recently enacted legislation. (See Appendix A.) The Commission will be charged with annually reviewing benefits, enrollment, costs, and performance of the program and recommending cost-containment strategies and cost-effective program improvements to the Governor. The purpose of the Commission will be to recommend whatever changes are needed to keep program spending within 26% of state revenues. In some years those changes will be modest, but in other years recommended changes may be more substantial.

The Advisory Commission's recommendations would be comparable to similar efforts made in the commercial world, such as changes in copays and broad coverage decisions. They would not take the form of specific recommendations on benefits by specific medical condition. The Commission could also make recommendations regarding opening or closing enrollment for certain subsets of the TennCare Standard population. The annual November 10 deadline for recommendations specified in the legislation would enable the Governor to consider the Commission's recommendations in making TennCare benefit and eligibility recommendations to the Legislature during the budget process. Consistent with the new legislation, the Governor would make all final decisions regarding recommended changes and could modify the Commission's recommendations as appropriate. Because the Advisory Commission provides a vehicle for adjusting benefits and eligibility on a regular basis, this initiative could make TennCare's costs more predictable.

The guiding principles for the Advisory Commission are as follows:

- TennCare should continue to serve as many people as possible, offering fewer services to the same number of people, if reductions are necessary.
- The most vulnerable populations should be protected from reductions until other options are exhausted.

- Eligibility would be reduced as a last resort and would focus on those non-Medicaid eligibles who have access to some other type of health insurance (such as Medicare) and those who have higher incomes.
- Whenever it appears that there are adequate funds to make additions to the TennCare program, the initial focus will be on eligibility expansions.
- Only after eligibility expansions have been fully explored should changes in benefits and copay requirements be considered.

Based on these principles, Tennessee has developed a specified range of modifications that the Advisory Commission could recommend based upon the TennCare Bureau's analysis of the TennCare budget. The state envisions four scenarios with a set of potential modifications for each scenario. Tennessee is requesting CMS pre-approval of specified modifications within these four defined scenarios in order to maximize the efficacy of the Commission and to enable rapid implementation of recommendations endorsed by the Governor. By requesting upfront authority to implement pre-approved modifications (upon the Advisory Commission's recommendation and the Governor's endorsement or revision of such recommendation), the state could implement cost reduction measures when necessary or expand eligibility and/or services when economic conditions permit. Tennessee will notify CMS when it plans to implement such changes and will receive streamlined approval of necessary modifications.

CMS-approved parameters would govern the modifications available under each scenario. The Governor would identify the applicable scenario based on his assessment of budget numbers, financial projections (including projected TennCare spending as a percentage of total state revenues in a given year) or other appropriate indicators. The Commission would then make its recommendations from among the benefit limits, copays, premiums, covered populations, etc., available under that scenario.

Pre-approved modifications could be applied singly or in combination, or the Commission could recommend against any modification. Similarly, the Governor could accept, modify, or reject the Commission's recommendations or propose his own changes, pursuant to the CMS-approved parameters. The authority to implement some combination of these pre-approved modifications would enable TennCare to expand or contract the program when economic circumstances warrant. Any expansions would be implemented only with a demonstration of continuing budget neutrality. In all circumstances, the state would adhere to the notice requirements applicable to any of the changes implemented as part of the scenarios described below.

The four potential scenarios at which the various pre-approved modifications could be applied are as follows:

Scenario I: Under an expansion scenario, the state would be able to expand eligibility and/or services. See Table 6 for more details.

**Table 6
Scenario I – Expansion**

Proposed Courses of Action for Advisory Commission	Pre-approved Modifications
Increase FPL ceilings for PLIS ²⁸	Up to 200% across age categories
Cover certain additional optional Medicaid groups	Add children eligible under a “Katie Beckett” waiver
Open enrollment for the “uninsurable” in the TennCare Standard population	Adults up to 200% of poverty; children up to 250% of poverty
Open enrollment for the “uninsured” in the TennCare Standard population	Adults up to 200% of poverty; children up to 250% of poverty
Decrease premiums for select beneficiaries in TennCare Standard	Reduce premiums for the 100-150% TennCare Standard eligibles to pre-reform levels.

Note: Any expansions will occur only when there is evidence that the budget neutrality cap is not threatened.

Scenario II: The amended waiver would initially be implemented with the “baseline” benefit/copayment package described in this proposal, with different criteria applied to TennCare Medicaid and TennCare Standard enrollees.

Scenario III: Modifications available under this scenario could be implemented when the Governor determines that cost reduction strategies must be considered. In this scenario, Tennessee could reduce any service to the lowest level then approved for a Medicaid program in peer southern states, including the exclusion of an optional benefit not covered by a peer southern state. Tennessee’s benefits are currently more generous than many of those available in other states. Modifications under this scenario could include the imposition of copayments, premiums, and/or benefit limits for TennCare Standard children who are currently protected from such restrictions. Although this population is not entitled to and has not been granted federal EPSDT benefits, we have requested clarification that to the extent our copayment, premium, or benefit limits policy could be deemed in conflict with EPSDT, such requirements do not apply to the waiver population. Changes to cost sharing might also be considered in this scenario. See Table 7 for more details.

**Table 7
Scenario III—Reduction**

Proposed Courses of Action for Advisory Commission	Pre-approved Modifications
Reduce services	Reduce any service, optional or mandatory, to the lowest level then approved for a Medicaid program in peer southern states

²⁸ PLIS = Poverty Level Income Standard for pregnant women and children.

Proposed Courses of Action for Advisory Commission	Pre-approved Modifications
Increase copays and premiums for the demonstration populations	Increase cost-sharing (i.e., copayments and premiums) for the demonstration population to at least partially offset the cost of medical inflation
Expose some previously exempt enrollees to benefit limits and/or copayments	Expose some or all members of the TennCare Medicaid or TennCare Standard population who are now exempt from any benefit changes to (a) nominal copayments and/or (b) benefit limits in line with those approved for the TennCare Standard population
Eliminate certain non-mandatory services	Eliminate from coverage identified optional services for some or all beneficiaries (e.g., pharmacy)

Scenario IV: This scenario would only be implemented if severe budgetary adjustments are necessary. Here, the state could eliminate optional services, such as the pharmaceutical benefit, for all beneficiary categories except the EPSDT population. See Table 8 for more details. To the extent that Scenario IV would trigger the elimination of coverage for certain optional benefits for the TennCare Medicaid population, such changes would be accomplished through State Plan Amendments.

