

medicaid
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**Tennessee's New "Medically Necessary" Standard:
Uncovering the Insured?**

by Andy Schneider

In May 2004, Tennessee enacted legislation making a number of changes to its Medicaid program, known as TennCare, in order to reduce program spending.¹ Among these changes is a new standard for determining whether an item or service is "medically necessary."² Under this new standard, in order to be paid for, each item or service covered by Medicaid must meet a number of criteria, including a requirement that the item or service be the "least costly" alternative course of diagnosis or treatment for which there is adequate "clinical scientific evidence" of its safety and effectiveness. On paper, the new Tennessee standard appears to be substantially more restrictive than standards used by other states, by Medicare, and by commercial carriers, including plans participating in the Federal Employees' Health Benefits Program (FEHBP). If applied as written, the standard has the potential to bar payment for many physician, hospital, and other services that currently are within the scope of benefits covered under Tennessee's Medicaid program.

Although there has been no operational experience with this new standard to date, there is interest on the part of other states in applying some or all of the Tennessee standard to their own programs. The purpose of this Issue Brief is to describe this new standard and to compare it with the prior standard in Tennessee as well as the standards used by other public and private payors. The Brief concludes with some questions regarding the implications of the new standard for the populations that Medicaid covers nationally, especially low-income children under age 21, individuals with disabilities, and the elderly, as well as the providers who treat them.

The "Medically Necessary" Requirement

Under federal law, Medicaid beneficiaries are entitled to have payment made on their behalf for items and services such as physician services, hospital care, and prescription drugs if those items and services are (1) included among the benefits covered by their state's Medicaid program and (2) "medically necessary" for the individual in question. Each covered service must be "sufficient in amount, duration, or scope to reasonably achieve its purpose."³ With one significant exception, there is no federal statutory or regulatory definition of "medically necessary."⁴ The exception involves children under age 21, who are statutorily entitled to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. State Medicaid programs are required to pay for specified screening services as well as diagnostic and treatment

services that are necessary “to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the [EPSDT] screening services.”⁵

There is considerable variation from state to state as to how a Medicaid program defines “medically necessary.” For example, a review of contracts between state Medicaid agencies and managed care organizations in 1998 found that among the contracts that incorporated a definition of “medically necessary,” no two definitions were identical.⁶ In some cases, a “medically necessary” service was defined by the physician’s professional judgment. In Oklahoma, for example, a medically necessary item or service was one which, “in the [physician’s] professional judgment is necessary to diagnose, treat, or ameliorate a physical defect, and/or mental symptom, illness or other abnormality.”⁷ Other states substituted a broad standard for the physician’s professional judgment. For example, the California contract defined “medically necessary services” to mean “reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness, or injury.”⁸ Finally, other states set forth multiple criteria that had to be met to establish medical necessity. Nebraska’s contract listed eight requirements, including a requirement that the service or supply be “consistent in type, frequency and duration of treatment with scientifically based guidelines of national medical, research or health coverage organizations of governmental agencies.”⁹

The Prior Tennessee Standard

Before enactment of the new standard, Tennessee’s Medicaid program defined “medically necessary” items and services for beneficiaries 21 and older as those that are:

- (1) “required to identify or treat a TennCare enrollee’s illness or injury;”
- (2) “consistent with the symptoms or diagnosis and treatment of the enrollee’s condition, disease, ailment, or injury;”
- (3) “appropriate with regard to standards of good medical practice;”
- (4) “not solely for the convenience of an enrollee, physician or other provider;”
and
- (5) “the most appropriate supply or level of services which can safely be provided to the enrollee.”¹⁰

In the case of beneficiaries under age 21, the state’s “medically necessary” regulation directed that services “shall be provided in accordance with EPSDT requirements including federal regulations as described in 42 CFR Part 441, Subpart B, and the Omnibus Budget Reconciliation Act of 1989.”¹¹

The New Tennessee Standard

The May 2004 Tennessee legislation sets forth a new standard of medical necessity that has four criteria. A medical item or service must satisfy each of these criteria in order to be considered “medically necessary” and thereby qualify to have payment made. The criteria are extensive (see Appendix A for complete text). In summary, each item or service must:

- (1) “be required in order to diagnose or treat an enrollee’s medical condition;”
- (2) “be safe and effective” – i.e., “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) “be the least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee;” (this may include “where appropriate, no treatment at all”); and
- (4) have “empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question” that is “adequate.” The only exception to this criterion is for off-label uses of FDA-approved drugs, and the exception only applies if the off-label use “can be shown to be widespread” and “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.”

