CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

July 27, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2390-P, Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability

Dear Mr. Slavitt:

The Cystic Fibrosis Foundation is a national organization that supports research and development of new therapies for cystic fibrosis (CF) and pursues the ultimate goal of finding a cure for the disease. The Foundation also supports a care system for those with CF, which includes health care facilities with special expertise and experience in caring for children and adults with CF. The entities in this network are engaged in constant quality improvement efforts.

There are approximately 30,000 Americans living with CF, and a significant portion of this population is enrolled in Medicaid, with some receiving their care through Medicaid managed care organizations. The proposed rules for Medicaid managed care and Children's Health Insurance Program delivered in managed care have direct relevance for individuals with CF.

We applaud the efforts of the Centers for Medicare & Medicaid Services (CMS) to modernize the requirements for Medicaid managed care organizations, harmonize many standards in Medicaid managed care, Medicare Advantage, and Affordable Care Act exchange plans, and establish important consumer and patient protections for those individuals evaluating enrollment or enrolled in Medicaid managed care. In general, we think that the proposed rules move the overall Medicaid managed care program more solidly in the direction of high quality, patient-centered care. However, our comments

National Office
6931 Arlington Road Bethesda, Maryland 20814
(301) 951-4422 (800) FIGHT CF Fax: (301) 951-6378 Internet: www.cff.org E-mail: info@cff.org

below will identify the obstacles that still remain for CF patients seeking high-quality CF care delivered in care centers that practice according to guidelines and best clinical advice.

Alignment with Other Health Coverage Programs

Marketing

We believe that CMS has modernized and strengthened the rules governing marketing by MCOs, including the exclusion of communication about qualified health plans (QHPs) from the marketing rules. The proposed rules should aid in the education of beneficiaries regarding enrollment options and the management of their eligibility for Medicaid and qualified health plans in the same plan year. This is a discrete but important provision that should assist individuals in preventing disruptions in their care through informed choice of insurance plans and easy transition from Medicaid to QHPs and back to Medicaid, if necessary.

Appeals and Grievances

We applaud the proposal to strengthen the rights of Medicaid managed care enrollees related to grievances and appeals. We note specifically the requirement that appeal decisions be made within 30 days and expedited appeals in 72 hours. These standards will help to harmonize Medicaid managed care requirements with those of Medicare Advantage and private insurers.

Of particular importance are the requirements that all states provide a 60-day period of time to request external review through a fair hearing and that Medicaid managed care enrollees have access to their case file, medical records, and other documents that have been used to conduct coverage determinations. A number of states currently provide a far shorter period of time for requesting external review, and this strict standard has effectively blocked access to external review for some.

The imposition of a requirement that beneficiaries exhaust internal review processes before requesting external review is a reasonable one because it is accompanied by appeal and grievance procedures that are protective of the rights of beneficiaries.

Beneficiary Protections

Enrollment and Beneficiary Support System

We applaud the principles that CMS has embraced in reconsidering and redefining the processes for enrollment in Medicaid MCOs. The preamble to the proposed rule states:

> In both voluntary and mandatory managed care programs, we believe that beneficiaries are best served when they affirmatively exercise their right to make a choice of delivery

system or plan enrollment. Optimally, this involves both an active exercise of choice and requisite time and information to make an informed choice.

CMS has attempted to make enrollment decision-making easier for beneficiaries by improving the education process and by mandating that states provide those in voluntary and mandatory managed care programs 14 days of fee-for-service (FFS) coverage so that they can make an active choice of their managed care plan. While we commend CMS for mandating the provision of this coverage, we recommend that this time period be extended to 30 days to allow beneficiaries sufficient time to make such an important determination. In addition, the agency has emphasized continuity of provider-beneficiary relationship in making assignments to managed care plans.

The beneficiary support system that will be required for all states is an important new element of the enrollment process. We support the emphasis on choice counseling for all beneficiaries, assistance for beneficiaries in understanding managed care, and the requirement that beneficiaries be contacted in multiple ways, including phone, internet, in-person, and via auxiliary aids and services upon request.

The beneficiary enrollment procedures that are proposed for states represent important process improvements. However, as the preamble to the proposed rules discusses, there may in fact be limited choices in certain rural and underserved areas. As a result, improving the education and enrollment process does not necessarily translate to stronger enrollment options. We believe that CF patients may in some cases confront limited acceptable managed care enrollment opportunities. The enrollment difficulties will be related not to rural location but instead to inadequate specialty care provider networks. Although the enrollment process improvements are to be applauded, they do not ensure choice of an appropriate plan if none is available.

Coordination and Continuity of Care

We strongly support the standards for coordination and continuity of care, as these processes may provide the means for protecting access to appropriate, quality specialty care for individuals with special health needs, including individuals with CF. Undertaking the initial needs assessment for MCO enrollees, sharing the results of the assessment with the state and MCOs, and coordinating care according to the plan are key elements of the proposed rules and could offer individuals with special health needs important protections.

Of special interest to beneficiaries with CF is the proposed requirement that MCOs have "… a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs." Care for individuals with CF is typically provided by specialists or teams of specialists practicing at CF care centers. If the process for assessing MCO enrollees' needs and planning care accordingly is

implemented successfully, we believe it would enhance the quality of care for CF enrollees by providing them a standing referral to specialty care in a CF care center.

Because of the promise of the coordination of care provisions, we urge their adoption as part of the final rule, followed by close oversight to ensure that states meet these standards.

