



December 21, 2020

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

RE: CMS-9914-P, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

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

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, advocate for access to care for people with CF, and fund and accredit a network of specialized CF care centers.

Cystic fibrosis is a life-threatening genetic disease that affects more than 30,000 children and adults in the United States. 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.

Many of our comments focus on access and affordability for our patients, as out-of-pocket costs weigh heavily on people with cystic fibrosis and cause some to delay or forgo care. The CF Foundation appreciates the opportunity to comment on the proposed Notice of Benefit and Payment Parameters (NBPP) for 2022.

Privatization of the Affordable Care Act Marketplace Exchanges

The CF Foundation is concerned the Centers for Medicare & Medicaid Services (CMS) is proposing to offer states the option to transition away from a single, centralized exchange (such as a state-based platform or HealthCare.gov) to a private sector model that would rely on insurers, web-brokers, and agents and brokers. The potential privatization of exchanges is the culmination of a series of past efforts to incorporate insurers and web-brokers in the enrollment process. CMS has approved a Section 1332

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waiver application from Georgia that would permit just this sort of exchange. In the NBPP, CMS would ease the process for states that are interested in following Georgia's example.

We have misgivings about the privatization of the exchanges, and we object strenuously to the process by which CMS would permit states to privatize their exchanges. In arguing for privatization of exchanges, CMS cites the cost and administrative burden of establishing state-based exchanges (SBEs), suggests that SBEs do not innovate effectively, and states that host these exchanges experience "choke points" at peak shopping and enrollment times. We are not persuaded that the SBEs are riddled with these problems and CMS has provided only anecdotes, no data, to support this claim. To the extent these problems exist, the solution is not privatization. We would instead support proposals to add more resource for states to ensure their exchanges are working effectively. Moreover, we are concerned that a model that relies on insurers and web-brokers will result in two serious risks to consumers: they may purchase non-qualified health plans that do not cover their pre-existing conditions and they may not receive reliable information about their Medicaid and advance premium tax credit (APTC) eligibility. In short, consumers may be at risk of making uninformed choices without full information about their coverage options and that do not reflect their eligibility for premium assistance or Medicaid benefits. In a covert testing initiative to assess whether consumers were provided misleading information about non-Affordable Care Act-compliant plans, the Government Accountability Office found a troubling pattern of misleading sales tactics by private sector insurance sales representatives.¹ CF Foundation does not support a movement toward privatization of exchange functions, absent strong assurances from states about consumer protections in their privately administered exchanges.

Additionally, the process that CMS identifies for states to move toward privatization is not a rigorous one and we do not believe that the Affordable Care Act (ACA) permits CMS to offer states such a flexible approach to privatization. It seems that states basically must inform CMS of their intention to move toward a private exchange model. Although CMS is required to approve the state action, there are no rigorous standards that include consumer protections. Sections 1311 and 1103 of the ACA require the Secretary to maintain an exchange portal that will assist states in developing and maintaining their own portal. These requirements of the law can only be waived through a formal Section 1332 waiver process of the sort that the state of Georgia pursued. We did not support the decision of CMS in the case of Georgia, but we acknowledge that the ACA permits such application. The law does not allow the very minimal application process that CMS proposes for states wishing to privatize exchange functions. Therefore, we ask CMS to rescind this proposal.

Codification of Section 1332 Guidance

Section 1332 of the ACA outlines four guardrails that any waiver application must meet for approval: coverage must be as affordable as it would be without the waiver; coverage must be as comprehensive as it would be without the waiver; a comparable number of people must be covered under the waiver as would be without it; and the waiver must not add to the federal deficit. In 2018, the Departments of Health and Human Services and Treasury, issued guidance that relaxed and broadened the guardrails, considering the number of people who have *access* to affordable comprehensive coverage, rather than the number who *enroll* in this coverage. This misinterpretation of the guardrails allows states to pursue policies that steer potential enrollees into substandard coverage, such as short-term, limited-duration plans or association health plans, which do not necessarily cover CF care.