Under the legislation, this standard “shall govern the delivery of all services and items to all enrollees or classes of beneficiaries in the TennCare program.”¹² The legislation specifies that the responsibility for determining what items and services are medically necessary for purposes of the TennCare program is “ultimately” that of the TennCare Bureau, the state Medicaid agency.¹³

The legislation authorizes (but does not require) the Bureau to make up to three exceptions to the new medical necessity standard. First, the Bureau has the discretion to “make limited special provisions for particular items or services, such as long-term care.”¹⁴ Second, the Bureau may “make limited special provisions ... as may be required for compliance with federal law.”¹⁵ Finally, the Bureau may authorize specific “medical protocols developed using evidence-based medicine;” these Bureau-authorized protocols satisfy the medical necessity standard. As of June 2004, the Bureau had not authorized any such protocols.¹⁶

Changes from the Prior Tennessee Standard

The new Tennessee medical necessity standard is a wholesale revision of the prior standard (Table 1).

**Table 1:
Prior and New TennCare “Medically Necessary” Standards**

<i>To have payment made, a covered item or service must satisfy each of the following criteria</i>	
Prior Standard	New Standard
Must be required to “identify or treat”	Must be required to “diagnose or treat”
Must be “consistent with the symptoms or diagnosis or treatment”	No comparable criterion
Must be “appropriate with regards to standards of good medical practice”	No comparable criterion
Must be “most appropriate supply or level of services which can safely be provided to the enrollee”	Must be “least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee”
No comparable provision	Must have “adequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question”
In the case of services to children under 21, must be “provided in accordance with EPSDT requirements”	No comparable requirement (TennCare Bureau authorized to make “special limited provisions...as may be required for compliance with federal law.”)

The effect of the revisions to the prior standard is to make the standard substantially more restrictive, prohibiting payment for services in cases where the prior standard would have allowed it. The new standard:

- Discards three criteria that were contained in the prior standard.** The fact that an item or service is “consistent with the symptoms or the diagnosis or treatment” of an enrollee’s condition, disease, or injury is no longer relevant. Nor is it any longer relevant that the item or service is “appropriate with regards to standards of good medical practice.” Finally, with respect to children under age 21, items and services covered under the EPSDT statutory and regulatory requirements are no longer expressly recognized as “medically necessary.” The TennCare Bureau is instead

authorized (but not required) to “make special limited provisions” to comply with “federal law.” It is unclear whether the Bureau will view the federal EPSDT statute and implementing regulations as “federal law” for this purpose.

- **Makes all of the criteria that remain from the prior standard more restrictive.** An item or service must now be required to “diagnose or treat” an enrollee’s medical condition, not just “identify or treat” an enrollee’s illness or injury.¹⁷ It is unclear whether “identifying” services, such as most screenings (e.g., for breast, cervical or prostate cancer, for TB, or for HIV infection) or preventive services would be considered “medically necessary” under this criterion.

Further, under the new standard, it is no longer sufficient that the level of care or supply of services be the “most appropriate” which can “safely be provided” to the enrollee. Instead, the level of care or supply of services must be the “least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee.” This may include “where appropriate, no treatment at all.” This appears to mean that a service is not “medically necessary” if it is more costly than another service, even if, based on clinical scientific evidence, it is demonstrably more effective than another intervention.

- **Introduces a criterion that had no counterpart in the prior standard.** The new standard introduces a requirement that there be “empirically-based objective clinical scientific evidence” of the “safety and effectiveness” of the item or service “for the particular use in question,” and that this evidence be “adequate.” The legislation does not further explain what amount of “empirically-based objective clinical scientific evidence” will meet the test of “adequate.”¹⁸ The legislation is explicit, however, that this test is not met by a treating physician’s “subjective clinical judgment” or by “a reasonable medical or clinical hypothesis.” Note that this criterion interacts with each of the others. In particular, under the new standard an item or service is only “medically necessary” if it is the “least costly alternative” among those diagnoses or treatments for which there exists “empirically-based objective clinical scientific evidence” that is “adequate.”

The New Tennessee Standard Compared

There does not appear to be any precedent for – or operational experience with – the new Tennessee “medically necessary” standard in either the public or private sector. Existing databases suggest that the new Tennessee standard is substantially more restrictive than those used by other state Medicaid agencies, by Medicare, by Federal Employee Health Benefits (FEHBP) contractors, and by private sector plans.