Modernizing Regulatory Requirements

Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards

CMS has taken important steps toward ensuring adequate networks of providers for Medicaid enrollees and also protecting timely access to routine, urgent, and emergency care. We generally support the requirement that the states must develop time and distance standards for a number of different provider types, including adult and primary care providers and adult and pediatric specialists. The distinction between pediatric and adult specialists is very important for individuals with CF and many others with complex chronic conditions who require multi-disciplinary, specialty care.

We also note the requirement that states, in developing network adequacy standards, consider the anticipated Medicaid enrollment, the expected utilization of services, the characteristics and health care needs of specific Medicaid populations, and the numbers and types of network health care professionals required to furnish the contracted Medicaid services. A careful analysis by the states of specific populations and their needs would identify the necessity for more flexibility in development of networks so that these special populations have access to necessary care. For example, individuals with CF have better outcomes if they are cared for in accredited CF care centers, where the quality of care is high, care is delivered according to clinical practice guidelines and best clinical judgment, and multi-disciplinary care teams with deep experience provide care. We recommend that states carefully consider the needs of individuals with CF and establish network adequacy standards that would require the inclusion of these care centers in networks. Time and distance standards for most providers, while an important baseline for network adequacy, will likely not result in an adequate network of providers for those with CF.

If states do not set network adequacy standards that would trigger inclusion of specialty care centers for specific populations – including those with CF and others with complex chronic needs that require multi-disciplinary care – they must aggressively enforce the "availability of services" standards, as proposed in §438.206. According to these standards, if a provider network is unable to provide necessary services, covered under a contract, to a particular enrollee, the MCO must adequately and promptly cover these services out of network for the enrollee for as long as the MCO network is unable to provide them. The application of the "availability of services" standards for CF patients would also require acceptance that care in an accredited care center is the only means to provide "necessary services" to those with CF. We believe that this is true and urge further definition of access to specialty care in the "availability of services" rules.

We noted above the potential that the coordination and continuity of care provisions related to direct access to a specialist after an initial needs assessment could facilitate access to necessary care for individuals with CF and others with complex chronic conditions. We recommend that the "availability of services" standards be amended to make specific reference to the initial needs assessment and any recommendations for specialty care that result from that assessment. If the needs assessment produces a recommendation for access to a specialty care center, for example, the availability of care standards should state clearly that the enrollee will have access to recommended care without limit and at no greater cost than if the services were furnished in the network.

Prescription Drug Coverage

In the proposed rules, CMS emphasizes that managed care plan contracts must meet federal Medicaid requirements for prescription drug coverage as they apply to all state plans. These standards relate to amount, duration and scope of coverage, coverage limits, utilization management and prior authorization. Managed care organizations will be permitted to maintain their own prescription drug formularies for covered outpatient drugs that are under contract, but the plans must have a prior authorization process for access to drugs that are not on formulary but still in the scope of the contract. Moreover, if a covered drug or class of drugs is outside the scope of a contract, the state will be required to cover the outpatient drug on a fee-for-service basis.

We are concerned that individuals with CF, who rely on a number of drugs that address the symptoms of CF and may also be prescribed disease-modifying drugs, will be required on a regular basis to pursue prior authorization for drugs that are not on formulary. We urge CMS to set prior authorization standards that must be met by managed care organizations. For example, we recommend that prior authorization standards of MCOs be based on clinical evidence and that fail-first or step therapy requirements have solid clinical support. CF patients far too routinely confront prior authorization requirements that are at odds with the labeling for therapies and that force them to undergo a "fail-first" therapy that provides no clinical benefit whatsoever and is inappropriate for their condition. Such prior authorization requirements at the very least delay patient access to appropriate therapy and on some occasions represent an absolute denial of appropriate care.

We also support the standards related to transparency of formularies. As a general matter, providing more information about formularies will enhance enrollment decision-making and improve the ability of enrollees to manage their care. In the case of individuals with CF, a more relevant inquiry is how a plan defines its prior authorization standard-setting and handles appeals for access to drugs that are not on formulary.

Quality of Care

The proposed rules reflect an important effort to improve the quality of care in Medicaid managed care organizations. The proposed rules in several ways emphasize transparency that will foster ongoing quality improvement.

We support the decision to align Medicaid managed care quality efforts with those of qualified health plans through an accreditation process that would likely include clinical quality measures, patient experience, utilization management, quality assurance, complaints and appeals, and network adequacy and access.

We are pleased that CMS has recommended notice-and-comment rulemaking on the performance measures that Medicaid managed care plans must meet as part of the ongoing comprehensive quality assessment and performance improvement programs.

CMS has also proposed a meaningful external quality review process that will, over time, provide much useful data about plan performance, permit comparison among plans, and foster a culture of ongoing quality improvement. Medicaid managed care enrollees will benefit from this consistent emphasis on quality improvement.

Primary Care Case Management

We support the proposed standards for primary care case management entities, which we hope will foster the transition of these care management services from gatekeeper/utilization control efforts to care coordination and management efforts. Primary care case management that focuses on gatekeeping may serve as a barrier to appropriate quality care. In contrast, primary care case management that has a goal of care coordination can facilitate access to quality care. The recommended criteria for these entities will hopefully foster that transition.

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We have offered a number of specific recommendations regarding the proposed rules. However, we would like to reiterate our support for the CMS effort to modernize Medicaid managed care delivery, bring the standards for Medicaid managed care more consistently in line with those of qualified health plans and Medicare Advantage, and strive for a more patient-centered system of care. With certain modifications to the proposed rules, we feel that the ambitious goals of CMS can be achieved. However, oversight and enforcement of the new rules by CMS and the states will be necessary.

Thank you again for the opportunity to comment on the proposed rules.

Sincerely,

Robert J. Beall, Ph.D.
President and Chief Executive Officer