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October 6, 2011

Donald Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS -9989-P, Proposed Rule on Establishment of Exchanges and Qualified Health Plans

Dear Dr. Berwick:

The Cystic Fibrosis Foundation, a national organization investing in cystic fibrosis (CF) research and quality care for individuals with CF, appreciates the opportunity to comment on the proposed rule creating standards for the establishment of health insurance exchanges and qualified health plans. The development of a vibrant marketplace for the purchase of health insurance is a very important milestone for individuals with CF, who have faced significant obstacles in maintaining health insurance coverage that ensures their access to quality CF care. Our recommended revisions in the proposed rule relate to the governance of the exchanges, consultation with stakeholders, operation of navigation programs and exchange network adequacy standards.

Entities Eligible to Carry Out Exchange Functions (§155.110)

The CF Foundation endorses the basic standards for the operation of exchanges, including those standards that: 1) govern the administration of the Exchange under a formal, publicly adopted charter; 2) require scheduling of public governing board meeting; and 3) mandate adoption of a requirement that the majority of governing board members have no conflicts of interest. We also appreciate that the proposed rule identifies diverse areas of expertise for governing board members including experience in health benefits administration, health care finance, health plan purchasing, health care delivery system administration, public health or health policy issues related to the small group and individual markets and the uninsured. We recommend that the prescribed membership of the governing board be expanded to include consumer representatives and patient representatives.

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It is imperative that the perspectives and needs of patients be adequately expressed in the governing board, and this can best be accomplished by including patient and consumer representatives, particularly those with experience in insurance issues associated with chronic conditions, as full members of the governing board. We think such representatives will be able to provide valuable advice about the structure and operation of the health insurance marketplace, guaranteeing that it functions appropriately to meet the needs of those with serious and life-threatening and chronic diseases. It will be a significant challenge to ensure that the exchanges provide adequate informational materials and access to counseling so that consumers are equipped to make well-considered decisions about insurance enrollment and consumer and patient advocates are particularly well-equipped to provide exchanges counsel regarding such issues.

Consumer and patient representatives will also be able to provide advice and insights regarding the insurance enrollment process, the benefit package, special enrollment periods and the process for the determination of eligibility for subsidies. On all of these matters, the perspectives of consumers and patients will be useful to the exchanges in designing a consumer- and patient-friendly marketplace for health insurance. We urge that the proposed rule be amended to require inclusion of patient or consumer representatives on the Exchange governing board.

Stakeholder Consultation (§155.130)

The Affordable Care Act (ACA) requires consultation by the exchanges with a wide range of stakeholders and the proposed rule identifies advocates for those with mental health or substance abuse diseases as a group that should be included in stakeholder consultations. We commend this provision of the proposed rule, but we strongly recommend that the proposed rule be amended to specify that advocates for those with chronic diseases, including those with intensive daily health care needs, be incorporated in the stakeholder consultation process.

The integration of chronic disease advocates is necessary to ensure that the exchanges receive comprehensive advice about the needs of these patients, the information and resources they may require for evaluation and purchase of health insurance through the exchanges and the possible utilization of special enrollment periods by these patients.

Modification of the stakeholder consultation process to include advocates for those with chronic diseases should not be considered a substitute for including consumer and patient representatives on Exchange governing boards. Instead, such stakeholder consultation should be a complement to the expansion of the governing board membership.

Functions of an Exchange (§155.200)

We commend the provisions of the proposed rule that, consistent with ACA, would require exchanges to evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures and data reporting. We understand that the proposed rule establishes the basic requirements for exchanges related to

quality improvement and that future rulemaking on these topics will further define these responsibilities.

We urge CMS to engage organizations that have expertise and experience in quality assessment and improvement – including those like the CF Foundation that have deep knowledge and engagement in a specific disease area – as it provides more detail and specificity to the quality assessment activities of exchanges. The CF Foundation maintains a patient registry that informs and guides clinical care for those with CF as well as ongoing quality improvement efforts. We also have deep relationships with the patients we serve; relationships that help us assess patient and family satisfaction regarding care. The CF Foundation and other comparable organizations involved in quality measurement and improvement can provide significant guidance to the agency in defining exchange quality improvement responsibilities, and we urge the agency to capitalize on the experience of those of us with long-standing involvement in and commitment to quality health care.

Consumer Assistance Tools and Programs (§155.205)

Section 155.205 describes the required tools and programs that an Exchange must establish, including a web site tool that is accessible to those with a disability. We believe that such a web site should be designed in such a way as to clearly elucidate those topics which are necessary and life-sustaining components of treatment for those with rare, chronic conditions like CF. For example, when describing benefits and the coverage for medications, the web site should reference any limits as well as the potential for exemption from such limits for someone dependent on multiple daily medications.