**Table 8
Scenario IV—Additional Reductions**

Proposed Courses of Action for Advisory Commission	Pre-approved Modifications
All actions from Scenario III	Same range as Scenario III
Eliminate non-mandatory benefits	Remove coverage of all optional benefits, starting with the pharmaceutical benefit ²⁹ , for some or all, except the EPSDT population

²⁹ Pharmaceuticals could potentially still be offered at Medicaid discount/rebate prices through a separate buy-in option plan.

5. Contractual Arrangements with Managed Care Organizations

Provisions of current TennCare waiver

We currently contract with seven different managed care organizations (MCOs) to provide services across the East, Middle, and West Tennessee Grand Regions. In the Middle Region, however, there is currently only one MCO providing services outside of Davidson County. CMS has clarified under the existing waiver that because the majority of the areas within the Middle Region qualify as rural, Tennessee may limit the choice of TennCare enrollees to one MCO in that area.³⁰ We understand that this limitation of one MCO is only applicable to the Middle Region of Tennessee.

When TennCare was first launched in 1994, we entered into full risk arrangements with MCOs, pursuant to which the MCOs were to provide all services to TennCare enrollees. Subsequently, behavioral health, then pharmacy services, and later dental services were carved out of these arrangements. We also received approval to establish a temporary relationship with the MCOs, in which they would serve as essentially non-risk administrative services organizations (ASOs). Providers continue to be compensated at rates set forth in their agreements with the MCOs as of April 2002. Although this ASO relationship was to be terminated in January 2004, it has been extended as we are now redefining some of the fundamental elements of the TennCare program.

Adequacy of current TennCare waiver

There currently are not a sufficient number of MCOs capable of meeting the high quality standards to which Tennessee would like to hold participating MCOs in all regions of the state. Tennessee is therefore seeking authority to limit MCO choice in order to ensure high quality services. We anticipate the possibility that, for certain interim periods of time, Tennessee may have only one MCO operating in certain rural and non-rural parts of the state.

We are also seeking permission to have only one BHO in each grand region of the state. This request, which has already been made to CMS but not yet approved, would allow us to contract with a single BHO in each of the three grand regions of the state. Enrollee choice would be assured through choice of providers operating within the BHO.

We are also seeking the ability to continue the current ASO arrangement with MCOs until we determine whether the proposed reform will be implemented. Upon any implementation of reform, Tennessee will be in a better position to determine what arrangements – full risk, partial risk or ASO relationship – will most appropriately ensure the future viability of the TennCare program.

³⁰ Medicaid law and regulations require states to provide Medicaid managed care enrollees with a choice of at least two MCOs, unless the areas at issue are rural. “Rural areas” are defined as any area other than an “urban area.” “Urban areas” are Metropolitan Statistical Areas as defined by the Executive Office of Management and Budget.

Proposed actions

Any reforms to TennCare must be implemented before MCOs will be able to accurately project risk under their contracts with the state. Thus, although Tennessee is considering transitioning TennCare MCOs to full or partial risk arrangements over time, such considerations will be subject to the finalization and implementation of the proposed program reform. In the interim, we will ensure that payment rates to providers and MCO medical policies and procedures are approved by TennCare. Having frozen the rates in the past does not preclude modifying the rates in the future, however.

We also wish to clarify that to the extent that MCOs are paid on a non-risk payment methodology, they will not be subject to the literal language of the upper payment limit applicable to non-risk contracts under 42 CFR § 447.362. That regulation limits payments to amounts Medicaid would have paid on a fee-for-service basis plus any administrative savings to the state. Since it has been more than a decade since Tennessee paid providers of managed care services directly on a fee-for-service basis, calculating this precise fee-for-service equivalent would be unnecessarily administratively burdensome. Moreover, with the MCOs essentially passing provider payments through to the providers, and Tennessee exercising authority over the rates, the payments to the MCOs are limited as was intended by the regulation. Finally, Tennessee assures that by meeting the budget neutrality standards applicable to waiver expenditures, it will comply with the intent of the regulation. To the extent that a waiver is required to implement this alternative to the upper payment limit for non-risk contracts, we have requested that authority.

Tennessee is also considering implementing structural reforms within the MCO system. Such changes would be made with the intent to improve the stability and efficiency of the MCOs, as well as to ensure that high quality care is provided to all TennCare enrollees. Potential reforms could include, as examples:

- Standardized reporting, requiring all participating MCOs to track and report information using the Health Plan Employer Data and Information Set (HEDIS); and
- Mandatory accreditation, requiring all participating MCOs to adhere to standardized performance measures such as mandatory accreditation by the National Commission for Quality Assurance (NCQA).

Given the objective of raising the performance standard for MCOs, there is a possibility that certain participating MCOs may be unable to meet these standards. In the event that an MCO fails to achieve these enhanced standards, we would seek to modify or terminate the relationship with this MCO, even if such termination would result in having only one MCO serving rural and non-rural areas within the state. In the event that existing relationships are terminated, we would make use of the appropriate procurement process to solicit interest from qualified MCOs. However, we remain committed to engaging only those MCOs that are able to meet the enhanced performance standards. Thus, even with the application of a procurement process, there is a possibility that for interim periods of time, only one MCO may serve a rural or non-rural area within the state, until such time as we are able to locate another appropriate MCO to provide services in that area. In the interim, TennCare Select will remain available to assist with any capacity issues that may result from having only a single MCO in place.

We intend to increase our enforcement of all financial and quality regulations for our MCOs.

Finally, we are requesting the ability to pay approved, supplemental payments directly to certain providers outside the managed care entities under certain situations.

6. Information Technology

Provisions of current TennCare waiver

The existing TennCare Management Information System supports the TennCare program by performing a variety of functions, including data and claims processing, eligibility, provider enrollment, and enrollee premium payment management. This system enables the state to manage day-to-day TennCare program operations, but it lacks the capacity to coordinate care across the health care system.