Comparison to Other Medicaid Programs

As noted, state Medicaid program definitions of “medically necessary” vary widely. The Tennessee Governor’s Communications Office has identified 13 states with medical necessity definitions that include a “convenience” requirement, 11 states with definitions that include a “cost effective” requirement, and 1 state with a definition that includes an “adequate” requirement. No state appears to apply all 3 requirements simultaneously, as the new Tennessee standard does.¹⁹ Nor is it not clear that the states with “cost effective” requirements apply the same meaning to this term as TennCare – i.e., that the service be the “least costly,” regardless of effectiveness or safety in relation to other treatments.

For example, Oregon’s Medicaid program is implementing an evidence-based evaluation process for identifying benchmark drugs within a class of drugs that are “the most effective drug(s) available for the best possible price.” To identify the “most effective” drugs, the state Medicaid program contracts with researchers at the Oregon Evidence-Based Practice Center, which reviews peer-reviewed literature relating to drugs in specified classes (12 classes have been reviewed to date). Using clinical recommendations from the evidence reviews, the state Medicaid agency identifies a benchmark drug based on published pricing data. Drugs in the class with a net price within 5 percent of the benchmark drug are included in a Medicaid Plan Drug List. Physician compliance with the PDL is voluntary.²⁰

Under the Oregon approach, clinical evidence is the prerequisite to making a cost-effectiveness determination – e.g., that a drug is a “benchmark drug” within its class. In the absence of clinical evidence, no “benchmark drug” is designated. In contrast, the TennCare “medically necessary” standard bars payment for any item or service that does not have “adequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question.” And, among the items or services that meet this criterion, the only item or service that is “medically necessary” is the “least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee.”

Comparison to Other Public and Private Payors

As seen in Table 2, the new Tennessee “medically necessary” standard is also significantly more restrictive than the standards used by other public and private sector payors, including Medicare, Federal Employee Health Benefits (FEHBP) contractors, and private sector plans

Comparison to Medicare Standard. As shown in Table 2, the Medicare program does not allow payment under Parts A or B for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”²¹ The Medicare program has not defined this “medical necessity” standard through regulation, in part because of the difficulty in defining what is “reasonable and necessary.”²² In practice, local Medicare

administrative contractors (e.g., Part B carriers) develop criteria for making medical necessity determinations in individual cases. In addition, CMS, after consultation with the Medicare Coverage Advisory Committee, issues national coverage determinations (NCDs) with respect to certain diagnostic procedures, treatments, and medical equipment.²³

There have been a number of efforts to incorporate cost-effectiveness criteria into Medicare's coverage determinations. To date, these efforts have been unsuccessful. As noted in a recent *New England Journal of Medicine* editorial, "...Medicare has not explicitly considered cost in making coverage decisions. Health care services are generally covered when there is adequate evidence that they improve health outcomes, irrespective of the unit or aggregate cost. However, technology that is associated with very high cost is also very likely to have substantial clinical ramifications for the Medicare population and, therefore, these forms of technology receive comparatively greater scrutiny than other devices, procedures, and services."²⁴ In contrast, under the new Tennessee standard, every item or service must meet all 4 criteria, including "least costly alternative course of diagnosis or treatment that is adequate."

Comparison to FEHBP Standard. FEHBP, which covers Members of Congress as well as employees of CMS and other federal agencies, does not have a statutory or regulatory definition of "medically necessary" services. Instead, each private health insurance plan from which FEHBP purchases coverage uses its own definition.²⁵ The largest of the FEHBP plans is the national Blue Cross/Blue Shield PPO plan, which applies a "medical necessity" standard that incorporates several criteria.²⁶ As seen in Table 2, the new TennCare criteria are substantially more restrictive than those used by the Blue Cross/Blue Shield national plan.

Comparison to Hawaii Commercial Health Insurance Standard. As in the case of the health insurance products offered by carriers participating in FEHBP, there is considerable variation in the definition of "medical necessity" among commercial health insurance products purchased by private sector employers. In part, this results from the absence of uniform regulatory guidance. The federal ERISA statute and implementing regulations, which govern the health insurance coverage offered to the majority of privately-insured Americans, do not define the term "medical necessity."²⁷ A 2003 survey of state laws regulating the content of health insurance contracts identified 17 different definitions of "medical necessity." Among these, the definition used by Hawaii "approximates those found in modern industry practices."²⁸ As shown in Table 2, the TennCare standard is considerably more restrictive than the Hawaii standard, which applies to insurance contracts covering all residents, not just Medicaid beneficiaries. Note that the Hawaii standard allows for the possibility that scientific evidence of an item or service's effectiveness may not exist, and that cost-effective does not necessarily mean lowest price.

