1/4/2021

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

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-9912-IFC)

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.

Thank you for the opportunity to comment on CMS-9912-IFC, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (hereinafter referred to as "the IFC"). We urge the Centers for Medicare and Medicaid Services' (CMS) to rescind the provisions related to the Families First Coronavirus Response Act (FFCRA) Medicaid maintenance of effort (MOE) that deviate from its previous interpretation of statutory requirements and the provisions related to Section 1332 waiver transparency rules. While we appreciate that CMS has taken some steps to extend coverage of a COVID-19 vaccine without cost-sharing, we also have concerns about critical gaps in vaccine coverage and urge the agency to ensure coverage without cost-sharing for all Americans.

The IFC Reverses Congressional Intent of Medicaid Coverage and Financing during the Public Health Emergency

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FFCRA provided a temporary 6.2 percent increase in FMAP through the end of the quarter in the calendar year in which the public health emergency (PHE) expires. As a condition of receiving the increased FMAP, state Medicaid programs must not implement standards, methodologies, and procedures that are more restrictive or charge higher premiums than were in place on January 1st, 2020. Furthermore, state Medicaid programs must cover COVID-19 testing and treatment (including a vaccine) without cost-sharing, and maintain coverage for any beneficiaries who were enrolled as of March 18, 2020, or newly enrolled beneficiaries after that date, through the end of the month in which the PHE ends. Congress included these MOE and continuous coverage provisions in order to hold beneficiaries harmless against the loss of coverage or benefits during the pandemic due to state financial constraints.

Furthermore, CMS issued guidance documents earlier this year interpreting the continuous coverage requirement as barring states from cutting benefits or increasing cost-sharing for Medicaid beneficiaries while they are enrolled. In April, the agency states in their FAQ, "while states may increase the level of assistance provided to the beneficiaries who experience a change in circumstances, such as moving the individual to another eligibility group which provides *additional benefits*, states *may not reduce benefits* for any beneficiary enrolled in Medicaid…and still qualify for increased FMAP"[i] (emphasis added). In CMS's June FAQ, the agency reiterates this point, stating, "states must maintain the eligibility, and benefits of all individuals who are enrolled or determined eligible for Medicaid as of March 18, 2020, through the end of the month of which the PHE ends."[ii] Moreover, that same FAQ further explains that a state is not eligible for the temporary FMAP increase if it increases cost-sharing for individuals because "an increase in cost-sharing reduces the amount of medical assistance for which an individual is eligible."[iii] In both of these guidance documents, CMS made it clear enrollee benefits cannot be cut during the public health emergency and that cost-sharing is considered as part of an enrollee's medical assistance.

This IFC is a complete reversal of CMS' guidance documents cited above and a violation of Congressional intent and the plain reading of FFCRA.

First, the IFC allow states to reduce the amount, duration, and scope of benefits, such as imposing visit limits or adding other utilization controls. For people with CF, Medicaid is a crucial source of coverage. It helps them afford medications and inpatient and outpatient care, ensuring access to life-saving services and allowing people with CF to maintain their health and well-being. Imposing limitations on benefits could be particularly harmful for people with CF, impacting their treatment schedule and access to their care team. This could lead to individuals delaying or forgoing treatment, resulting in worse health outcomes.

Moreover, under the IFC, states may add or increase cost-sharing and beneficiary liability under the state's post-eligibility treatment of income rules, even though it is clear that such increases would constitute a reduction in benefits in violation of FFCRA. Adding cost-sharing for beneficiaries, particularly in the time of a pandemic, may impose unmanageable health care costs on financially vulnerable and medically complex adults. People with CF bear a significant cost burden and out-of-pocket costs can present a barrier to care. Specifically, a survey conducted by the George Washington University of 2,500 people living with CF found that while 98 percent of people with CF have some type of health insurance coverage, 58 percent postpone necessary medical care or forgo prescribed treatment due to cost concerns. Such actions could seriously jeopardize access to care for people with CF and ultimately lead to costly hospitalizations and fatal lung infections. Allowing states to cut benefits and impose cost-sharing not only violates the FFCRA but could result in significant harm to a particularly vulnerable population during this public health emergency.

