



February 25, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Draft 2015 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Administrator Tavenner:

The Cystic Fibrosis Foundation is a private, nonprofit organization that represents individuals with cystic fibrosis (CF). We support research and therapeutic development of CF therapies through a venture philanthropy model to accelerate the development of new therapies. We also invest in a network of high-quality CF care centers that are engaged in self-assessment and quality improvement. Finally, we represent CF patients in important policy efforts to ensure their access to high-quality CF care.

We have strong background and experience to inform our comments on the 2015 Letter to Issuers in the Federally-facilitated Marketplace (FFM). We are pleased that the Centers for Medicare & Medicaid Services (CMS) has proposed modifications of some of the standards for certification of health plans as qualified health plans, as these changes are responsive to the needs of those with serious chronic illnesses, including those with CF.

As requested in the letter to issuers, we have organized our comments according to the chapter and section of the letter.

Chapter 2, Section 3. Network Adequacy

We approve the CMS decision to establish a process for determining network adequacy that does not rely solely on plan accreditation and state review, including the decision to undertake a “reasonable access” review of the lists of network providers and facilities submitted by issuers. However, we do not believe that the “special focus” on oncology providers, mental health providers, hospital systems, and primary care providers is adequate. This focus omits a review of the networks that will serve those with

CF and other complex chronic diseases. We recommend that the reasonable access review include the networks of providers who care for those with complex chronic diseases.

Individuals with CF currently depend on a network of specialized care centers that provide care of high quality. These accredited CF care centers, which are located in children's hospitals, academic health centers, and other health systems, provide care to children and adults with CF according to care guidelines. These centers encourage lifelong adherence to the CF care regimen, which is necessary to address the serious and life-threatening effects of the disease. Care in these centers also ensures appropriate genetic testing and access to genetically targeted therapies that address the underlying defect that causes CF and that are available currently for a small portion of the CF population.

We urge CMS to undertake network adequacy reviews not just for the four categories of health providers identified in the letter to issuers. Instead, the agency should extend its reviews to networks for individuals with complex chronic diseases. Disruptions in care and inability to access high-quality, specialized care can affect these individuals' health status for a lifetime.

Chapter 2, Section 4. Essential Community Providers

Some individuals with CF depend on essential community providers (ECP) for access to important health services. We approve the recommendation that issuers be required to demonstrate that they include in their network at least 30 percent of available essential community providers in each plan's service area. This threshold is a step in the right direction, but we urge that it be considered only a floor for ECP participation.

We also propose that the major ECP categories be amended. For example, children's hospitals are currently included as a provider type in the hospital category. Issuers are able to meet the ECP participation for hospitals without including children's hospitals among its ECPs. We have in fact seen networks that do not provide adequate access to children's hospitals, and children in those networks have suffered interruptions in their care and hospitals have provided care without assurance that their patients have insurance coverage for services provided.

CMS should also consider designating special provider networks that provide highly specialized care to individuals with complex chronic diseases of limited prevalence – including but not limited to the CF care centers – as essential community providers. Some of these networks are “essential” as the source of high quality care for certain populations of patients. Encouraging their inclusion in networks will not only ensure access to quality care for patients but will ensure appropriate utilization of health care resources and will protect against inappropriate and unnecessary utilization of care. In short, these networks are essential for individual patients and for the health of the delivery system, as well.

Chapter 3, Section 1. Discriminatory Benefit Design: 2015 Approach

We commend the decision by CMS to strengthen its review of plans to identify possible discriminatory benefit designs that should be corrected. We note that the agency proposals to review plans for outliers based on “an unusually large number of drugs subject to prior authorization and/or step therapy requirements in a particular category and class” and to require revisions of possibly discriminatory practices.

Although we believe these are steps in the right direction, they will be hampered in their effectiveness by the lack of a definition of discrimination in benefit design. Clarity about what constitutes “discrimination” in benefit design will inform insurers and consumers and benefit designs that are not permissible and also inform them when federal enforcement action is necessary.

Chapter 3, Section 2. Prescription Drugs

The call letter states that issuers will be permitted to indicate whether a drug is a “medical drug” covered under a plan’s medical benefit or a drug covered under the prescription drug benefit. Because this is not a requirement of issuers and it is unclear whether issuers will choose to classify all drugs as either prescription benefit or medical benefit drugs, consumers will not benefit from a clear ability to compare coverage across plans. More troubling is the fact that this permission would also seem to be accompanied by the ability of issuer to count both prescription drugs and medical benefit drugs to meet formulary adequacy standards. This is not in the best interest of patients with complex conditions who rely on access to a wide range of drugs.

CMS indicates that in the future it will consider rulemaking to set standards for transitions of care. We are pleased that CMS is considering transitions in drug coverage as well as coverage transitions for other types of care. Although we applaud the movement in this direction and will offer more comments when CMS advances a more specific proposal, we are concerned that a transitional fill or transitional access to a health care provider will only delay interruptions in care. At a minimum, consumers who have access to a transitional fill or transitional access to care should be notified that they must begin an exceptions process immediately to retain access to the same care and care providers after the “transition” period.

We note that the Office of Personnel Management, in its Multi-State Plan Program Issuer Letter of February 2, 2014, has recommended that multi-state plan (MSP) issuers have in place a timely exceptions process that will guarantee that consumers “who need care from out-of-network providers (because of rare or complex medical conditions or lack of in-network providers in a geographic area) can receive it with reasonable cost-sharing, applying enrollee costs to the in-network out of pocket maximum, and protection from balance billing.” We recommend that the transitions policy that CMS is considering be accompanied by a clearly defined exceptions policy.

The CF Foundation appreciates the opportunity to comment on the 2015 letter to issuers.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Beall". The signature is written in a cursive, flowing style with a prominent initial "R".

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