

## **ANALYSIS OF PROPOSED TENNCARE DEFINITION OF MEDICAL NECESSITY**

This memorandum addresses a troubling change in Tennessee’s Medicaid program, which is known as TennCare. The change involves a limitation on what qualifies as a medically necessary service within TennCare. The new definition of “medical necessity” is included in Tennessee House Bill No. 3513, recently enacted as Chapter 673 of Tennessee Public Acts of 2004. In this context, medical necessity refers to the legal authority of the state to determine whether a particular service will be covered in a specific situation. While the legal definitions of medical necessity may differ from the way a physician uses the term in everyday practice, the differences introduced in the Tennessee law are unprecedented. If implemented,<sup>1</sup> Tennessee’s new definition of medical necessity would:

- Give the state virtually unlimited power to classify much of today’s standard and accepted medical practice as “experimental”, and thereby exclude it from coverage;
- Eliminate coverage for much if not all prophylactic screening and care, including childhood immunizations;
- Eliminate coverage for almost all care, including pain medication, designed to ameliorate a symptom of a disease rather than treat the medical condition itself;
- Require providers to prescribe care for their TennCare patients that is merely “adequate”, even if that care is not the most appropriate, or that which they would prescribe for any of their patients insured through other means; and
- Create a nearly insurmountable burden for patients seeking care that is not the least costly possible, even if that care would be more effective, or even more cost effective.

The TennCare definition of medical necessity would give Tennessee’s TennCare Bureau unparalleled power to determine whether services, even those considered mandatory under the Medicaid Act, would in fact be covered by the TennCare program. To the best of our knowledge, no other health care insurer – private or public – has ever sought to exercise this kind of authority. The definition would permit, if not indeed encourage, the state to reject all forms of professionally appropriate treatment in favor of the least costly alternative.

### **Background on the Definition of Medical Necessity**

While no federal statutory definition of medical necessity exists, much research has focused on articulating an appropriate definition. The prevailing definitions focus on whether a particular item or service is contractually covered, for example whether it is in the insurance

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<sup>1</sup> It is anticipated that the Tennessee definition will be submitted to the Centers for Medicare & Medicaid Services as part of a Section 1115 waiver request.

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contract or Medicaid State Plan. If a service is not in a state's Medicaid plan – and the state has wide latitude in determining what services to cover – the state can appropriately deny the service, just as a patient in the private insurance market will only receive services defined in the insurance contract.

Even if a service is contractually covered, the insurer can still determine whether the service is medically necessary for a particular person. Medical necessity definitions have evolved into a multidimensional evaluation that by and large includes consideration of the following issues: whether the treatment accords with professional standards of practice, whether it will be delivered in the safest and least intrusive manner, whether the treatment is medical (as opposed to social or otherwise non-medical), and whether the treatment is cost-effective.<sup>2</sup> This multidimensional evaluation has become the prevailing industry standard.

For example, the American Medical Association suggests a definition of medical necessity as:

health care services or products that a prudent physician would provide to a patient for the purposes of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is a) in accordance with generally accepted standards of medical practice; b) clinically appropriate in terms of type, frequency, extent, site, and duration and c) not primarily for the convenience of the patient, physician, or other health care provider.<sup>3</sup>

In addition, existing medical necessity definitions often include a reference to the cost of a particular treatment, but always do so within the context of comparing equally efficacious treatments. For example, in the health services research community, a seminal article developed a consensus definition of medical necessity which states that an intervention should be:

“cost-effective for this condition compared to alternative interventions, including no intervention. ‘Cost-effective’ does not necessarily mean lowest price.”<sup>4</sup>

In sum, then, any attempt to impose a medical necessity requirement beyond that inherent in a doctor having prescribed the particular treatment should: seek appropriate outcomes within the relevant clinical framework; explicitly address the information that will be utilized in the decision making process; identify who will participate in the decision making process; articulate specific standards; and, support flexibility in the sites of service delivery.<sup>5</sup>

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<sup>2</sup> Rosenbaum, S., Kamoie, B., Mauery, D.R., Walitt, B. *Medical Necessity in Private Health Plans: Implications for Behavioral Health Care*. DHHS Pub. No. (SMA) 03-3790. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration (2003).

<sup>3</sup> From the American Medical Association's Model Managed Care Contract project, available at <http://www.ama-assn.org/ama1/pub/upload/mm/368/supplement1.pdf>.

