January 30, 2020

Andrew Saul
Commissioner
Social Security Administration
6401 Security Boulevard
Baltimore, MD 21235

RE: SSA-2018-0026, Rules Regarding the Frequency and Notice of Continuing Disability Reviews

Dear Commissioner Saul:

On behalf of people living with cystic fibrosis (CF), the Cystic Fibrosis Foundation is pleased to comment on the Social Security Administration's draft rule regarding the frequency and notice of continuing disability reviews. The CF Foundation has a number of serious concerns about the rule including the new diary category (medical improvement likely), the assignment of new conditions to diary categories, the burden of continuing disability reviews on beneficiaries, and the effect of continuing disability review backlogs on beneficiaries.

Background on the Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation is a national organization that is dedicated to curing cystic fibrosis and helping people with CF lead long fulfilling lives. The CF Foundation supports a strong program of basic, translational, and clinical research on CF; leads a network of CF care centers providing quality care to children and adults with CF; provides a wide range of support services to people with CF; and seeks to ensure access to health insurance and health care for all with CF. Advances in therapies and care have resulted in improvements in the life expectancy for those with CF, and the work to cure the disease continues.

Background on disability and CF

When the CF Foundation was founded in the 1950s, children with the disease rarely lived to attend elementary school. Despite the improvements in treatment and life expectancy, CF is a disabling disease for many. CF remains a chronic, progressive disease. People with CF and their families shoulder a significant burden associated with managing the symptoms of CF and multiple, time-consuming daily treatments for the disease. We understand that Continuing Disability Reviews are necessary for integrity of the program but have substantial concerns about the impact the proposed changes outlined in this rule will have on beneficiaries.

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Summary of Concerns

We have significant reservations about the proposal to establish a fourth medical diary category and change the conditions that are assigned to each diary category. The proposed rule fails to assess the impact of the continuing disability review (CDR) changes on disability beneficiaries, does not include a clear rationale for establishing a new diary category, and does not articulate standards for the assignment of conditions to the categories. Although the Social Security Administration (SSA) has the authority to set standards for CDRs at intervals more frequent than anticipated in the statute, it must articulate the reasons for more frequent reviews. In the proposed rule, SSA has failed to provide the public adequate notice of the proposed changes and the rationale for them and therefore does not provide the public a meaningful opportunity to comment on the proposal. The agency has not met its Administrative Procedure Act responsibilities for notice-and-comment rulemaking.

The Burden of Continuing Disability Reviews

CDRs are a serious burden for beneficiaries. Both the "mailer" form and the full medical form for CDRs require significant time, effort, and expense to complete. Beneficiaries may be required to provide medical records to respond to a CDR, a requirement that imposes a time and financial burden on beneficiaries. The forms themselves are complex, requiring time and effort to complete by beneficiaries and their families. The modest time estimates for completion of the CDR forms included in the proposed rule do not accurately reflect the experience of people with CF who are faced with CDRs and the responses required of beneficiaries. Completing the required forms, in addition to being complex to understand, requires a very significant investment of time on both the part of the beneficiaries and his/her medical care team. Moreover, for the last year for which we have data, about one-third of initial cessations were reversed on appeal. Under the proposed rule, beneficiaries will be required to respond to more frequent CDRs in a process that has a high rate of reversal.

The proposed rule does not include data about the number of people who will lose benefits as the result of the increased number of CDRs. Absent this information, the public cannot assess the impact of the proposed rule on the disability program and on beneficiaries, including people with CF. Also, without this information, it is impossible to complete a full risk and benefit analysis that takes into consideration the impact of the proposed rule on beneficiaries, the SSA, and federal expenditures.

The New Diary Category, Medical Improvement Likely

SSA argues that a new diary category, with CDRs conducted every two years, is necessary in order to identify medical improvement at the earliest possible opportunity. However, the agency fails to identify the standards for the new diary category and the assignment of conditions to the diary category. SSA says only that there have been advances in medical technology and treatment that have resulted in improved outcomes for some impairments. It seems that a new diary category is intended to capture those impairments for which there are improved outcomes.