Although TennCare providers utilize existing health information systems, they are largely inadequate to accommodate the social and administrative complexity of today's health care delivery. Gaps exist among the health information systems of hospitals, clinics, health plans and other TennCare providers. The lack of a comprehensive information technology infrastructure results in inadequate information standards, fragmented approaches to care and duplication of services as well as gaps in care.

Adequacy of current waiver

The current waiver does not directly address information systems issues.

Proposed actions

An investment in a centralized clinical information system is critical to enhancing Tennessee's ability to manage the TennCare program more effectively and efficiently. To meet this goal, Tennessee and various stakeholders are working on multiple projects across the state to develop improved health information systems designed to share data among health care providers, payors and patients. Tennessee is seeking federal and state funding for some of these initiatives to lay the groundwork for better quality care, disease management and evidence-based medicine.

Development of a health information system will improve patient care, enhance interactions among providers, managed care organizations and patients, and reduce costs to providers and the TennCare program. Such a comprehensive system, involving multiple stakeholders, has the potential to benefit the broader patient population as well as TennCare enrollees.

Tennessee anticipates that the development of such information technology will be of critical importance to formulating strategies to address TennCare's challenges, including

addressing high and rising costs inherent with limited and difficult interchange of information among providers, improving easy access to information for beneficiaries, and improving care delivery by helping physicians arrive at diagnoses more rapidly and identifying the most effective course of treatment for patients.

The state anticipates that there will be several initiatives as part of its health information technology program. For example, there are efforts already underway to develop a regional-based model in West Tennessee that will include the following components:

1. *Six-Month Accelerated Planning Process*

Tennessee will implement a state-based regional data sharing and interoperability service that links health care entities within three counties surrounding Memphis, Tennessee. The goal of this project is to achieve a plan for improvements in information technology that ultimately will significantly benefit not only the TennCare population, but also the broader patient population within the state.

In order to implement this service, Tennessee intends to embark upon a six-month accelerated planning process to assess opportunities to improve health care for TennCare enrollees and other individuals through information access. The two primary goals are: (i) development of a high level plan for a self-sustaining and evolving statewide health information infrastructure, and (ii) creation of a detailed roadmap for implementing interventions for TennCare enrollees and others residing in the three-county region surrounding Memphis, Tennessee. Development of these plans may involve the collaboration of multiple health care providers, payers, public health agencies, pharmacies, commercial laboratories, suppliers and communities throughout the state.

Tennessee is committed to ensuring that this project is initiated and completed within its six-month time frame. In evidence of such commitment, Tennessee has allocated a significant level of state resources and the planning effort commenced effective July 1, 2004.

2. *Five-Year Regional Demonstration Project*

Building upon the six-month planning effort and the resulting road map, Tennessee has responded to a request for proposals from the Agency for Health Care Research & Quality (AHRQ) for a regional demonstration in health information technology. Such funding may be a critical component for successful implementation of this information technology initiative.

Tennessee anticipates that a data sharing service and/or system will be implemented as a demonstration in the three counties surrounding Memphis, Tennessee over the next five years. During this implementation phase, Tennessee anticipates evaluating the system to measure its potential for success in improving the quality and efficiency of care provided to TennCare enrollees and other patient populations across the state.

Tennessee also expects that if awarded an AHRQ contract, this project would commence in October 2004. If Tennessee does not receive an AHRQ contract for this five-year project, although the elements of this project may change, Tennessee will consider providing a significant level of support for the project while seeking

supplemental funding from other sources. For example, Tennessee has partnered with Vanderbilt University for this project and Vanderbilt University has already committed substantial funding to this project. To support the project, Vanderbilt has made patient indexes, communication and clinical software available to the initiative.

As the implementation of improved information technology is vital to the continued viability of the TennCare program, Tennessee remains committed to the potential long-term success of this project, which includes securing funding beyond even the five year period that may be covered by a contract with AHRQ. Regardless of whether Tennessee receives AHRQ funding, the state will commit a very significant level of state funding towards the operation of the project over the next five years.

Tennessee believes that a portion of the costs of these enhanced information systems is properly allocated to TennCare as a matchable administrative expense necessary for the proper and efficient administration of the program. To the extent that CMS determines that such costs do not meet the standard for routine administrative matching, Tennessee seeks authority under section 1115 to receive federal match for these expenditures. Given the crucial link between this advanced technology and many of the other quality-related initiatives being implemented in TennCare, Tennessee believes that TennCare should cover some of the costs. We will ensure an appropriate methodology for allocating TennCare's share of the costs, and we will not use federal funds, including any AHRQ funding, as the non-federal share of these expenses.

7. Medical Necessity, Fraud and Abuse, and Third Party Liability

There are a number of initiatives that, while not requiring overt approval from CMS, provide insight into the objectives and goals of the TennCare program. Accordingly, we have summarized a few of these important initiatives with the purpose of shedding light on some of the reforms that we anticipate will assist in ensuring the continued viability of the TennCare program.

Medical necessity

A key aspect of the TennCare reform proposal is a newly enacted but not yet implemented statutory definition of "medical necessity" which will replace the current regulatory standard. (See Appendix B.) Tennessee's new definition provides clearer guidance than the previous one. It will be implemented consistent with current federal law, including EPSDT requirements, and within the states' authority to define what constitutes a medically necessary Medicaid service. We therefore do not need and are not requesting any waivers by CMS in relation to this definition.

At the root of many of the TennCare financial challenges is the inability of the state to curb the excessive provision of TennCare health services. The "as medically necessary" standard that underlies most TennCare benefits is a major driver of the program's growing costs. It requires coverage of services prescribed by a physician without consideration of cost effectiveness and less costly alternatives that may be available and effective. As a prudent purchaser, Tennessee seeks to inject some balance into the definition, while still ensuring that medical needs are met. The new definition will provide

the state with the legal authority to ensure that important cost effectiveness considerations are incorporated into the operation and administration of the TennCare program, so that we may continue to extend coverage to as many people as possible.