<sup>4</sup> Singer, S.J., Bergthold, L.A., Vorhaus, C., and Enthoven, A. *Decreasing variation in medical necessity decision-making* (Palo Alto, CA: 1999).

<sup>5</sup> Ireys, H., et. Al., *Defining Medical Necessity*, published by the Health Resources and Services Administration, Maternal and Child Health Bureau (Sept. 1999).

## Tennessee's New Medical Necessity Definition

Tennessee's new definition of medical necessity runs counter to the voluminous literature on the topic. The previous TennCare definition of medical necessity was similar to prevailing medical necessity definitions, as it authorized services that were "appropriate with regard to standards of good medical practice."<sup>6</sup> The new definition, inserted as part of sweeping changes to TennCare, not only contradicts nationally accepted concepts of medical necessity, but also would remove all predictability from the TennCare program. Under it, even covered services – those enumerated in the State Plan – will not be available as a matter of course because some other treatment may be deemed by the state to be less costly, even if also less effective or more risky. The definition would give the state the power to foreclose many of the services and benefits Congress specifically mandated for Medicaid enrollees. If this definition is implemented, many TennCare beneficiaries would find themselves holding a Medicaid card that offers no assurance of access to health care services that would be considered clinically appropriate for their conditions.

Specifically, enrollees may receive only medical items and services, which are within the scope of defined benefits and determined by the TennCare program to be medically necessary.<sup>7</sup> The definition is divided into four parts, each of which is discussed below. To obtain a medical service, even if included within the scope of benefits, the service must meet *all* four parts of the medical necessity definition. The burden of demonstrating that any given service meets the test rests solely with the patient and/or her provider.

**Part 1 – [A medical item or service] 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 serviced is medically necessary.**

The first part of the definition limits medical necessity determinations to those items and services, which are required to "diagnose or treat an enrollee's medical condition." The problems with this part are twofold – it allows only services that "diagnose or treat" and limits such diagnosis or treatment to "medical conditions." Each of these limitations would restrict access to many Medicaid services. In addition, the failure to define "convenience" creates further hurdles for patients.

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<sup>6</sup> The full definition is found in the TennCare rules, Chapter 1200-13-13-.01: medically necessary "shall mean services or supplies provided by an institution, physician, or other health care provider that are required to identify or treat a TennCare enrollee's illness or injury and which are: (a) Consistent with the symptoms or diagnosis and treatment of the enrollee's condition, disease, ailment, or injury; and (b) Appropriate with regard to standards of good medical practice; and (c) Not solely for the convenience of an enrollee, physician or other provider; and (d) The most appropriate supply or level of services which can safely be provided to the enrollee. 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.

<sup>7</sup> See Tennessee H.B. 3513 § 22.

## **Required to diagnose or treat**

The requirement that a service be required to “diagnose or treat” a medical condition eliminates much of the preventive screening and care authorized, and in some cases mandated, by Medicaid. It would eliminate immunizations, newborn hearing screens, children’s developmental screens, lead blood tests, diabetes and colorectal screenings, pap smears and mammograms. Also, any service that is provided to monitor – but not actually treat – an enrollee’s condition would be excluded. For example, glucose monitoring of a diabetic patient would no longer be deemed medically necessary.

The definition would also exclude a number of other services, which TennCare now covers, that maintain functional capacity and/or improve the quality and length of life but do not actually treat or diagnose. These include home health care for ventilator dependent children and adults; personal care and home health aid services for elderly patients with Alzheimer’s disease; and physical and occupational therapy services that prevent regression for children with severe cerebral palsy. Other services that would likely be precluded by this definition include genetic testing and services for individuals with mental illness. The definition also undermines the expectation of comprehensive health care that many people rely on when they agree to provide foster and adoptive homes through the Title IV-E program for children suffering from abuse or neglect.

## **Medical condition**

The definition further requires that an item or service will only be provided if related to a “medical” condition. Yet Medicaid currently provides many services for non-medical conditions. For example, children with developmental disabilities do not have a “medical” condition *per se* but receive Medicaid services essential to assist in day-to-day functioning. It is also questionable whether prosthetic devices and durable medical equipment would ever be covered under this definition.

