



| Adding *tomorrows* every day.

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August 27, 2010

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

RE: OCIO-9994-IFC

The Honorable Hilda Solis  
Secretary  
Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20210

RE: RIN 1210-AB43

The Honorable Douglas Shulman  
Commissioner  
Internal Revenue Service  
1111 Constitution Ave NW,  
Washington, DC 20224

RE: REG-120399-10

Dear Secretary Sebelius, Secretary Solis, and Commissioner Shulman:

On behalf of the Cystic Fibrosis Foundation and 30,000 patients with CF across the country, I am pleased to submit the following comments on the interim final rules regarding preexisting condition exclusions, lifetime and annual limits, rescissions, and patient protections. We applaud the Departments of Health and Human Services, Labor, and Treasury for their timely issuance of interim final regulations implementing critical provisions of the Patient Protection and Affordable Care Act. We agree with the departments that the interim final rules at hand are particularly important because they implement provisions of the Affordable Care Act that offer protections to many with chronic and serious health conditions who require significant medical care, make large expenditures for care, and encounter special risk of loss of insurance coverage.

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**National Office**

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We commend the departments for a clear and forceful description of the benefits of these interim final rules, including 1) reductions in mortality and morbidity, 2) reduction in medical risk, 3) improved workplace productivity, and 4) reductions in uncompensated care and resulting cost-shifting.

We recommend several modifications of the regulations. While discussed in greater detail below, these modifications include extending the minimum annual and lifetime limits, increasing them for each year of the three-year phased transition to 2014, when annual limits will be prohibited; clarification of the protections against rescissions of benefits that will be afforded consumers and additional protections to consumers who find themselves in the position of suffering a rescission of employer-sponsored coverage due to action by the plan sponsor; additional demonstrations and pilot projects to test and evaluate case management and care coordination for those with chronic and serious illnesses.

We urge a continued strong emphasis on consumer education about the Affordable Care Act, to ensure that consumers take appropriate advantage of the law's protections and benefits.

Those with cystic fibrosis (CF) and their families will be clear beneficiaries of these benefits, as described below.

### ***Preexisting Condition Exclusions***

Those with CF and their families are at substantial risk of being uninsured as a result of the application of preexisting condition exclusions. Those with CF who experience gaps – which may be for extended periods of time – in coverage may forgo critical health care and experience significant deterioration in lung function and overall health status as a result. The impact on their own health and the overall cost to the health care system for care delayed may be great. The extension of dependent coverage in the Affordable Care Act offers special promise to young adults with CF who have previously found themselves confronting loss of insurance coverage at a time when they were seeking to become self-supporting and enter the workforce. The extension of preexisting condition protections to those under age 19 enrolled in certain plans and policies will also provide some relief to families with young children and teenagers with CF.

The commentary to the interim final rule explains that the extension of preexisting condition limits will not apply to individual policies that enjoy grandfathered status. The departments recommend that a parent with a child who is excluded from coverage under a grandfathered individual plan consider terminating the existing plan and purchasing a new individual plan that would be subject to the preexisting condition rules. Families with a child with CF have by necessity become sophisticated health care consumers and purchasers of health insurance coverage. However, the Affordable Care Act imposes new regulatory requirements and important patient protections that will not be immediately understood by CF families and others. We urge that the Departments continue their aggressive public education efforts regarding the Affordable Care Act, to

be complemented by the efforts of many states, to ensure that consumers are aware of all opportunities to improve their access to affordable health care, such as the purchase of new coverage through an individual plan.

We note that the commentary to the rules also identifies a population of children whose parents are offered employer-sponsored insurance but are unable to afford that insurance. The departments make clear that the interim rules do not address the issue of affordability of coverage, meaning that some will remain outside the insurance market because of inability to purchase employer-sponsored insurance. We understand that addressing this issue is outside the scope of the interim final rules, but we appreciate the acknowledgement by the departments of those whose insurance needs will not be addressed immediately by the Affordable Care Act or the interim final rules.

### *Annual and Lifetime Limits*

We understand the need to balance individuals' access to essential health benefits against the potential for premium increases for all plans and policies in developing the three-year phased approach to restricted annual limits. However, we have concerns about the minimum limits that are included in the interim final rule. For the policy or plan years beginning on or after September 23, 2010, but before September 23, 2011, the minimum limit is \$750,000. This is a limit that may be reached by individuals with CF in any year when they must be hospitalized for pulmonary exacerbations of CF as well as by those with CF who have lung transplants. The minimum limits for 2011-2012 and 2012-2013, although greater, might also be reached by a small number of those with CF.

We admit that the number of individuals reaching the minimum limits established by the interim final rule will be small. As the Departments recognize throughout the commentary to the rules, the benefits of the protections outlined in the rules are enjoyed by a relatively limited population. As a result, the cost of the benefits – and the potential impact on premiums – will also be limited.

Because of the limited overall fiscal impact associated with such a change, we urge the Departments to reconsider the minimum limits, increasing them for each year of the three-year phased transition to 2014, when annual limits will be prohibited.

### *Rescissions of Coverage*

We are pleased that the interim final rules clarify the protections against rescissions of benefits that will be afforded consumers and define the actions that might trigger rescissions. The interim rules make clear that rescissions would be permitted only if there was fraud or an intentional misrepresentation of material fact. The commentary provides examples that further explain the grounds for rescissions.

According to language in the preamble, an individual consumer might be at risk for rescission on the basis of an action by a plan sponsor. The preamble states, "Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group,

the standards of these interim final regulations would also apply.” Individuals with CF who were included in such an employment-based group might find themselves without access to insurance coverage at an affordable price. It seems that the only protections available to such individual would be thirty days’ notice of the rescission and the possibility of seeking coverage in the individual market. However, such coverage may not be readily affordable.

We understand that any misrepresentation by the employer would relate to the contractual relationship between the sponsor and issuer and that the language of the Affordable Care Act related to intentional misrepresentation of material fact is relevant. We urge that the departments consider whether there is any option, consistent with the Affordable Care Act, for providing protections to consumers who find themselves in the position of suffering a rescission of employer-sponsored coverage due to action by the plan sponsor.

### ***Patient Protections Related to Choice of Physicians***

We are pleased that the Affordable Care Act and the interim final rules protect the rights of patients to designate a primary care physician who participates in the plan, choose a pediatrician as a primary care physician, and access emergency services at in-network rates. The departments make a strong case for these patient protections, citing the positive impact of designating a primary care physician on quality of care, patient compliance with care, and coordination of all elements of care. The benefits related to patient choice of physician and care coordination are very strong, and we encourage additional demonstrations and pilot projects to test and evaluate case management and care coordination for those with chronic and serious illnesses. The CF Foundation has a strong clinical care network supported by practice guidelines and routine reporting of patient outcomes in a readily accessible patient care registry. These efforts have supported significant quality improvements in CF care and should be expanded and replicated in other chronic disease areas. We believe the Affordable Care Act creates the opportunity for experimentation in health care delivery and urge that this opportunity be seized.

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We commend the departments for the interim final rules, which offer important protections to individuals with serious illnesses who require significant health care and have substantial health care expenses.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Beall". The signature is fluid and cursive, with the first name "Robert" being the most prominent part.

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