We are aware that the new definition has caused concern for some health advocacy groups and have discussed these concerns with them and with interested members of Congress and their staffs. We are sensitive to their concerns and have worked hard to ensure that the new definition includes many protections for patients, including a requirement that all medical necessity determinations begin with a physician's determination. In addition, Tennessee intends that appropriate preventive care and screenings, including vaccinations, be encompassed by the definitional requirement that medical items must be necessary in order to "diagnose or treat" an enrollee's medical condition. The definition expressly provides for the "off-label" use of pharmaceuticals that generally meet the requirements of medical necessity if such use is "widespread" and "generally accepted by the professional medical community as an effective and proven treatment." Finally, the definition guarantees that cost considerations will not override a patient's medical needs because all TennCare services must be "safe and effective" and "adequate for the medical condition of the enrollee." We will continue to be sensitive to the protection of patients as we develop regulations to implement the statutory definition.

Fraud and abuse initiatives

Fraud and abuse in TennCare undermines the financial stability of the program, minimizes public faith and threatens to deprive recipients of quality health care services. In accordance with federal and state law, we have significantly improved upon our capacity to investigate and prosecute fraud and abuse within the TennCare program through our Medicaid Fraud Control Unit (MFCU).

We are taking additional steps to enhance current efforts to combat fraud and abuse within the TennCare program. In particular, we have created an Office of TennCare Inspector General (TennCare OIG), effective July 1, 2004. The TennCare OIG is separate and distinct from the existing MFCU and has a specific mission of not only assisting the MFCU in its current efforts, but also significantly expanding our ability to investigate and prosecute recipient fraud.

An important aspect to combatting fraud within TennCare is imposing strong disincentives for committing TennCare fraud in the future. A key element to eliminating such fraud and abuse is the expansion of our ability to impose significant penalties upon individuals who commit such fraud. In accordance with federal and state law, we currently employ a number of mechanisms to deter individuals from committing TennCare fraud. For example, under our Operational Protocol and in accordance with federal law, TennCare enrollees who are incarcerated are disqualified from eligibility. We also have the ability to disqualify for a period of up to one year TennCare enrollees who are convicted under federal law of fraud involving federal health care programs.

Finally, we are separately submitting a waiver request to CMS to allow Tennessee to disqualify for one year TennCare enrollees who have been convicted under state law of fraud against the TennCare program or the illegal sale of prescription drugs. See Appendix C.

Third party liability initiatives

We currently engage in both cost avoidance and pay-and-chase strategies for third party recoveries. For example, pursuant to contractual arrangements, MCOs are responsible for making every reasonable effort to determine the legal liability of third parties to pay for services rendered to TennCare enrollees.

Despite these efforts, we currently fall short of third party recoveries for state Medicaid programs. In some instances, for example, MCOs may not have access to valuable databases that would otherwise permit the MCOs to better detect the existence of third party liability (TPL). As a result, we are formulating various strategies to improve our TPL initiatives including:

- Expansion of TPL staff;
- Provision of increased incentives for MCOs to engage in cost avoidance third party recoveries,
- Expansion of the use of contractors for pay and chase strategies, and
- Implementation of a small pharmacy-related project to explore TPL options.

Chapter 3: Transition Plan for Implementing Changes

We anticipate beginning our roll-out of the new TennCare program on January 1, 2005.

The following tasks will be conducted during the summer and fall of 2004:

- A draft of the waiver will be sent to the TennCare Oversight Committee and the Tennessee Justice Center 30 days prior to submission to CMS.
- The Office of the TennCare Inspector General will be established.
- All current enrollees will be categorized into three groups (Medicaid enrollees, TennCare Standard enrollees with no benefit limits, TennCare Standard enrollees with benefit limits). All adults in TennCare Standard will be further categorized according to income: 0-49% poverty, 50-99% poverty, 100%-299% poverty, and 300% poverty and over.
- Enrollees will be notified of their classification, applicable benefit changes and/or benefit exclusions based on their classification, their new copay responsibilities (if any), and their new premium obligations (if any).
- Contracts with TennCare contractors will be amended to allow for implementation of program revisions and submitted to CMS in advance in accordance with the current Special Terms and Conditions.
- TennCare contractors will be reviewed to assess their operational readiness to offer the new program.
- Public necessity rules will be filed, to be followed by promulgation of permanent rules.
- Six-month accelerated planning process for regional sharing of data in Memphis and two surrounding counties will begin.

The following tasks will be conducted during the 2005 calendar year:

- New premiums and copays will go into effect.
- New benefit limits will go into effect.
- New appeals process will go into effect.
- New pharmacy program will go into effect.
- Disease management program will begin.
- The TennCare OIG will publish its first summary report, in accordance with the new legislation (within 60 days of the close of the fiscal year).

- Advisory Commission will be appointed by the Governor and will make its initial recommendations for SFY 06-07 (no later than November 10, 2005).
- A ballot period will be conducted in the fall of 2005 to allow enrollees to change MCOs if they wish, effective January 1, 2006.

Chapter 4: Legal Authority

TennCare has been operating since January 1994 pursuant to waivers of several statutory and regulatory requirements and a set of special terms and conditions as set forth in previous waiver approval documents. A new waiver was granted in 2002 to allow changes to the TennCare program. In addition to the existing waivers granted in 2002 (including authorizations to include expenditures that would not otherwise be includable), Tennessee is now requesting additional waivers and expenditure authority to permit implementation of certain program changes or modifications as described above. In most cases, however, new waivers are not required to implement the changes that Tennessee is proposing. Rather, changes can be implemented under current authority and/or through clarification and expansion of existing waivers. New requests are outlined below. To the extent that additional legal authority is required to implement the changes described in this proposal, we are hereby requesting such authority.

I. Waivers Requested

Methods of Administration 1902(a)(4)(A)

To enable the state to have only one Behavioral Health Organization to provide behavioral health services in a grand region of the state.

Comparability 1902(a)(10)(C)

To enable the state to provide Medicaid coverage to some medically needy individuals without providing Medicaid coverage to all individuals eligible to be members of that group

Statewideness 1902(a)(1).

To enable the state to contract with one or more health care providers qualified to participate as covered entities in the federal drug discount program established under Section 1927(a)(5) (“the 340B Program”) for the provision of disease management, case management, telemedicine, or other services to TennCare recipients only in areas of the state where patients can be served by such facilities.