COVID-19 Vaccine Coverage Policy

The CF Foundation appreciates CMS implementing the FFCRA vaccine coverage policy for most individuals without-cost sharing. Specifically we support the provisions in the IFC to require most private insurance plans to cover administration of COVID-19 vaccines (as well as the vaccines themselves) without cost-sharing and to waive patients' cost-sharing even if vaccines are administered by out-of-network providers.[iv] However, critical gaps in vaccine coverage still remain.[v] We ask CMS to encourage Congress to require coverage of COVID-19 vaccines regardless of insurance type.

Medicaid

The FFCRA requires states to cover COVID-19 testing and treatment (including vaccines), specialized equipment, and therapies without cost-sharing through the end of the quarter in which the PHE ends, as a condition of receiving the higher federal match. The statute does not allow any exceptions to this requirement or limit it to only certain eligibility groups. However, under the IFC, states would be permitted to continue to receive the extra federal funding even if they do not provide COVID-19 testing, treatment, and vaccine coverage to all Medicaid beneficiaries. CMS specifically invites states to limit access to COVID-19 vaccines in Medicaid by excluding such coverage for people enrolled in Medicaid limited benefit plans.

The FFCRA makes no such distinction between full and limited Medicaid benefit categories, and specifically applies the requirement to section 1115 waiver programs. CMS does not have the authority to allow states to continue to receive the enhanced federal funding without complying with the provisions laid out in FFCRA. People with CF are at increased risk for COVID-19, and it's critical that individuals enrolled in the Medicaid program have coverage of COVID-19 vaccines regardless of their benefit package.

Non-Compliant Plans

Individuals enrolled in private health insurance plans that do not comply with the Affordable Care Act's (ACA) coverage requirements – including grandfathered health plans, short-term limited duration plans and association health plans – may not have coverage for a COVID-19 vaccine or may face significant cost-sharing. These plans put enrollees at substantial financial and physical risk. Despite Congressional and administrative action to ensure COVID-19 vaccination be provided at no-cost to promote the public health, Americans enrolled in insurance-like products will not be protected. For example, the Commonwealth Fund found that short-term plans have significant coverage gaps that would extend to COVID-19 vaccines.[vi] If a non-compliant plan doesn't cover the COVID-19 vaccine, enrollees should be considered uninsured, and therefore receive the vaccination without cost-sharing.

Modifications to 1332 Waiver Notice and Comment Period during the Public Health Emergency

Under section 1332 of the ACA, states may apply for state innovation waivers to alter key ACA requirements in the individual and small group health insurance markets. Under the IFC, CMS is allowing modifications to the public notice, comment, and hearing requirements for section 1332 waiver proposals, including allowing the state public notice and comment period to come after the state files its application and the federal comment period to come after CMS conducts its review during the PHE. The Secretary does not have the authority to bypass the statutory requirements related to meaningful stakeholder input in waiver policy. The CF Foundation relies heavily on the public comment process to provide feedback on how waiver proposals will impact people with CF. We urge the Administration to rescind these provisions of the IFC.

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Thank you for the opportunity to comment. The CF Foundation asks CMS to rescind the provisions of the IFC that reverse CMS' earlier MOE and continuous coverage guidance and the provisions that modify the section 1332 waiver public notice and comment periods. We further urge the agency to ensure all Americans can access a COVID-19 vaccine without cost-sharing.

Sincerely,

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy

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[i] https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf
[ii] https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf
[iii] Ibid.
[iv] https://www.shvs.org/ensuring-access-to-the-covid-19-vaccine-for-enrollees-in-private-health-insurance-a-roadmap-for-states/
[v] Sara Rosenbaum, Sabrina Corlette, and Alexander Somodevilla. "Why We Can't rely on Health Insurance Alone to Guarantee Universal Immunization Against COVID-10. June 16, 2020. The Commonwealth Fund. Available at: https://www.commonwealthfund.org/blog/2020/why-we-cant-rely-health-insurance-alone-guarantee-universal-immunization-against-covid-19
[vi] https://www.commonwealthfund.org/blog/2020/age-covid-19-short-term-plans-fall-short-consumers