March 30, 2005

Dear Dr. McClellan,

The undersigned organizations write to express our grave concerns about the Section 1115 TennCare Waiver Amendment submitted on September 24, 2004 and revised on February 18, 2005. While many of us have a range of specific concerns about different provisions of the waiver, this letter highlights three crosscutting issues that would remove basic protections for Medicaid beneficiaries in Tennessee. If approved, this waiver would establish an extremely troubling precedent for Medicaid beneficiaries nationwide. These cross-cutting concerns include the request for “pre-approval” authority to make significant unspecified changes in the program to manage spending within a spending target; the proposed new definition of medical necessity; and far-reaching changes to the pharmacy benefit.

First, the waiver seeks “pre-approval” for a wide range of changes that the state could make at any point in the future without seeking specific authority from the Centers for Medicare and Medicaid Services (CMS). The waiver document lists possible future changes -- such as reducing mandatory or optional services to the lowest level approved in any southern state; expanding eligibility; and raising and/or imposing premiums or copayments on populations such as optional children – but the waiver does not limit the changes to these strategies. The Governor could make these or variations of these changes whenever he (or any future governor) at his sole discretion. As such, the “pre-approval” provision amounts to a request for virtually unfettered and unprecedented discretion to remove or modify federal standards and beneficiary safeguards.

If this “pre-approval” provision is approved, harmful changes affecting most beneficiaries and services in the program could be implemented -- whether or not the changes comport with the intent of federal Medicaid law or the purposes underlying the Medicaid program. This type of “blank check” waiver request was denied to Washington state, and we urge you to similarly reject Tennessee’s request.

Secondly, we believe that the state should not be permitted to operate its program under the state’s revised definition of medical necessity. As written, this definition undermines all beneficiaries’ ability to obtain appropriate health care services, including the guarantee provided to children by the Early Periodic Screening Diagnosis and Treatment (EPSDT) benefit. We urge you to reject this definition for all Medicaid beneficiaries.

Specifically, the definition’s requirement that the “least costly alternative” that is “adequate for the medical condition of the enrollee” be used represents a sharp departure from standard definitions of medical necessity in both public and private insurance programs. In addition, its failure to consider prevailing practices in the community, particularly where clinical tests relating to certain procedures are not available, opens the door for denials of care that treating physicians have determined, with sound basis, are necessary for their patients. Together, these features of the definition would allow for an arbitrary and essentially standardless system for approving or denying coverage.
We strongly believe that CMS should make it clear to Tennessee and to other states that this
definition of medical necessity – which would serve as the gateway to *all services for all Medicaid beneficiaries*-- is not compatible the statutory provisions and objectives of the
Medicaid program. Implicit or explicit approval would set a dangerous precedent for the nation.

The third issue of significant concern to our organizations is the potential for very stringent
limitations on prescription drugs included in the waiver proposal. Many of us have a number of
concerns about the changes that the state is proposing in this area, but we are particularly
troubled by the state’s request to eliminate coverage for two broad classes of medications –
gastric acid reducers and antihistamines, and its request for authority to implement a drug
formulary that would put certain unspecified drugs or classes of drugs on an excluded list,
available only in extremely rare circumstances. The state has not proposed any clear criteria for
determining which drugs or classes of drugs would fall within the excluded category. If
approved, these changes would result in considerable suffering for Medicaid beneficiaries, and
possibly higher Medicaid costs over the long term. Although over the counter alternatives are
available for gastric acid reducers and antihistamines, many Medicaid beneficiaries would be
unable to afford these costs, particularly because these drugs are often prescribed to treat chronic
conditions. Both the two-drug exclusion and the formulary proposal would break new ground by
authorizing a state to exclude entire classes of medications and by undermining federal drug
rebate agreements.

At your confirmation hearing you expressed your belief that the waiver process should not be
used to erode basic protections critical to the integrity of the Medicaid program. We hope that
you will agree that Tennessee’s proposal requires fundamental changes before it can receive
federal approval. Thank you for your attention to our concerns.

Sincerely,

African American Health Alliance
Alliance for Children and Families
Alzheimer's Association
American Association of People with Disabilities
American Association on Mental Retardation
American Congress of Community Supports and Employment Services
Association of Academic Physiatrists
Association of University Centers on Disabilities
Bazelon Center for Mental Health Law
Center for Medicare Advocacy, Inc.
Children's Defense Fund
Disability Service Providers of America
Families USA
Family Services of the Mid-South
Family Voices
Gay Men's Health Crisis
Generations United