CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

December 22, 2014

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

RE: CMS-9944-P, Proposed Rule on Notice of Benefit and Payment Parameters for 2016

Dear Secretary Burwell:

The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis (CF) and to provide all people with the disease the opportunity to lead full, productive lives by funding and facilitating research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. As part of this mission, the Cystic Fibrosis Foundation accredits a network of cystic fibrosis care centers to ensure patient access to quality care. These centers participate in ongoing quality improvement efforts. The Foundation also maintains a comprehensive patient registry that provides vitally important information about patient access to care and identifies the financial, coverage, and other obstacles to care that CF patients encounter. We draw on these interactions with patients and their caregivers to inform our comments on the Proposed Rule on the Notice of Benefit and Payment Parameters for 2016.

We commend the Department of Health and Human Services (HHS) for several provisions of the proposed rule which will improve the access of individuals with chronic diseases to appropriate care. In addition, we applaud the movement toward greater transparency regarding health plan benefits, as such transparency will permit those with chronic diseases to make better informed decisions about plan benefits and plan costs.

In this comment letter, the Cystic Fibrosis Foundation respectfully:

- Recommends that reliance on 2014 plans for benchmarking purposes begin in 2016 rather than 2017 and urges reconsideration of the overall benchmarking process,
- Commends the utilization of pharmacy and therapeutic (P&T) committees and recommends procedural requirements for such committees,
- Suggests measures to protect patient access to treatments as formularies are developed and maintained,
- Supports the decision to provide patients more flexibility in obtaining their covered drugs,

- Asserts the importance of requiring transparency regarding drug formularies, which is critical to ensuring that patients can pick the appropriate plan that provides the necessary drug coverage for their medical condition,

- Urges HHS to analyze plan choices in 2014 and plan offerings in 2015 and offer specific regulatory action on discriminatory benefit design on the basis of that analysis,

- Recommends establishment of network adequacy standards that reverse the trend toward ultra-narrow networks and that protect those with serious chronic diseases, including patients with CF,

- Asks that HHS clearly delineate the services that are included in the definition of "habilitative services" such as nutritional services and counseling, respiratory therapy, and mental health,

- Suggests a requirement that plan issuers contract with children's hospitals as essential community providers, and

- Recommends uniformity in the collection of data from the federally facilitated exchange and state exchanges and that this data be displayed for the public in a simple and consistent method, and that information about the outcomes of both appeals and exceptions processes be collected and displayed.

Benchmark Approach to Essential Health Benefits - §156.100

We support the decision to permit states to base their benchmark plans on 2014 plans, beginning in 2017. Updating the benchmark standard to 2014 will likely result in a stronger definition of essential health benefits (EHB). We recommend that reliance on 2014 plans for benchmarking purposes begin in 2016 rather than in 2017. We realize that this represents an aggressive implementation schedule for the exchanges, but such action is necessary for the protection of consumers.

We note that HHS makes no movement toward a different approach to definition of essential health benefits and instead retains the reliance on benchmarking. We are pleased that the department has in this proposed rule sought advice on specific EHB issues, and we urge a reconsideration of the overall benchmarking process in the future.

Prescription Drug Benefits - §156.122

We applaud the efforts of the department to develop a formulary process that "would cover drugs based on a qualitative rather than merely quantitative perspective, which we believe will provide enrollees with a more robust formulary drug list." We agree that utilization of a pharmacy and therapeutic (P&T) committee to define prescription drug benefits will result in a stronger formulary. In general, the proposed rule defines a solid P&T process. We are pleased that the proposed rule states that the P&T committee must make "clinical decisions based on scientific evidence such as peer reviewed medical literature, standards of practice such as well-established clinical practice guidelines and other sources of appropriate information." P&T committees would also be required to "consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs and making recommendations on placing them on formulary

tiers." These P&T requirements will help move formularies toward quality and away from simply meeting quantity requirements.

The proposed rule would also require P&T committees to develop and document procedures for their work that would "ensure appropriate drug review and inclusion" and would require that the committees meet at least quarterly. We recommend that the proposed rule include more specific procedural requirements for P&T committees. For example, P&T committees should be required to provide sufficient advanced notice of their meetings to permit public participation and comment. P&T committees should also be mandated to define the standards that will govern comment by members of the public at meetings and in writing for the official record.

