



March 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Notice of Benefit and Payment Parameters for 2021 Proposed Rule, CMS–9916–P

Dear Administrator Verma:

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies and advocate for access to high-quality, specialized care for people with CF.

Cystic fibrosis is a complex, multi-organ disease requiring multi-disciplinary, specialty care. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. This milestone reflects over 50 years of hard work to improve CF treatments, develop evidence-based standards of care, and encourage adherence to a lifetime of chronic care. This system of care and the improvements in length and quality of life for those with CF can only be realized if patients have access to adequate and affordable insurance.

The CF Foundation appreciates the opportunity to comment on the proposed Notice of Benefit and Payment Parameters for 2021. Many of our comments focus on affordability for patients, as out-of-pocket costs weigh heavily on people with cystic fibrosis and cause some to delay or forgo care. We hope you bear these concerns in mind as you evaluate the proposals in this rule.

Automatic re-enrollment

The CF Foundation is concerned the Centers for Medicare & Medicaid Services' (CMS) proposal related to automatic re-enrollment will result in unaffordable premiums and coverage losses for some enrollees, and urges the agency to rescind this proposal. For people enrolled in zero premium plans, the agency proposes to automatically renew their coverage but not their advanced premium tax credits, instead requiring enrollees to go through a new eligibility determination process to get subsidies. CMS notes that this change would affect approximately 270,000 enrollees.

We are concerned that affected individuals who are unaware of the new policy will be subject to unaffordable premiums that could result in loss of coverage. Individuals who currently qualify for zero premium plans are low-income. If they do not renew their subsidies, they will be responsible for the full cost of a plan—which substantially exceeds their financial means. Even nominal premiums can be unaffordable for low-income individuals and families. A Kaiser Family Foundation literature review of the effect of premiums on Medicaid and CHIP coverage found numerous studies showing that unaffordable premiums led to coverage losses.¹ Individuals who are unaware of the need to renew their subsidies will be unable to afford their new premiums and will likely lose coverage as a result. The agency also proposes a variation on their proposal in which enrollees' coverage would be renewed with a small premium instead of the full subsidy that they currently receive. We have the same concerns about that option, as low-income consumers may have trouble making even small premium payments.

Additionally, while CMS says they will educate consumers about this policy change, experience with major public program eligibility changes shows that such outreach is challenging and can often fail to reach its target audience. For instance, when Arkansas began requiring Medicaid enrollees to report the hours they work or participate in community engagement activities, the state disenrolled more than 18,000 people within 6 months for failing to report.² A survey published in the *New England Journal of Medicine* of Arkansas enrollees subject to work requirements found that nearly half of the target population was unsure whether the new requirements applied to them.³ Similarly, a survey of Medicaid enrollees' experience with health savings accounts in Indiana found that nearly 40 percent of enrollees were not familiar with the accounts, despite use of navigators, other outreach programs, and back-end processes to remind high-risk individuals to make payments.⁴ The experiences in Arkansas and Indiana highlight the difficulties of reaching and educating consumers enrolled in public programs and we encourage CMS to rescind this proposal.

Copay accumulator programs

The CF Foundation opposes the agency's decision to allow accumulator adjustment programs, which do not count copay assistance towards consumers' cost-sharing requirements. We urge CMS to reinstate the policy outlined in the 2020 Notice of Benefit and Payment Parameters (NBPP), which banned copay accumulators except when a drug has a generic equivalent.

People with CF bear a significant out-of-pocket cost burden and often rely on co-pay assistance to access critical care they need to maintain their health and well-being. According to a 2018 survey by researchers at George Washington University, one out of four people with CF and their families pay more than \$10,000 in out-of-pocket expenses each year, not including premiums and deductibles. In

¹ The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings. Kaiser Family Foundation. 2017. Retrieved from: <https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/>

² Arkansas Department of Health and Human Services, Arkansas Works Program, December 2018. Retrieved from http://d31hzhk6di2h5.cloudfront.net/20190115/88/f6/04/2d/3480592f7fbd6c891d9bacb6/011519_AWReport.pdf

³ Benjamin Sommers, et al. Medicaid Work Requirements—Results from the First Year in Arkansas. *New England Journal of Medicine*. 2019;381:1073-1082. doi:10.1056/NEJMSr1901772.

⁴ Benjamin Sommers, et al. New Approaches in Medicaid: Work Requirements, Health Savings Accounts, And Health Care Access. *Health Affairs*. 2018. 2018;37(7). doi:10.1377/hlthaff.2018.0331.

order to make ends meet, 78 percent of people received some form of financial assistance to help pay for their care. Despite high rates of financial assistance, 58 percent of people with CF still skipped or delayed care due to cost concerns.

We recognize the agency's concerns that copay assistance could incentivize the use of higher cost brand-name drugs over generics; however, most CF therapies do not have generic equivalents. People with CF use coupons to help alleviate their out-of-pocket cost burden but they generally do not have many choices when it comes to their treatment regime. This is true for most patients who use coupons—an analysis of high-cost drugs with coupons found that 79 percent had no generic equivalent.⁵ For people with CF, continuing to allow accumulator programs will not reduce their pharmacy costs but instead, will make their care less affordable.