II. Clarification or Expansion of Existing Waivers

CMS has previously granted Tennessee waivers that require clarification and expansion to permit the state to implement its disease management proposals and managed care contracting reforms, as well as certain of its proposed pharmacy benefit reforms. Tennessee is requesting the following clarifications and expansions of existing waivers (additions to current authority indicated in bolded italics):

Amount, Duration, and Scope 1902(a)(10)(B)

To enable the state to modify the Medicaid benefit package to: (a) offer a different benefit package than would otherwise be required under the State plan; (b) to offer benefits for some beneficiaries without offering the same coverage to others; (c) to limit benefits offered to individuals who elect the TennCare Assist program to payment of part or all of the cost of coverage under a group health plan, **(d) to provide additional specialized benefits to certain subsets of TennCare enrollees as part of the disease management program, (e) to cover certain drugs when they are prescribed for children, notwithstanding exclusion of these drugs from the state’s formulary for the purposes of treating adult TennCare enrollees, and (f) to permit certain subsets of TennCare enrollees (which may be determined by factors such as geographical location or membership in particular disease populations) to receive pharmacy and other associated services from a designated provider participating in the federal 340B drug discount program.**

Freedom of Choice 1902(a)(23)

To enable the state (a) to restrict freedom of choice of provider through the use of mandatory enrollment in managed care plans that would not be consistent with the requirements of Section 1932 **and to permit the state to contract with only one MCO to serve non-rural areas for interim periods of time, and (b) to permit the state to mandate enrollment by recipients within certain target populations in programs for delivery of disease management, case management, telemedicine, or other health care services of providers participating in the 340B program, as well as use by such recipients of the in-house or contract pharmacies of such providers.**

Pharmacy Benefit Restrictions 1902(a)(54)

To enable the state to establish a formulary based on cost, therapeutic comparability, and clinical efficacy, and to restrict coverage of drugs for which there are less costly, therapeutically comparable, and clinically efficacious alternatives available over the counter or by prescription. The expanded waiver of Section 1902(a)(54) that is requested to accomplish these purposes would enable the state to implement limitations on drug coverage and related prior authorization programs that would otherwise not be consistent with the provisions or Section 1927 (d).

III. **Costs Not Otherwise Matchable**

Although no new waivers are requested to alter eligibility, Tennessee is requesting the authority under Section 1115(a)(2) of the Social Security Act to treat certain additional expenditures (which are not otherwise included as expenditures under Section 1903) as expenditures under the State’s Title XIX plan. Tennessee is submitting the following requests for costs not otherwise matchable:

1. Expenditures for the following demonstration populations not covered by the State Plan would need to be approved as costs not otherwise matchable:

- medically needy aged, blind, and disabled,
 - medically needy children under age 21,
 - medically needy specified relatives, and
 - women needing treatment for breast and/or cervical cancer.
2. For purposes of budget neutrality, expenditures for the above populations would be treated as “Group II” eligibles under Attachment B, “Monitoring Budget Neutrality for the TennCare Demonstration” of the TennCare Special Terms and Conditions, defined as “those who could be eligible for Medicaid if Tennessee amended its State plan.”
 3. Expenditures associated with the provision of disease management services to individuals determined to be eligible.
 4. Expenditures for services rendered in non-rural areas, including the eight urban counties in the Middle Grand Region, even if choice is limited to one MCO in those areas.
 5. Expenditures for services to a TennCare enrollee residing in an institution for mental disease for services provided outside of the institution.
 6. Expenditures for Special Pool Payments where the state has adjusted the actuarially sound capitation rates paid to MCOs, as applicable, to account for the Special Pool Payments made directly to providers.
 7. Expenditures associated with the implementation of the comprehensive health information technology system, to the extent that they are not matchable as administrative costs under Medicaid.

IV. Exceptions to Medicaid Requirements for the Demonstration Population

Using the authority requested to receive Federal matching funds for costs not otherwise matchable for demonstration populations, Tennessee will provide TennCare Standard enrollees with the coverage as outlined in this waiver amendment application and as approved by CMS. Tennessee understands and requests CMS confirmation that these enrollees are not entitled to the full coverage required for mandatory and optional categories of Medicaid recipients provided through Title XIX and the State Plan, including the following provisions. To the extent that any other exceptions may be necessary to implement the proposals described in this amendment application, Tennessee hereby requests such exceptions.

Amount, Duration, and Scope 1902(a)(10)(B)

To permit the state to offer demonstration participants benefits that are not equal in amount, duration and scope to benefits available to other TennCare enrollees and Medicaid recipients and to enable the state to provide a different amount,

scope, or duration of benefits or coverage to some segments of the demonstration population than the state provides to other segments.

Fair Hearings 1902(a)(3)
1932(b)(4)
42 CFR 438, Subpart F

To clarify that Medicaid fair hearing rights and managed care notice and appeal rights do not apply to TennCare Standard participants who would seek to appeal denial of coverage or services because enrollee failed to pay premiums or copayments or because of the imposition of benefit limits.

Premiums and Cost Sharing 1902(a)(14)
1916

To permit premiums in excess of standards otherwise prescribed by the Secretary and cost sharing that is more than nominal to be imposed upon TennCare Standard participants and to permit denial of services for TennCare Standard participants who fail to pay premiums or copayments.

EPSDT 1902(a)(43)

To clarify that TennCare Standard participants are not eligible nor entitled to receive federal EPSDT benefits.

Pharmacy Benefit Restrictions 1902(a)(54)
1905(a)(12)
1927(d)

To clarify that the state may eliminate coverage of outpatient drugs from the benefits package provided to demonstration populations in the event that insufficient modifications are made to the provisions of applicable consent decrees to permit the state to implement the proposed TennCare reforms and/or should such action be deemed financially necessary in the future.

Continuous Enrollment 1902(a)(4)
42 CFR § 435.930

To permit the state to disenroll TennCare Standard participants in the event that the Governor exercises his contingent authority to modify the waiver to eliminate coverage for certain TennCare Standard eligibility categories without the need to redetermine eligibility for those enrollees, provided that such enrollees are permitted to reapply under other eligibility categories.

Chapter 5: Contingent Gubernatorial Authority to Modify the Waiver

In addition to the TennCare reform proposals outlined throughout this document, Tennessee is seeking to enable the Governor to alter the TennCare benefits package and/or eligibility categories should the state encounter difficulty implementing the TennCare reforms otherwise envisioned. Tennessee would provide notice to CMS (and to enrollees) of any such proposed changes and would work with CMS to achieve streamlined consideration and approval of the changes.