Well-defined procedures for public participation in P&T committees will be especially important for consideration of drugs for rare diseases. It is highly unlikely that P&T committees will include experts on rare diseases like CF, and as a result it will be important that expertise on those diseases be brought to the P&T committees through public participation. In general, we support the requirements of the proposed rule that P&T committees must have "members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees." However, we do not anticipate that implementation of these requirements will result in the appointment of pulmonologists, gastroenterologists, or pediatric subspecialists who treat those with CF to P&T committees. Such expertise must still be provided to the P&T committees, and procedural safeguards can ensure the participation of such experts.

The movement toward use of the American Hospital Formulary Service (AHFS), the drug classification system of the American Society of Health-System Pharmacists, is a positive one because that system has more classifications than the currently used United States Pharmacopeia (USP) and could result in a more comprehensive formulary. The switch to the AHFS may be eased by the fact that it is updated annually and already widely used. However, we also note that the AHFS is not currently available to the public, an advantage of USP. If AHFS is to be used for formulary definition, it must be readily accessible by the public.

Although we are not philosophically opposed to a formulary process that would use P&T committees and the AHFS as complementary elements of the process, we would note that the relationship of these elements is not clearly defined by HHS. We urge more specificity regarding the formulary process.

We also anticipate, even with an improved process that produces a robust formulary drug list, that there will be formulary gaps for individuals with CF and other chronic diseases. It is likely that formulary drug lists will still place limits on the number of drugs in a class. Such limits pose challenges for individuals with CF who may not obtain a therapeutic benefit from the single pancreatic enzyme on a formulary and may instead need an enzyme that is not listed on the formulary. There will also likely be a lag – even with the requirement that P&T committees meet quarterly – in the formulary listing of new CF drugs that address the fundamental cause of the disease. These drugs, which are targeted according to the individual's genetic profile, might not be immediately available to patients under the proposed formulary process. As the department continues its review and overhaul of the formulary process, special attention should be paid to the incorporation of new drugs into formularies. For individuals with CF, a delay of even a few months in access to a disease-modifying drug that may stabilize disease progression or improve health status is unacceptable.

We approve the decision to provide patients more flexibility in obtaining their covered drugs. Under the proposed rule, a health plan would not be permitted to have a mail order-only prescription drug benefit. Many CF patients have relationships with their retail pharmacists, and the proposed rule would permit

them to obtain medications from those pharmacies. The provision to permit higher cost sharing for drugs obtained at retail pharmacies may represent a financial burden for CF patients, but the ability to count those amounts toward the annual limitation on cost sharing provides some financial protection to patients. On balance, we think the expansion of pharmacy options helps patients.

Exceptions Process – §156.122(c)

We commend the department for improvements in the exceptions process. Establishing a standard exceptions process in addition to the expedited exceptions process will provide individuals with chronic diseases important protections as will the availability of a process for external review of denials in both expedited and standard exceptions. Establishing a process for an enrollee to request that an independent review organization review the exception request and the denial of that request by the plan adds an additional layer of protection for patients. These protections may be especially relevant to the situations identified above, when a new drug is not included on formulary in timely fashion for patients with serious health needs and when only one drug in a class is included on formulary.

Considering drugs provided through an exceptions process as essential health benefits and counting related cost-sharing against the out-of-pocket limit are important consumer protections.

Transparency Regarding Formulary Drug Lists - §156.122(d)

The department makes an important step toward consumer education and informed decision-making regarding health plans by including in the proposed rule a requirement that a health plan publish an "up-to-date, accurate and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained." The proposed rule sets out a reasonable definition for accessibility of information. These data transparency requirements, when fully implemented, will represent real movement toward consumer education and empowerment.

Prohibition on Discrimination - §156.125

Although we are pleased that the department acknowledges the possibility of discriminatory benefit design and urges plan issuers to avoid discriminatory benefit design, we urge action beyond this encouragement to issuers. Two examples of discriminatory design have particular relevance to those with CF. Age limits on benefits may pose significant barriers to care for adults with CF, and the placement of all or most drugs in a class of CF drugs on the highest cost tiers also represents a discriminatory benefit design.

We urge HHS to analyze plan choices in 2014 and plan offerings in 2015 and offer specific regulatory action on discriminatory benefit design on the basis of that analysis.