**Table 2:
New TennCare “Medically Necessary” Standard Compared to Public and Private Standards**

<i>To have payment made, a covered item or service must satisfy each of the following criteria</i>					
Criterion Type	New TennCare Standard (May 2004)	Medicare Standard	FEHBP Blue Cross/Blue Shield National Plan Standard	Hawaii Commercial Health Insurance Standard	
Purpose	Must be required to “diagnose or treat” an enrollee’s “medical condition”	Must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”	Must be “appropriate to prevent, diagnose, or treat [an enrollee’s] condition, illness, or injury”	Must be “for the purpose of treating a medical condition”	
Benefit/Risk Analysis	“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”	No comparable requirement	Must be “consistent with standards of good medical practice in the United States”	Must be “the most appropriate delivery of level of service, considering potential benefits and harms to the patient”	
Cost	Must be the “least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee”	No comparable requirement	No comparable requirement	Must be “cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention....cost-effective shall not necessarily mean lowest price.”	
Evidence	Must have “adequate empirically-based objective clinical scientific evidence of its safety and effectiveness for the particular use in question”	No comparable requirement	No comparable requirement	Must be “known to be effective in improving health outcomes; provided that (A) Effectiveness is determined first by scientific evidence; (B) if no scientific evidence exists, then by professional standards of care; and (C) if no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion”	

Issues Raised by the New Tennessee Standard

Since there is no operational experience with the new Tennessee standard, it is not possible to assess the standard's impact on TennCare's 1.3 million low-income beneficiaries or the providers who currently serve them. On paper, however, the new TennCare standard raises some important questions, both in Tennessee and nationally. Among these are:

- **Is adequate clinical scientific evidence available?** What items and services covered under current law will still be considered “medically necessary” under the new TennCare standard, particularly in light of criterion (4), which requires “adequate empirically-based objective clinical scientific evidence of safety and effectiveness for the particular use in question”? The only exception to this requirement concerns the off-label use of FDA-approved prescription drugs. In addition to meeting the other three criteria, these off-label uses must be shown to be “widespread” and 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.” What off-label uses prescribed for an FDA-approved drug will qualify for this exception and pass the other three filters?
- **What prenatal, maternity, and infant care will continue to be paid for?** Medicaid is the nation's single largest health insurer for pregnant women and infants. About 40 percent of all deliveries and 50 percent of hospital stays for preterm and low birthweight infants are paid for by Medicaid.²⁹ The NGA Center for Best Practices concludes that “States have a vital interest in improving birth outcomes and reducing such adverse outcomes as birth defects, low birth weight, premature birth, and maternal mortality. ...Governors can play a fundamental role ...through expansion of prevention and monitoring, education, and outreach activities.”³⁰ If the new TennCare standard were to be applied to Medicaid programs in all states, what prenatal care, maternity, neonatal, and early childhood development services – including “prevention and monitoring, education, and outreach activities” – that are currently paid for by Medicaid would satisfy all four criteria and therefore be reimbursed as “medically necessary”?
- **What EPSDT services will continue to be paid for?** Currently, TennCare beneficiaries who are children under 21 are entitled to EPSDT services. Under the new TennCare “medically necessary” standard, which of these services would still be paid for? For example, do all of the statutorily required screening and prevention services (e.g., health and developmental history, unclothed physical exam, age-appropriate immunizations, lead blood level assessments, and health education) satisfy the criterion that the service be required to “diagnose or treat” (not “identify”)? If not, will TennCare no longer make payment for these required services to which Medicaid beneficiaries under 21 are entitled?
- **What family planning services will continue to be paid for?** Nationally, Medicaid is the largest public purchaser of family planning services and supplies; it covers

more than 1 out of 5 low-income women of reproductive age.³¹ If the new TennCare standard were to be applied to Medicaid programs in all states, what family planning and other women’s reproductive health services that are currently paid for by Medicaid would meet all four criteria and therefore still be considered “medically necessary”?