Provisions of current TennCare waiver

Currently, the scope of coverage provided by TennCare is fixed, with the benefits package and eligibility categories defined pursuant to the terms of CMS's approval. With limited exceptions (e.g. decisions to open or close enrollment for certain subsets of the TennCare Standard population), Tennessee must seek approval from CMS each time it wants to vary the benefits package or modify eligibility.

Adequacy of current TennCare waiver

The success or failure of the TennCare program is affected by a variety of circumstances. While some of these are within the control of the state, others are not. Clearly, for example, there will be a number of operational challenges facing the state in implementing the reforms. However, we must also contend with certain unique external challenges including an ongoing series of federal court lawsuits filed by interest groups.

These lawsuits have resulted in the need to operate the TennCare program under multiple consent decrees and agreed orders, each mandating the state to provide substantive or procedural benefits to TennCare enrollees, in some significant instances beyond the requirements of federal law. Taken together, these consent decrees make it extremely difficult to implement the reforms needed to preserve enrollment at current levels and to ensure high quality care while addressing spiraling costs. In order to implement the waiver amendments requested in this submission, we therefore believe that parts of those consent decrees will need to be modified in light of the changes we are now proposing. We intend to seek such modifications from the courts, and it is our hope and expectation that we will be able to work cooperatively with the plaintiff representatives in those cases to agree to any changes necessary. There is, however, no guarantee of success in this regard.

Nevertheless, recognizing that time is running out for the TennCare program, and understanding our obligations to the people of Tennessee to address a severe fiscal crisis, we feel the need to move forward with a fallback plan that can be implemented quickly should we be unable to implement the responsible reforms outlined in this application. The fixed benefits package and eligibility categories in the current demonstration, and the need to undergo *de novo* review by CMS any time we want to make adjustments, does not provide the flexibility we believe we could need to gain control over rising TennCare costs in a timely fashion.

Actions under consideration

We therefore are developing a mechanism by which the Governor, in the first year after approval of the waiver amendment, may make changes to the benefits package and/or eligibility categories without going through the Advisory Commission process as described in Chapter 2 (which will not yet be fully functioning until the end of the first year). Tennessee would notify CMS (as well as enrollees) of any changes recommended by the Governor and then work with CMS to achieve streamlined approval of those changes. This mechanism would only be implemented in the event that we are unable to implement our proposed reforms due to legal impediments or due to a determination by CMS that major aspects of the reforms cannot be approved.

The demonstration amendment proposed in this submission represents our best efforts to craft sensible reforms that protect vulnerable populations while controlling program growth and fulfilling our obligation to restore balance among competing priorities within Tennessee's budget. These proposed reforms are admittedly different from the "off-the-shelf" options that states typically have at their disposal to control Medicaid expenditures – alternatives such as eliminating optional benefits or reducing eligibility for optional populations. Instead, we want to make more nuanced and tailored changes, with the emphasis on preserving eligibility and protecting those populations most in need.

If our efforts to adopt such modifications prove unsuccessful, however, we want to be prepared to make immediate changes to the program to control costs without delay and without the need to start from scratch in seeking and obtaining CMS approval. We would view this alternative approach as a last-resort, fallback plan. However, we feel strongly enough about our responsibility to Tennessee taxpayers to regain control of the growth in the TennCare budget that we believe we must have such an alternative plan ready to implement if we cannot make the proposed TennCare reforms in a timely fashion.

Specifically, under the fallback plan that is under consideration, the Governor would be empowered to take some or all of the following actions, based on his assessment of the state's ability to implement the proposed reforms and the financial impact of any changes imposed by CMS or restrictions arising from the judicial process.

- Elimination of the pharmacy benefit for all TennCare Standard adults;
- Elimination of the pharmacy benefit for all TennCare Standard enrollees;
- Elimination of the pharmacy benefit for all TennCare Standard and TennCare Medicaid enrollees;
- Elimination of coverage for all TennCare Standard adults who do not fall into an optional Medicaid category previously covered in the state plan (non-institutionalized individuals who meet the criteria for the Medically Needy category and uninsured women under age 65 who have been screened by a CDC site and found to need treatment for breast and/or cervical cancer);
- Elimination of coverage for all TennCare Standard enrollees who do not fall into an optional Medicaid category previously covered in the state plan (non-institutionalized individuals who meet the criteria for the Medically Needy category and uninsured women under age 65 who have been screened by a CDC site and found to need treatment for breast and/or cervical cancer); or

- Elimination of coverage for all TennCare Standard enrollees.

Tennessee has adequate authority under federal and state law to make the changes under consideration in the fallback plan, subject to CMS approval. We are describing these changes in this section in the expectation that if it becomes necessary to implement this fallback plan, such approval would be forthcoming on an expedited basis. Any or all of these changes could be adopted upon receipt of CMS approval and in conformance with applicable notice requirements to enrollees. To the extent that the changes involve eligibility reductions, we would seek to implement them without undertaking a broad-based eligibility redetermination process, although we would permit enrollees losing coverage to reapply under other eligibility criteria. Beyond this issue, we believe we have all of the additional legal authority that would be necessary to implement any of these options.

We have chosen these particular changes as options for our fallback plan because they represent coverage and benefits that the state is not mandated to provide but has chosen to provide. Pharmacy is an optional service under Title XIX, and in traditional Medicaid the state has the authority to eliminate coverage of this service through a simple State Plan amendment, even for mandatory Medicaid populations. In addition, the eligibility categories that we have targeted for potential reductions are those groups that are eligible solely through the TennCare waiver (including those formerly optional Medicaid groups that would, under the amendment, be part of the demonstration population).

We recognize that the final option listed above, elimination of coverage for all TennCare Standard enrollees, could result in a termination of the TennCare demonstration. All of our efforts to date have been focused on preserving the program, not eliminating it, and we would only implement eliminations of coverage if forced to, and with deep regret. Nevertheless, we recognize that we must face this possibility realistically and make all necessary preparations to adopt this change if required. Thus, we will develop a series of proposed State Plan amendments that we would be ready to submit upon termination of the TennCare demonstration project. Because TennCare has largely operated outside of the State Plan for more than a decade, the Plan will need to be updated and modified to reflect the greatly changed environment under which it would operate. We would anticipate that even upon termination of the waiver, certain aspects of the TennCare program and its financing (including the use of certified public expenditures) would be retained. We would plan to follow all applicable procedures for waiver termination as required by CMS and under federal law.

