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October 21, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-1850

RE: CMS-9982-P and CMS-9982-NC

Filed electronically at <http://www.regulations.gov>

Dear Sir or Madam:

The Cystic Fibrosis Foundation (CFF) supports an innovative and aggressive research program, including a clinical trials network, to find new treatments for cystic fibrosis (CF). We also maintain a system of specialized care centers that provide high-quality care to those with CF and engage in ongoing quality improvement activities. Finally, we provide patient services, including counseling related to health insurance access and health care payment, to a diverse population of individuals with CF and their families. We are pleased to bring our experience in service to the CF community to the review of the summary of benefits and coverage (SBC) and uniform glossary.

The SBC is of great importance to the implementation of the Affordable Care Act in a manner that will encourage consumers to make informed decisions about their insurance coverage options. A quality SBC will allow consumers to assess their own health care needs or their families' needs, what insurance plans will cover, and what plans will not cover. We are pleased with the process that the Departments of Health and Human Services, Labor, and Treasury have undertaken in proposing the SBC, a process that relied on the public working group process of the National Association of Insurance Commissioners (NAIC).

We appreciate the significant challenges associated with developing a four-page, double-sided

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

document to educate consumers. While we applaud the product to date, we offer some recommendations for additions to it. We focus especially on the addition of coverage examples and the expansion of the uniform glossary.

Coverage Examples

We commend the inclusion of three coverage examples in the SBC, as the use of such examples helps consumers understand what plans will and will not cover in concrete terms. We note that the three examples, although addressing diverse diseases and populations, fail to focus on several important populations with intensive health care needs and therefore with the need for assistance in assessing insurance coverage for its adequacy.

We recommend inclusion of additional coverage examples, even though we understand that incorporation of more will trigger edits to the overall document to meet its length limit. It is important that one of the examples focus on a chronic disease whose patients have intensive medical needs that may shift over a lifetime. The example would foster aggressive consumer analysis of coverage options if it also focused on a disease whose patients have need for services and items that may not in all plans be considered “medically necessary.”

We offer CF as a chronic disease that would accomplish these consumer education goals not only for those with CF but for others with chronic diseases. If CF is included, the following health care services should be included in the list of sample care costs: office visits and procedures, including visits to specialists; laboratory tests; hospital charges; inpatient medical care; prescription drugs; medical devices for delivery of aerosolized antibiotics; other durable medical equipment; home care services; transplant charges; and nutritional support.

The example of CF or another chronic disease affecting children will also encourage analysis of cost-sharing in family coverage, as compared to an individual plan.

Glossary

The uniform glossary can serve as a critically important tool for consumers, who generally do not have adequate understanding of health insurance terms, even if they understand medical terms related to their disease or condition. In patient education and support efforts of the Foundation, we find that there is a special need for greater understanding of health care cost-sharing responsibilities.

We appreciate the need for brevity and simplicity in the uniform glossary, but we recommend a glossary entry for “cost-sharing” that could incorporate the terms “co-insurance” and co-payments.” We think this organizational strategy might help to clarify cost-sharing responsibilities. We also think that there must be additional terms related to prescription drug coverage options, to aid those consumers who need access to a wide variety of medications that may be subject to different coverage and payment standards.

The rate of participation in clinical trials among those with CF is very high, as it is in other chronic disease communities. Although the CF Foundation and others support a strong educational effort related to clinical trial participation, the glossary should be expanded to address the topic of clinical trials and thereby aid in the evaluation of clinical trials coverage by insurance plans.

The following terms should be added to the glossary:

- Prescription drugs –preferred brand, non-preferred brand, generic
- Prescription drug tiers
- Specialty drugs
- Formulary
- Drugs and biologicals – self-administered prescription drugs and physician-administered drugs
- Participating providers
- Network
- Out-of-network provider
- Clinical Trials – routine patient care costs
- Diagnostic tests --to inform treatment decision-making and treatment monitoring

Distribution of the SBC to Consumers

Electronic communication tools can be very effective in consumer education, and the CF Foundation and other patient organizations increasingly rely on these methods. However, there remain significant limits in reliable access to the internet. As a result, the SBC must be available in both printed format that can be distributed by mail as well as in electronic form.

Effective Date

We support the implementation of the SBC and uniform glossary as soon as possible and preferably by the statutory date of March 23, 2012. While consumers need these tools at the earliest possible time, we acknowledge that we and others are recommending changes that require evaluation and possible incorporation in the materials and that this process could delay

the date of implementation. If modest delay in implementation would be accompanied by an enhanced SBC and stronger glossary, we think that course of action should be pursued by the Departments. Such an approach would also be responsive to the needs of insurers who need predictability about the SBC and glossary.

We also recommend ongoing evaluation of the SBC and glossary and refinements of it based on such evaluation. The CF Foundation and other patient and consumer organizations can contribute to an ongoing and consumer-focused evaluation process.

We appreciate this opportunity to comment on the SBC and uniform glossary and look forward to working collaboratively to serve consumers in a changing health care system.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Beall". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping tail.

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