Further, since pain medications are almost always used for treatment of a symptom rather than a medical condition, this definition would seem to exclude coverage for all pain medications. This would disqualify: medication to ease the suffering of the terminally ill or to assist those with painful chronic illnesses such as rheumatoid arthritis and multiple sclerosis; epidurals for a woman in labor; and, nausea medications for the side effects of chemotherapy.

## **Convenience**

The first prong of the TennCare medical necessity definition also precludes consideration of “convenience”, but it fails to provide a definition of that term. The previous definition of medical necessity appropriately provided that a prescribed service could not be *solely* for the convenience of the patient or family. The new definition eliminates any consideration of convenience at all. This might well eliminate coverage of virtually all pain medication. Because convenience cannot be considered at all, there will be many services in jeopardy of non-coverage under this definition.

**Part 2 – [A medical item or service] 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.**

### **Safe and effective**

“Safe and effective” are terms of art within the medical community that have been limited in use to the rigorous evaluative process for new drugs and devices. It is unclear how these terms could be adapted to determine the medical necessity of services such as physician visits. Where consensus regarding a particular disease or treatment has been reached, professional organizations have established standards of practice. These standards of practice are recognized as the appropriate methods of evaluating medical services. But these standards are often not developed from clinical trials or from determinations of safety and efficacy. By limiting treatment to that which is “safe and effective”, the definition would foreclose coverage of many existing standard practices. This limitation is particularly significant for children and pregnant women, who, for ethical and legal reasons, are seldom subjects of clinical trials.

### **Scientifically supported evidence**

The medical necessity definition further limits services and items to those supported by scientific evidence. Yet Tennessee has not defined what will be considered “scientifically supported evidence.” Many of the evidence-based guidelines in use today are not based on clinical trials or scientific studies. While eventually they may be subjected to a scientific study, much of their development has arisen from observation, hypotheses and replication.

Where existing definitions do refer to scientifically supported evidence, it is usually only one part of the evidence considered. For example, the seminal article on this issue limits scientific evidence to justifying new procedures: “For new interventions, effectiveness is determined by scientific evidence. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion.”<sup>8</sup>

By restricting the definition to scientifically supported evidence, Tennessee constrains the ability of health care providers to apply new research before a clinical study has been completed. For example, the clinical experience of physicians treating pregnant women with at-risk fetuses has led to the accepted practice of admitting these women to the hospital prior to initiation of labor because having at-risk infants born in the hospital leads to healthier babies. But this practice has not been subjected to a scientific double-blind research study and thus would apparently be precluded from coverage even if clinically indicated and cost-effective.<sup>9</sup>

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<sup>8</sup> See footnote 4.

<sup>9</sup> While the Tennessee definition does not explicitly refer to double-blind studies as the only acceptable scientific support for an intervention, it is hard to discern what other approach would suffice, given that the definition specifically excludes professional clinical judgment and clinical hypotheses based on extrapolation. See Part 4 below.

**Part 3 – [A medical item or service] 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.**

### **Least costly alternative**

When considered in combination with the previous two parts, this part forecloses any treatment that is not the cheapest, regardless of efficacy. The definition allows prescription of an alternative treatment, including a wait-and-see approach, even if it is inconsistent with prevailing practices. The driving factor is providing the cheapest alternative that is “adequate.” The likely result is a reliance on “observation” or lifestyle changes rather than testing and treatment.

As stated above, existing definitions of medical necessity contemplate that cost-effectiveness is an element of determining medical necessity, but only when comparing equally efficacious treatments.<sup>10</sup> However, Tennessee, in its efforts to cut the costs of TennCare, has constructed its definition of medical necessity in such a way that the lowest price service for any particular medical condition will almost always be the only one approved. This could, for example, result in significant deterioration for children with mental health issues. Observation of such a child, rather than short-term crisis and family intervention, medication and medication monitoring, can have serious consequences. These preventive services would be excluded under this definition, leaving observation as one of the few alternatives. Children who do not receive these services are at high risk for becoming violent and ending up in the juvenile justice system.

### **Adequacy**

Tennessee would impose an additional limitation that the alternative service need only be “adequate.” But “adequate” is not a medical term, and implies treatment of a lesser standard than “most appropriate” or even “most cost effective,” the terms generally used in medical necessity definitions. A likely result is the denial of much medical treatment because observation is explicitly stated to be an “adequate” alternative.