The provision also calls for the Navigator program to refer consumers to consumer assistance programs in the state when available and appropriate. We applaud this inclusion and suggest that clarity be provided as to which programs consumers could be referred to, believing that both local advocacy programs and recognized, accredited care centers be included.

Navigator Program Standards (§155.210)

We are pleased that the ACA requires the availability of navigation services in the exchanges. As our comments above indicate, we anticipate that the exchanges will experience some challenges in the design and execution of a marketplace that is consumer-oriented and facilitates the informed purchase of health insurance. Navigators can play a pivotal role in the effective operation of the exchanges. Many nonprofit organizations currently provide counseling on matters of insurance, beneficiary cost-sharing, and access to appropriate health care, in many cases combining deep knowledge of specific patient communities with their counseling capabilities. We believe there is promise in the exchanges collaborating with these organizations to provide counseling and navigation services to consumers who will be relying on the exchanges for insurance needs.

The statutory prohibition against the use of federal funds to the exchanges for navigator services will serve as an obstacle to such a system. Although collaboration with non-for-profit organizations to

provide counseling services might be an effective solution for navigation – both in terms of cost and quality of navigation services – it will not be without some expense. Collaboration of exchanges and nonprofits on navigation will at least require training and communication among the parties about the exchanges, their structure and the qualified health plans (QHPs) that will be offered. We urge the agency to consider options, consistent with the statutory limits, to guarantee that appropriate resources are dedicated to high-quality navigation services.

Exclusions of Prohibitions against Costly Procedures (§155.1000)

The proposed rule indicates that the Exchange may certify a health plan as a qualified health plan (QHP) as long as it meets a number of requirements. However, the Exchange “must not exclude a health plan on the basis that the health plan provides treatments necessary to prevent patients’ deaths in circumstances the Exchange determines are inappropriate or too costly.” We applaud the intent of this provision because we believe that it is important that any plan that provides for a patient who needs a costly, advanced treatment, such as a lung transplant, in order to stay alive must not be excluded from participating.

Lung transplants are an established component of late-stage pulmonary conditions like CF, however insurance plans are not always compelled to cover them, stranding patients without a medical option in order to stay alive. We ask that the Department of Health and Human Services clarify the provision to ensure that health plans that provide for such treatments would not be excluded on that basis. We also believe the example of lung transplants is illustrative and could serve as an example of the correct reading of this provision as a procedure that cannot be denied on the basis of its cost.

Establishment of Exchange Network Adequacy Standards (§155.1050)

The proposed rule sets a broad standard that qualified health plans, or QHPs, must set network adequacy standards that are appropriate to states’ geography, demographics, local patterns of care and market conditions. The agency also asks for comment on potential additional requirements that the exchanges might impose on QHPs, including a process to ensure that an enrollee can obtain care from an out-of-network provider at no additional cost if no network provider can provide that benefit in timely manner.

The CF Foundation strongly urges that network adequacy standards be defined to require QHPs to permit access to out-of-network providers without additional cost when care is not available from network providers. Both children and adults with CF customarily receive their care from interdisciplinary CF care centers that provide care that is of high quality and consistent with current practice guidelines and expert clinical advice. We believe that this system ensures the highest level of care for those with CF and is also ultimately an efficient system of care from the perspective of third-party payers. This coordinated system protects against gaps in care, ensures access to prophylactic treatments that may forestall hospitalization or other care in expensive settings, and slows the loss of lung function and occurrence of lung exacerbations.

The outstanding system of CF care may not in all occasions – or even most occasions – be provided by providers in the QHP networks. We encourage CMS to set a standard for QHPs that would require access to specialized systems of care, even if out of network, if such systems and out-of-network providers constitute the best treatment system for those with chronic and serious and life-threatening illnesses.

We strongly recommend that this provision also be considered to include pharmacy services, particularly in those situations where there is a limited group of pharmacies distributing a specialty drug that is not otherwise available. Pharmacy Benefit Managers (PBMs) should be prohibited from excluding specialty drugs as well as penalizing patients when the PBM's captive pharmacies are not included in the distribution network. The majority of the drugs that treat rare chronic diseases like cystic fibrosis are not commonly used in other patient populations due to how highly specific care is for these diseases. We have already seen cases where a PBM has penalized enrollees because their captive pharmacy is not included in the drug's distribution network, charging patients an unaffordable co-insurance rate for a specialty drug that is much higher than the normal co-pay they would have otherwise paid. Applying this provision to pharmacy services as well as other health networks will create a more equitable environment for patients.

The CF Foundation appreciates the opportunity to comment on the standards for establishing the exchanges.

Sincerely,

A handwritten signature in black ink that reads "Robert J. Beall". The signature is written in a cursive style with a large, sweeping initial "R".

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