We are not persuaded that more frequent reviews are necessary, but at the very least the agency should explain what standards it is suggesting when it references medical technology and treatment advances that would justify a new diary category. For example, is the agency judging a treatment advance by the impact on outcomes as reported in clinical trials? This may not be an accurate manner

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for assessing medical improvement from a new technology or therapy. Looking only at outcomes from a treatment, as included in product labeling, fails to consider the adherence and compliance burdens associated with a treatment, the side effects of the treatment, and the late and long-term effects of the disease and the treatment. Finally, real world evidence of a new treatment's benefits may not match the benefits as confirmed in a clinical trial. The benefits observed in a clinical trial may be experienced by some patients but not by others. SSA must take care not to overstate the benefits of a new treatment for a group of patients or to assume optimal or uniform benefit for all.

If the agency is to proceed with a new diary category and assignment of conditions to that category, it must provide a rationale for those actions. A general reference to new treatments providing medical benefit is inadequate and the issues associated with utilization of a new therapy must be included in an analysis of risks and benefits of the treatment, the potential impact on medical improvement, and way in which a medical treatment supports a new diary category and assignment of conditions to that diary.

The Assignment of Conditions to Diary Categories

The proposed rule fails to provide sufficient evidence regarding the assignment of conditions to diary categories. The rationale for assignment of conditions to the Medical Improvement Expected (MIE) and Medical Improvement Likely (MIL) categories is unclear. There is also no clear process or impairment-specific evidence for assigning conditions to the Medical Improvement Not Expected (MINE) category. Although we began the process of reviewing this proposed rule with an assumption about the assignment of cystic fibrosis, we find at the end of the review that we cannot be certain about the assignment.

As we noted above, the lack of precision and detail in the proposed rule makes this a significantly flawed notice-and-comment rulemaking process. The standards of the rulemaking process are not honored in this rule, and we recommend that the agency rescind this proposal and consider a new process to address the issue of identifying medical improvement.

CDR Backlogs

SSA has a long history of difficulty managing its CDR workload. The agency eliminated its longstanding CDR backlog in CY 2002, but in the years since it has built up backlogs that had to be eliminated. As of fall of 2019, there was a substantial backlog of pending CDRs at state agencies.

The agency has not evaluated how the proposed new diary category – with a requirement for CDRs at a two-year interval – will affect its backlog.

We urge the agency to consider the potential impact on beneficiaries of more frequent CDRs in light of the backlogs in the system. We fear that beneficiaries who are in the medical improvement likely diary category may find themselves in the untenable situation where one CDR is not yet complete when another review is scheduled to begin. This situation is obviously not acceptable for beneficiaries, but neither is it a positive for a system that is struggling to meet its responsibilities. We urge the agency to resolve its existing backlogs first before adding more process and complexity to the system.

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Conclusion

In the proposed rule, SSA notes that when Congress passed the Social Security Disability benefits Reform Act of 1984, it expressed concern that "people who are found eligible for benefits after a lengthy administrative appeal not find themselves subjected to a second eligibility review after only a relatively brief period." We are concerned that this is exactly what may happen under the proposal to establish a new medical diary category, medical improvement likely, which will trigger continuing disability reviews for those in the category every two years.

SSA notes that existing rules will be used for evaluation of whether a beneficiary has a continuing disability, including those who are evaluated under the medical improvement likely category. This is the single element of the proposed rule that we support.

We believe the impact of the proposed changes – the addition of a new medical diary category and adjustments to the intervals for continuing disability reviews – will be to subject a number of disability beneficiaries to frequent reviews that are a substantial and unnecessary burden, even if the result is a determination that the beneficiary retains disability benefits. We are concerned that the result will be the situation that Congress warned against more than 35 years ago, a situation where certain disability beneficiaries are facing almost constant review of their status. The result of such a situation would be place additional onus on a population that already faces significant burdens managing the symptoms, treatments and complexities of their disease.

We appreciate the opportunity to comment on the proposal setting new standards for when and how continuing disability reviews will be conducted. We urge the SSA to rescind this regulatory effort and to begin again with reliance on data to drive any changes in diary categories or intervals for CDRs.

Sincerely,

Mary Dwight
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Cystic Fibrosis Foundation