If the least costly approach need only be adequate, rather than appropriate or most effective, then for a woman who finds a lump in her breast, the permissible response will likely be observation rather than a biopsy, because the lump could either be cancerous or non-cancerous. Not until there is evidence of spreading to other areas would observation confirm cancer rather than a benign lump. For a young child exhibiting signs of autism, it could be

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<sup>10</sup> See Rosenbaum, *et al.*, footnote 2.

“adequate” to observe the child rather than conduct diagnostic testing. For an elderly diabetic man, it might be “adequate” to recommend that he “eat right and exercise” rather than prescribe insulin and undertake glucose monitoring.

It is unlikely that more than a handful of treatments will satisfy this least costly adequate treatment standard. The two most likely services to be determined less costly to undertake than mere observation are immunizations and preventive dentistry. But neither would meet the requirement of Part 1 of the definition “to treat or diagnose” and thus would not be determined medically necessary.

This new aspect of the definition, in particular, places providers in a wholly untenable position. Physicians who attempt to treat TennCare patients are bound by an ethical and legal duty to meet prevailing community standards of care. Under the new TennCare law, physicians will no longer be guaranteed reimbursement for care they are ethically required to prescribe and will realistically be limited to offering treatments that are reimbursable but fall short of the prevailing standard of care.

**Part 4 – [A medical item or service] 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 the 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.**

This part would foreclose a wide array of medical services since most medical care in the United States is formulated pursuant to tradition and collective experience. Tennessee’s definition fails to recognize these essential elements of the practice of medicine and would categorize most medical care – despite proven efficacy – as experimental or investigational. Again, this runs counter to existing definitions of medical necessity, which recognize a variety of acceptable justifications for treatment including scientific evidence, professional standards, and expert opinion.<sup>11</sup> The term “inadequate” in this Part is undefined and could result in denial of a treatment needed by a child with a rare disease, if only a few physicians specialize in that treatment, because the determination might well rest on the number of enrollees with a disease or physicians treating it rather than examining the actual benefits of the procedure. Further, the definition forecloses the use of clinical judgment or hypotheses based on extrapolation, which are recognized as part of the national benchmark for professional standards of care.<sup>12</sup>

Even for services or items that are not based on clinical judgment, the definition constrains medical necessity by prohibiting extrapolation from another setting. The definition implicitly recognizes that this provision will eliminate much care that is regarded by the medical community as necessary and appropriate, for it makes an exception that permits off-label use of drugs. Such use is permitted if it is shown to be “widespread [and] generally accepted by the

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<sup>11</sup> See footnote 4.

<sup>12</sup> See *Shilkret v. Annapolis Emergency Hospital*, 349 A.2d 245, 249-50 (Md. 1975).

professional medical community as an effective and proven treatment in the setting and condition for which it is used.” However, under this paragraph many treatments, other than medications, which are also “widespread and generally accepted by the professional medical community as an effective and proven treatment” will nonetheless be deemed “experimental and investigational” and therefore be excluded. Indeed, even off-label uses of some medications may be disallowed if there are relatively few people with the particular disease that the medicine is used to treat.

## **Conclusion**

The new four-part definition of medical necessity that Tennessee has adopted will, if implemented, foreclose access to wide variety of Medicaid services for TennCare enrollees, many of which are listed by the Medicaid Act as mandatory. Allowing a state to circumvent mandatory services in this manner would undermine Congressional judgments that have been made for the Medicaid program and would likely represent an invitation for others, in both public and private plans, to act in a similar manner.

The Tennessee definition of medical necessity limits services to those that are scientifically determined safe and effective and that treat or diagnose medical conditions at the lowest cost possible. This represents a significant deviation from current industry definitions of medical necessity, which utilize a multidimensional definition that entails balancing of a number of factors.

Requiring compliance with each part of the new definition would impose a significant burden on patients and their providers, and would, intentionally or otherwise, almost certainly drive many of the latter out of the Tennessee’s Medicaid program. By vesting ultimate authority with the state to reject virtually all forms of professionally appropriate treatment in favor of the least costly alternative, the definition would impose a nearly insurmountable burden on providers and patients to demonstrate that standard medical practice is not experimental, a burden that is unprecedented in medicine today. The net effect is to establish as a matter of state law that Medicaid patients are entitled to a level of medical care that is, literally, substandard, in that it falls far below what is required of providers by professional ethical and medical malpractice standards for all their other patients.