Cost-Sharing Requirements - §156.130
Network Adequacy - §156.230

Although HHS notes in the preamble that plan issuers have the option to count cost-sharing for out-of-network services toward the annual limitation on cost-sharing, the fact remains that there is no requirement that issuers do so. We do not anticipate that issuers will count out-of-network cost-sharing toward the annual limit. The issue of out-of-network access remains a very important one for individuals with CF and other serious chronic diseases. These individuals may need specialty care available only at a

few health care centers, and the trend toward narrow and ultra-narrow networks is distinctly at odds with those needs. We will continue to press for responsible network adequacy standards through the process that the National Association for Insurance Commissioners is advancing and through the HHS regulatory process. Without reasonable provider networks or cost-sharing protections for out-of-network care, qualified health plans may not in fact provide individuals with serious chronic diseases access to appropriate care.

We commend the proposal to strengthen the provider directory requirement, so that issuers are required to publish an up-to-date, accurate, and complete provider directory. Providing this information to enrollees and prospective enrollees will equip them to make more informed decisions about enrollment and will assist them in managing their care after enrollment.

We are concerned with efforts to require plan issuers to permit new enrollees access to their network of providers for 30 days after enrollment in the new plan. The transition period of 30 days is not adequate for individuals with significant health care needs to properly evaluate network and treatment coverage. Further, no transition period, regardless of the amount of time provided, is useful if there is no equivalent in-network specialized care facility.

Ensuring a 30-day network transition period to new plan enrollees and publishing provider information for enrollees and prospective enrollees are modest patient protections, but they are inadequate unless followed by establishment of network adequacy standards that reverse the trend toward ultra-narrow networks and that protect those with serious chronic diseases, including patients with CF.

Habilitative Services - §156.115(a)

We commend the HHS approach to defining habilitative services and at the same time accepting advice regarding this definition. It is an important step forward for HHS to define habilitative services instead of permitting insurers to develop their own definitions of such services. Several health care services to individuals with CF and their parents and caregivers would meet the HHS definition of habilitative services as "[h]ealth care services that help a person keep, learn, or improve skills and functioning for daily living." These services include nutritional services, such as vitamins and nutritionals and nutrition counseling and planning; respiratory therapy, including teaching of inhalation skills and huff coughs; and mental health services, including coaching and coping skills for the person with CF and his or her parents and caregivers.

Setting a separate visit limit for habilitative services instead of including habilitative and rehabilitative services under a single visit limit is an important patient protection.

Essential Community Providers - §156.235

We are concerned that the proposed rule does not include a provision that would ensure that plan issuers contract with children's hospitals as essential community providers. Children's hospitals are identified with other hospitals as a class of essential community providers, but that does not guarantee that issuers will contract directly with children's hospitals. In the case of CF and many other pediatric diseases, children's hospitals may represent the best site for care. Under current standards, these institutions are too often excluded from provider networks. We urge HHS to address this matter.

Data Collection – §156.120

We are pleased that HHS intends to collect information from qualified health plans and provide access to that information in 2016. We recommend uniformity in the collection of data from the federally facilitated exchange and state exchanges and that this data be displayed for the public in a simple and consistent method. The public and regulators will enjoy the greatest benefit from the data if they permit comparison among plans.

In addition to information about enrollment, disenrollments, claims denials, and cost-sharing for out-of-network care, we recommend that information about the outcomes of both appeals and exceptions processes be collected and displayed. These latter categories of data may provide some insights about the adequacy of coverage for individuals with serious chronic diseases. Cost-sharing for out-of-network care will complement these data. However, we think that the appeals and exceptions data are critical because they may also provide insights about the extent to which patients may forgo care if it is not available on-formulary or in-network.

Minimum Essential Coverage - §156.602

The CF Foundation applauds the decision to eliminate the one-year transition period for individuals transitioning from state high risk pool coverage to a qualified health plan through the exchanges or into another form of minimum essential coverage. This delay is problematic especially for those with chronic diseases like cystic fibrosis, for whom quality coverage is critical to maintaining health and well-being, and we believe the elimination of this delay will help ensure the provision of quality coverage for vulnerable populations.

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We appreciate the opportunity to comment on the Notice on Benefit and Payment Parameters for 2016. We are pleased that HHS is taking steps to improve specific benefit categories, including prescription drug coverage and rehabilitative and habilitative services. We also commend the steps the department outlines for greater transparency related to the data on qualified health plans. The collection and sharing of data will permit consumers to make more informed decisions about the purchase of their health plan and about their health care.

Sincerely,

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