¹ Government Accountability Office to Senators Robert Casey, Jr. and Debbie Stabenow, Private Health Coverage: Results of Covert Testing for Selected Offerings, August 24, 2020. Accessed on December 13, 2020, at <https://www.gao.gov/assets/710/708967.pdf>.

In the NBPP for 2022, CMS proposes to codify this guidance, weakening consumer protection in the marketplace and potentially driving people to coverage that is less comprehensive or less affordable. CFF opposed the 2018 guidance when it was released, and we ask CMS to rescind this proposal.

Calculation of Premium Adjustment Factor

CMS has proposed for the third year in a row to base the premium adjustment factor on the most recent estimates and projections of per enrollee premiums for all private health insurance from the national Health Expenditure Account. We recommend against including exchange 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 protections in their utilization of health care services. We therefore urge CMS, as we did in our NBPP 2020 and NBPP 2021 comments, to use its discretion in the calculation of the premium adjustment factor and rely instead on the 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 CMS 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 2022 to \$9,100 for self-only coverage and \$18,200 for other than self-only coverage – a 6.4% increase from 2021's limits.

As described above, people with CF have high health care expenses and typically hit their out-of-pocket maximums each year. Insurance alone is not enough to afford the cost of CF care, and the financial burden is pervasive. A recent survey of people with CF conducted by researchers at the George Washington University found that the cost of care resulted in 45% of individuals with CF delaying or forgoing care, 20% delaying filing a prescription, and 10% skipping a routine visit to their care center. As the out-of-pocket maximum continues to increase, people with CF face an increasing out-of-pocket cost burden and are at greater risk of being unable to afford their care.

CMS should take steps 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.

Insurer User Fees for Federally Facilitated Exchanges

CMS is proposing to reduce the user fee for insurers on the federally facilitated exchanges from 3 percent to 2.25 percent. This is the second cut in recent years, totaling a 1.5 percent reduction. Although CMS is claiming these user fee cuts will lead to premium reductions for consumers, we are concerned about additional implications. In prior years, user fees were reinvested into improving and updating Healthcare.gov, marketing and advertising for the ACA, and expanding Navigator programs. These activities are essential to ensuring a robust, high functioning marketplace for consumers and therefore, we ask CMS to rescind this user fee reduction.

Special Enrollment Periods

In light of the pandemic, we recognize now more than ever the importance of special enrollment periods (SEP) and we appreciate the proposed changes to SEPs across all marketplace plans, which would allow people to more easily take advantage of SEP eligibility. First, CMS is proposing changes to the notice of a triggering event, for both on and off exchange coverage, ensuring individuals who were reasonably unaware that the triggering event occurred are able to select a plan within 60 days after they

were made aware. This flexibility increases the likelihood individuals enroll in a plan during the allotted enrollment period and have the time to enroll in a plan that best fits their needs.

Furthermore, CMS is proposing to allow current exchange enrollees to qualify for a SEP if they become ineligible for advance premium tax credits (APTC) and would like to enroll in a more affordable qualified health plan (QHP) of a lower metal tier. The CF Foundation appreciates CMS seeking to prioritize affordability and continuous coverage, and not penalizing enrollees no longer eligible for APTCs.

Finally, CMS is proposing to authorize the cessation of employer contributions for COBRA coverage period as a triggering event for SEP. Additionally, CMS is seeking comment on whether a SEP should be available when an employer reduces, but does not cease, its contributions for COBRA. In the event of a layoff or job loss, COBRA coverage can often feel like the only option, but is not always affordable. Providing the opportunity to enroll in a QHP when the cost of COBRA coverage increases ensures individuals with CF are able to access the care they need through an affordable and comprehensive plan.

If finalized, we ask CMS to provide and resources to the public and enrollees who may be unaware of these consumer-friendly benefits.

The CF Foundation appreciates the opportunity to provide comment on the Notice of Benefits and Payment Parameters for 2022. We look forward to working with CMS on these critical issues to ensure access and affordability for people with CF.

Sincerely,



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Cystic Fibrosis Foundation