- **How might the new standard impact health disparities?** Racial and ethnic minorities are disproportionately represented among Medicaid beneficiaries, both in Tennessee and nationally.³² Among racial and ethnic minorities, African Americans have higher mortality rates for breast and cervical cancer and asthma than whites.³³ Currently, Medicaid pays for a range of screening and diagnostic and treatment services for these conditions. If the new TennCare standard were to be applied to Medicaid programs in all states, would Medicaid continue to pay providers for identifying and clinically managing breast and cervical cancer and asthma? If not, what impact will this have on the nation’s ability to achieve its Healthy People 2010 goals with respect to reducing African-American mortality rates from these conditions, and health disparities generally?
- **What HIV/AIDS prevention and treatment services will continue to be paid for?** Nationally, Medicaid is the largest public purchaser of services for individuals with HIV/AIDS.³⁴ Although the global HIV/AIDS epidemic continues – an estimated 40,000 Americans are newly infected each year – the development of highly active antiretroviral therapy has made possible dramatic declines in illness, disability, and death. HIV infection, when appropriately treated, can now be managed as a serious chronic illness. If the new TennCare standard were to be applied to Medicaid programs in all states, what HIV services currently paid for by Medicaid would meet all four criteria and therefore still be considered “medically necessary”?
- **What are the policy implications of medical necessity standards that differ among Federally-funded programs?** As enacted, the new TennCare “medically necessary” standard applies only to Tennessee’s Medicaid program, TennCare, and its 1.3 million low-income beneficiaries. The Federal government pays nearly two-thirds (nominally 64.4 percent) of the costs of the TennCare program. The Federal government also pays most of the costs of health care coverage for elderly and disabled Medicare beneficiaries and Federal government employees and retirees living in Tennessee. Even though federal funds are helping to finance Medicare and FEHBP as well as TennCare, the “medical necessity” standards used by Medicare and the national FEHBP plan are substantially less restrictive than the new TennCare standard. Are federal healthcare dollars flowing through Medicare and FEHBP paying for services that are not truly medically necessary? Or will the TennCare standard result in the denial of payment for services that are truly medically necessary to low-income children, individuals with disabilities, and elderly Tennesseans not eligible for Medicare or FEHBP?

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APPENDIX A

New TennCare “Medically Necessary” Standard Tennessee Public Acts of 2004, Chapter 673, Section 22

(22) Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following language as a new appropriately designated 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 health care 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.

CITATIONS

¹ House Bill 3513, signed by the Governor May 17, 2004, Public Acts of 2004, Chapter 673. The legislation was enacted in response to the Governor's commitment to "fixing TennCare so the state can continue investing in its other vital priorities," <http://www.tennessee.gov/governor/tenncare.htm>. TennCare operates under a section 1115 demonstration waiver that began in January 1994 and was most recently revised on May 30, 2002; the TennCare II waiver is currently scheduled to expire on June 30, 2007. Federal spending for TennCare II is projected at \$3.24 billion in FY 2004. *United States Budget FY 2005: Analytical Perspectives* (January 2004), Table 24-5. Waiver documents, including terms and conditions and budget neutrality computations, are posted at <http://www.cms.hhs.gov/medicaid/1115/tn1115tc.asp>.

² Tennessee Public Acts of 2004, Chapter 673, Section 1 authorizes the state Medicaid agency "to develop and implement initiatives or program modifications to control the costs of the TennCare program," including the elimination of covered benefits, imposition of cost-sharing requirements for enrollees, and "elimination from TennCare eligibility of some or all of the non-mandatory Medicaid or waiver expansion categories" of enrollees.

³ 42 CFR 440.230(b). See A. Schneider and R. Garfield, *Medicaid as a Health Insurer: Current Benefits and Flexibility* (December 2003), Kaiser Commission on Medicaid and the Uninsured, www.kff.org/medicaid/4150.cfm.

⁴ 42 CFR 440.230(d) permits state Medicaid agencies to "place appropriate limits on a service based on such criteria as medical necessity...." but does not define the term. The Centers for Medicare & Medicaid Services (CMS) has expressly declined to promulgate a national definition, 67 *Fed. Reg.* at 41047 (June 14, 2002). See Kaiser Commission on Medicaid and the Uninsured, *The Medicaid Resource Book* (July 2002), pp. 60-61, 65, www.kff.org.

⁵ Section 1905(r)(5) of the Social Security Act, 42 U.S.C. 1396d(r)(5); 42 CFR 441.56(b), (c).

⁶ S. Rosenbaum et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts, Third Edition* (1999), Table 2.7, pp. 2-922 through 2-957, www.gwhealthpolicy.org. Of the 39 full MCO contracts reviewed, 30 incorporated explicit medical necessity standards. These MCO contract criteria may or may not have applied to the fee-for-service portion of the state's Medicaid program.