We expect that after a year has passed and the waiver amendment has been implemented substantially as proposed, we will be able to rely on the mechanisms set out in Chapter 2 – and in particular the Advisory Commission process – to adopt any necessary modifications to the program to meet our budgetary goals.

Appendixes

Appendix A

Statute on TennCare Advisory Commission

SECTION 3. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated section:

Section _____: (a) There is established in the Department of Finance and Administration a TennCare Advisory Commission. The Advisory Commission will be separate and distinct from the bureau of TennCare but will be allowed access to all data concerning the operations, management, and program functions of the TennCare program, including information relevant to the TennCare program held or maintained by other state agencies. In accordance with 45 CFR Section 160.101, et seq., members of the Advisory Commission will provide non-paid consulting services to the bureau of TennCare and may have access to protected health information to the extent necessary to perform their advisory function.

(b) The Advisory Commission shall be appointed by the Governor and will be composed of eleven members who should reflect the broad impact that the TennCare program has on the State of Tennessee. The membership of the Advisory Commission shall include one representative of the advocacy community, two representatives from the Tennessee business community, and three representatives from the provider community. In making the appointments, the Governor shall strive to ensure that the Advisory Commission's membership is representative of the state's geographic and demographic composition with appropriate attention to the representation of women and minorities. In making the initial appointments, the Governor will designate three initial appointees to serve until December 31, 2005, four initial appointees to serve until December 31, 2006, and four initial appointees to serve until December 31, 2007. Except for initial appointments, members shall be appointed to three-year terms. At the time of the initial appointments of the Advisory Commission, the governor shall appoint a chair and vice-chair of the Commission from the membership of the Commission who shall serve until December 31, 2005. The Governor shall thereafter appoint a chair and vice-chair to one year terms from the membership of the Commission.

(c) The purpose of the Commission is annually to review the health care operations, including but not limited to, cost-management analysis, benefits, enrollment, eligibility, costs, and performance, of the TennCare program and to make recommendations to the Governor regarding cost-containment strategies and cost-effective program improvements. Such recommendations by the Commission will include an assessment of the effectiveness of the existing TennCare program, specific steps that could be taken to reduce program costs, and an evaluation of whether the program is optimizing its use of resources to best meet the needs of TennCare enrollees. Proposed modifications submitted by the Commission that may result in increased program expenditures should be accompanied by recommendations to achieve commensurate savings in other program areas in order to achieve overall management of program costs. The Commission shall present its recommendations in writing to the Governor no later than November 10 of each year.

(d) Subject to an appropriation set forth in the General Appropriations Act, the Commission will have the power to engage expert assistance, in accordance with state procurement processes. The department of finance and administration will provide the Commission with appropriate staff and assistance.

(e) Members of the Advisory Commission shall maintain strict standards of confidentiality in the handling of all matters before the Commission in accordance with Federal and State law. All material and information, regardless of form, medium, or method of communication, provided to or acquired by a member or the Commission staff in the course of the Commission's work, shall be regarded as confidential information and shall not be disclosed and are deemed not to be a public record. In addition, all material and information, regardless of form, medium, or method of communication, made or generated by a member or the Commission staff in the course of the Commission's work, shall be regarded as confidential information and shall not be disclosed and are not public records. All necessary steps shall be taken by members and staff to safeguard the confidentiality of such material or information in conformance with Federal and State law.

(f) Items or matters discussed by the Commission may from time to time present real or apparent conflicts for members of the Commission. Due to the importance of the Commission's work and the advisory nature of its recommendations, in the event that a matter being considered by the Commission presents a real or apparent conflict of interest, the affected member of the Commission shall disclose the conflict to the chair but shall be allowed to discuss and take official action on the particular matter. The professional backgrounds of each member of the Advisory Commission as well as any conflicts disclosed by a member to the chair during a given year shall be reported in the Commission's recommendations as set forth in subsection (c) of this section.

(g) Members shall receive no compensation for their services on the Commission but may be reimbursed for those expenses allowed by the provisions of the comprehensive travel regulations promulgated by the department of finance and administration and approved by the attorney general and reporter.

Appendix B

Medical Necessity Definition

SECTION 22. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated section:

Section _____. (a) Enrollees under the TennCare program are eligible to receive, and TennCare shall provide payment for, only those medical items and services that are:

- (1) within the scope of defined benefits for which the enrollee is eligible under the TennCare program; and
 - (2) determined by the TennCare program to be medically necessary.
- (b) To be determined to be medically necessary, a medical item or service must be recommended by a physician who is treating the enrollee or other licensed healthcare provider practicing within the scope of his or her license who is treating the enrollee and must satisfy each of the following criteria:
- (1) It must be required in order to diagnose or treat an enrollee's medical condition. The convenience of an enrollee, the enrollee's family, or a provider, shall not be a factor or justification in determining that a medical item or service is medically necessary;
 - (2) It must be safe and effective. To qualify as safe and effective, the type and level of medical item or service must be consistent with the symptoms or diagnosis and treatment of the particular medical condition, and the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee's condition and scientifically supported evidence;
 - (3) It must be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee. When applied to medical items or services delivered in an inpatient setting, it further means that the medical item or service cannot be safely provided for the same or lesser cost to the person in an outpatient setting. Where there are less costly alternative courses of diagnosis or treatment, including less costly alternative settings, that are adequate for the medical condition of the enrollee, more costly alternative courses of diagnosis or treatment are not medically necessary. An alternative course of diagnosis or treatment may include observation, lifestyle or behavioral changes or, where appropriate, no treatment at all; and
 - (4) It must not be experimental or investigational. A medical item or service is experimental or investigational if there is inadequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question. This standard is not satisfied by a provider's subjective clinical judgment on the safety and

effectiveness of a medical item or service or by a reasonable medical or clinical hypothesis based on an extrapolation from use in another setting or from use in diagnosing or treating another condition.