We understand the challenge insurers face in managing the rising cost of drugs, and that copay assistance programs mask bigger cost and affordability issues in the health care system. However, cost containment strategies that place a further burden on patients are unacceptable and accumulator programs increase the financial strain on patients who are already struggling to afford their care.

Calculation of premium adjustment factor

The agency has proposed for the second straight year to base the premium adjustment factor on the most recent estimates and projections of per enrollee premiums for all private health insurance (excluding Medigap and property and casualty insurance) from the National Health Expenditure Account. Although the unpredictability of exchange premiums has been moderated to some degree, we nonetheless recommend against including those premiums in the premium adjustment factor calculation. Reliance on employer-sponsored insurance rates will result in a more modest premium adjustment factor and provide consumers better financial protection in their utilization of health care services. We therefore urge the agency, as we did in comments on the NBPP for 2020, to use its discretion in the calculation of the premium adjustment factor and to rely instead on employer-sponsored insurance rates.

The premium adjustment percentage included in the NBPP sets the rate of increase for the maximum annual limitation on cost sharing, the employer mandate penalty amounts, and the required contribution percentage for exemption eligibility. The decision of the agency to set the premium adjustment factor on the basis of all private insurance premiums, including those in the individual market, means that out-of-pocket cost sharing limits will rise in 2021 to \$8,550 for self-only coverage and \$17,100 for other than self-only coverage—a nearly 5 percent increase from this year's limits.

The press release announcing the Notice of Benefit and Payment Parameters for 2021 applauds the actions of President Trump to lower premiums for exchange plans.⁶ While we certainly support lower premiums for adequate health insurance coverage, we also think it is important to take a more

⁵ A Perspective on Prescription Drug Copayment Coupons. Leonard D. Schaeffer Center for Health Policy and Economics. 2018. Retrieved from: https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-1.pdf

⁶ CMS Releases Proposed Notice of Benefit and Payment Parameters Rule for 2021, Press Release, January 31, 2020. Accessed on February 18, 2020, at <https://www.cms.gov/newsroom/press-releases/cms-releases-proposed-notice-benefit-and-payment-parameters-rule-2021>.

comprehensive view of affordability of health care. As described above, people with CF have high health care expenses and typically hit their out-of-pocket maximums each year. As the out-of-pocket maximum continues to increase, people with CF face an increasing out-of-pocket cost burden which increases the likelihood that the critical life-sustaining care they need will become unaffordable and they will be forced to forgo care.

The agency can take a modest step to address the affordability of insurance and health care by using its discretion to calculate the premium adjustment factor based on employer-sponsored insurance rates.

Promoting Value-Based Insurance Design

In past regulatory efforts, the agency announced its interest in value-based insurance design (VBID), and in the NBPP for 2021 provides advice to issuers about how they might offer VBID plans for the exchanges. In its advice to issuers, the agency says that it has borrowed from the work of the Center for Value-Based Insurance Design at the University of Michigan. We have reviewed the recommendations of the agency regarding VBID, as the model generally supports a move toward insurance that incentivizes utilization of high value services and discourages the use of low value services. While we agree with the idea that high value services and treatments should be available to patients with minimal or no barriers, we do not find the lists of low and high value services and drug classes borrowed from the Center for Value-Based Insurance Design to have relevance for people with cystic fibrosis or for others with special health needs.

The agency asks if minimum standards should be set for VBID and we believe that minimum standards will be essential for VBID. We urge that the agency work closely with plan issuers that might be interested in VBID to address the development and issuance of plans that might be of interest to those with special needs, chronic conditions, or serious and life-threatening illnesses. To ensure the plans meet the needs of consumers, particularly those with serious chronic conditions, we recommend more work among stakeholders – including patient organizations – before VBID options are offered on the exchanges. We look forward to more discussion of minimum standards for VBID.

If issuers offer VBID plans, there will also be the need for educational efforts for consumers, so that they can evaluate and choose VBID plans that are appropriate for their needs. When presented with VBID options, consumers have expressed skepticism about value-based options and trade-offs and have sought additional information from trusted sources, to supplement the information that health plans provide about their value-based options. Research on this topic suggests that there will be the need for more information sources and education to support consumer decision-making related to value-based options.⁷ This will require the agency to renew prior commitments to navigators and providing additional educational resources that are specific to value-based options to aid consumer decision-making. Because these educational efforts are critical to the success of VBID, we recommend that strong navigation and other educational options be in place when VBID options are offered on exchanges.

⁷ Perez SL, et al. Consumers' perceptions and choices related to three value-based insurance design approaches. Health Affairs 38:3. March 2019.

We appreciate the opportunity to comment on this proposed rule.

Sincerely,

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

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President of Policy & Advocacy
Cystic Fibrosis Foundation