⁷ *Ibid.* at p. 2-945.

⁸ *Ibid.* at p. 2-922.

⁹ *Ibid.* at p. 2-939.

¹⁰ TennCare Rule 1200-13-13-.01(64). With respect to the last criterion, the regulation provides: "When applied to the care of an inpatient, it further means that services for the enrollee's medical symptoms or condition require that the services cannot be safely provided to the enrollee as an outpatient."

¹¹ *Ibid.* Section 6403(a) of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, enacted section 1905(r)(5) of the Social Security Act 42 U.S.C. 1396d(r)(5), which sets forth a medical necessity standard for EPSDT diagnostic and treatment services.

¹² Tennessee Public Acts of 2004, Chapter 673, Section 22(d).

¹³ Tennessee Public Acts of 2004, Chapter 673, Section 22(c).

¹⁴ Tennessee Public Acts of 2004, Chapter 673, Section 22(d).

¹⁵ The State has entered into a consent decree with a class of TennCare beneficiaries relating to the provision of EPSDT services. *John B. v. Menke* (M.D. Tenn, March 11, 1998), posted at <http://www.tnjustice.org/TJC.html>. Following findings in 2001 that the State had not complied with federal EPSDT requirements in accordance the consent decree, the court appointed a special master to oversee compliance. *John B. v. Menke*, 176 F. Supp. 2d 786 (M.D. Tenn. 2001). In 2003 the State agreed as part of a global settlement of four TennCare class actions to withdraw its request to exclude waiver-eligible children from the protections of EPSDT and of the consent decree. <http://tnjustice.org/Links/Summary%20of%20Settlement.doc>.

¹⁶ Tennessee Public Acts of 2004, Chapter 673, Section 2(g), authorizes the TennCare Bureau "in collaboration with one or more medical schools located in Tennessee, to establish an evidence-based medicine initiative for the purpose of developing medical protocols and integrating standards of best practice within the delivery of TennCare services."

¹⁷ The new standard rules out the “convenience” of the beneficiary or provider as a factor or justification altogether; under the previous standard, “convenience” could be a factor but not the sole factor.

¹⁸ There does not appear to be a consensus among experts in evidence-based medicine as to what proportion of health care interventions in common use today are supported by “adequate” clinical scientific evidence. See A. Booth, *What Proportion of Healthcare is Evidence-Based? Resource Guide*, <http://www.shef.ac.uk/scharr/ir/percent.html>.

¹⁹ Governor’s Communication Office, *Briefing Info* (6/17/2004).

²⁰ C. Bernasek et al., *Oregon’s Medicaid PDL: Will an Evidence-Based Formulary with Voluntary Compliance Set a Precedent for Medicaid?* (June 2004), pp. 9-10, 13-14, p. 43, www.kff.org.

²¹ Section 1862(a)(1)(A) of the Social Security Act, 42 U.S.C. 1395y(a)(1)(A). There are separate standards for Medicare-covered vaccines (must be “reasonable and necessary for the prevention of illness” and Medicare hospice care (must be “reasonable and necessary for the palliation or management of terminal illness”).

²² In May 2000 the Health Care Financing Administration issued a notice of intent to publish a proposed rule on criteria to be used to make coverage decisions at the national and local levels,

65 FR 31124 (May 16, 2000). A proposed rule has not been promulgated.

²³ www.cms.gov/coverage.

²⁴ S. Tunis, “Why Medicare has not established Criteria for Coverage Decisions,” *NEJM* (May 20, 2004), p. 2197.

²⁵ M. Merlis, *The Federal Employees Health Benefits Program: Program Design, Recent Performance, and Implications for Medicare Reform* (May 2003), www.kff.org.

²⁶ “We determine whether services, drugs, supplies, or equipment provided by a hospital or other covered provider are:

1. Appropriate to prevent, diagnose, or treat your condition, illness, or injury;
2. Consistent with standards of good medical practice in the United States;
3. Not primarily for the personal comfort or convenience of the patient, the family, or the provider;
4. Nor part of or associated with scholastic education or vocational training of the patient; and
5. In the case of inpatient care, cannot be provided safely on an outpatient basis.

The fact that one of our covered providers has prescribed, recommended, or approved a service or supply does not, in itself, make it medically necessary or covered under this Plan.”

Blue Cross and Blue Shield Service Benefit Plan 2004 Brochure, p. 112,

<http://www.opm.gov/insure/04/brochures/pdf/71-005.pdf>

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