- (A) Use of a drug or biological product that has not been approved under a new drug application for marketing by the United States Food and Drug Administration (FDA) is deemed experimental.
 - (B) Use of a drug or biological product that has been approved for marketing by the FDA but is proposed to be used for other than the FDA approved purpose will not be deemed medically necessary unless the use can be shown to be widespread, to be generally accepted by the professional medical community as an effective and proven treatment in the setting and for the condition for which it is used, and to satisfy the requirements of (b)(1)-(3).
- (c) It is the responsibility of the bureau of TennCare ultimately to determine what medical items and services are medically necessary for the TennCare program. The fact that a provider has prescribed, recommended or approved a medical item or service does not, in itself, make such item or service medically necessary.
 - (d) The medical necessity standard set forth in this section shall govern the delivery of all services and items to all enrollees or classes of beneficiaries in the TennCare program. The bureau of TennCare is authorized to make limited special provisions for particular items or services, such as long-term care, or such as may be required for compliance with federal law.
 - (e) Medical protocols developed using evidence-based medicine that are authorized by the bureau of TennCare pursuant to Section 2 of this act shall satisfy the standard of medical necessity. Such protocols shall be appropriately published to all TennCare providers and managed care organizations.
 - (f) The bureau of TennCare is authorized to promulgate such rules and regulations as may be necessary to implement the provisions of this section.

Attachment C

**Draft of Letter to CMS Regarding Disenrollment of Persons
Convicted of TennCare Fraud**



STATE OF TENNESSEE
BUREAU OF TENNCARE
DEPARTMENT OF FINANCE AND ADMINISTRATION
729 CHURCH STREET
NASHVILLE, TENNESSEE 37247-6501

DRAFT

September __, 2004

VIA FACSIMILE

Mr. Joseph Millstone
Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations
Family and Children Health Programs Group
7500 Security Boulevard, Room S2-01-16
Baltimore, MD 21244-1850

Dear Mr. Millstone:

I am writing to seek further modification to the current TennCare waiver to allow the State of Tennessee (Tennessee) to better control fraud against the TennCare program. On behalf of the State, I am requesting that the Centers for Medicare and Medicaid Services (CMS) grant the State a waiver to allow Tennessee to disqualify for one year TennCare enrollees who have been convicted under State law of fraud against the TennCare program or the illegal sale of prescription drugs obtained through the TennCare program.

Tennessee law provides its judicial system with the discretionary authority to incarcerate TennCare enrollees who are convicted of TennCare fraud or the illegal sale of prescription drugs received from TennCare. If and when such individuals are incarcerated, they become ineligible for TennCare.¹ However, to avoid further overcrowding within the Tennessee penal system, Tennessee courts often seek alternatives to incarceration, such as probation or the imposition of fines, for convictions of TennCare fraud. Thus, most if not all individuals who are convicted of TennCare fraud or the illegal sale of prescription drugs received from TennCare are not incarcerated and as a result, remain eligible for TennCare benefits.

In recognition of the importance of employing additional deterrence mechanisms, in April of 2004, the Tennessee General Assembly enacted legislation reaffirming the authority of Tennessee courts to disqualify from TennCare individuals who have been convicted of criminal offenses for

¹ SSA § 1905(a) (2004); 42 C.F.R. § 435.1008 (2003).

TennCare fraud or the illegal sale of prescription drugs received from TennCare. The imposition of any such penalty, however, must be consistent with federal law and the TennCare waiver as interpreted by CMS.² See Attachment A.

The legislation limits such penalty to a certain class of offenses, which are those acts that significantly threaten the viability of the TennCare program. For example, the following TennCare enrollees were recently convicted under State law of fraud against the TennCare program and/or the illegal sale of prescription drugs:

- An enrollee was convicted of possession of 181 tablets of Lortab and 379 tablets of Xanax for the purpose of resale. TennCare records reflect that TennCare funds were used to pay for the drugs. The drugs were sold to an undercover officer. The enrollee was sentenced to four years of probation but was not incarcerated.
- An enrollee worked as a billing clerk in a physician's office, where the enrollee stole one of the physician's prescription pads and forged prescriptions. TennCare records reflect that TennCare funds were used to pay for the drugs. The enrollee was convicted of obtaining prescription drugs by fraudulent means. The enrollee was sentenced to six years of probation.
- An enrollee used the identity of a licensed insurance agent to forge letters of uninsurability for over 150 individuals who used the letters to enroll in TennCare. The letters falsely stated that the individuals were not insurable by the insurance company. The enrollee was convicted of TennCare fraud and forgery and was sentenced to two years of probation.

Individuals convicted of fraud against the Medicaid program under the federal anti-fraud statute may be disqualified from the program for a period of up to one year.³ But no parallel authority exists for states to disqualify individuals who are convicted of fraud under State law. Because these individuals are generally not incarcerated and have been convicted under State law (as opposed to federal law), they continue to qualify for TennCare benefits under existing eligibility criteria for TennCare Medicaid. Providing TennCare benefits to individuals who have committed fraud against the TennCare program undermines our anti-fraud efforts.

Accordingly, in order to implement Tennessee's recently enacted legislation, we are requesting authority from CMS to disqualify TennCare enrollees who are convicted of TennCare fraud. Specifically, Tennessee requests the following waiver under Section 1115 of the Social Security Act (SSA):

Comparability of Eligibility _____ 1902(a)(17)

To enable the State to restrict TennCare eligibility in order to disqualify for a period of one year enrollees who have been convicted of a criminal offense involving TennCare fraud or the illegal sale of prescription drugs received from TennCare.

² 2004 Tenn. Pub. Ch. 784 (H.B. 3512, Section 1, Section ____, (b)(2)), *amending* Tennessee Code Annotated, Title 71, Chapter 5.

³ SSA § 1128(B)(a) (2004).

This additional waiver will not require any adjustments to Tennessee's budget neutrality calculus. We anticipate that the change will reduce overall TennCare expenditures as our ability to deter and combat fraud against the program is enhanced.

We appreciate your consideration of this issue and look forward to working with CMS throughout the TennCare reform process.

Sincerely,

J.D. Hickey
Deputy Commissioner