American Lung Association.

December 21, 2020

Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Honorable Steve Mnuchin
Secretary
Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Honorable Eugene Scalia
Secretary
Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Secretaries Azar, Mnuchin and Scalia:

The American Lung Association is pleased to have the opportunity to provide feedback on the interim final rule (IFR) regarding Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.

The American Lung Association is the oldest voluntary public health association in the United States, representing the millions of Americans living with lung diseases, including asthma, chronic obstructive pulmonary disease (COPD), lung cancer, and pulmonary fibrosis. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

The Lung Association is deeply concerned by the IFR provisions related to the Families First Coronavirus Response Act (FFCRA) Medicaid Maintenance of Effort (MOE) provisions and the IFR provisions allowing states to circumvent required transparency procedures for Section 1332 Waivers. And while we appreciate some of the steps that the Centers for Medicare and Medicaid Services (CMS) has taken to address surprise billing associated with COVID-19 testing and extend coverage of a COVID-19 vaccine without cost-sharing, we continue to have several concerns, including about critical gaps in vaccine coverage for the patients we represent. The Lung Association therefore offers the following comments and recommendations to the Department on the IFR:

<u>Medicaid Coverage and Financing during the Public Health Emergency</u>
The MOE provisions of the FFCRA are critical to ensuring that low-income individuals and families have access to health coverage and needed care during the pandemic. Earlier this year, in Frequently Asked Questions (FAQ) guidance documents to states, CMS interpreted the

continuous coverage requirement of the FFCRA as barring states from cutting benefits or increasing cost-sharing for Medicaid beneficiaries while they are enrolled.[1] This is consistent with the plain reading of the FFCRA statutory language. It would constitute a violation of the continuous coverage requirement and make a state ineligible for the 6.2 percentage point federal medical assistance percentage (FMAP) increase if the state eliminated or scaled back beneficiaries' benefits or increased their cost-sharing. This interpretation should be reinstated. Specifically, the IFR violates the plain reading of the statute with respect to: (1) maintaining benefits, (2) beneficiary financial liability, (3) requiring beneficiaries to be "validly enrolled," (4) maintaining comprehensive coverage for lawfully residing children and pregnant women, and (5) requiring coverage of COVID-19 vaccines in Medicaid, as outlined below.

Benefits

Under the IFR, state Medicaid programs are permitted to eliminate optional benefits such as adult dental and vision, prescription drug coverage, and home and community-based services (HCBS) and reduce the amount, duration and scope of covered benefits (such as imposing lower visit limits or adding other utilization controls), compared to what was covered on March 18, 2020, even as they continue to receive the increased FMAP. Eliminating optional benefits would clearly violate the statutory requirement that beneficiaries continue to receive *such benefits* as they received in January – March 2020 (or, if enrolled after March 18, 2020, the benefits received at the time of enrollment) through the end of the month in which the PHE ends as a condition of receiving the higher federal match. Similarly, allowing states to reduce the scope of services covered would mean beneficiaries no longer receive *such benefits*.

These benefit changes could have particularly harmful consequences for beneficiaries with lung disease. For example, prescription drug coverage is critical to helping patients with lung diseases like asthma and COPD manage their conditions and stay out of the emergency department with urgent breathing problems. Additionally, physicians report that restrictions like prior authorization can lead to delays in patients' access to necessary care – in some cases, leading to serious adverse events for patients – and lead some patients to abandon treatment.[2]

The IFR would also permit states to transfer beneficiaries from one eligibility category to another in certain circumstances, even if it may reduce the benefits available to them. Again, this is in direct conflict with the statutory requirement noted above ensuring beneficiaries continue to receive the same benefits through the end of the month in which the PHE ends as a condition of receiving the additional federal funds.

Finally, the IFR would also allow states to terminate coverage for Medicaid beneficiaries if they do not respond to requests to verify residency following a data match indicating simultaneous Medicaid enrollment in two or more states. The FFCRA continuous coverage provision does not provide for the disenrollment of beneficiaries unless the beneficiary requests a voluntary termination or ceases to be a state resident, but a possible discrepancy on state residency is not grounds for disenrollment. Even before the pandemic, Medicaid beneficiaries struggle to maintain coverage during redetermination periods because of lost or delayed mailings.[3] These challenges have been exacerbated by the PHE and are precisely why Congress acted to ensure continuous coverage despite possible changes in circumstances. For example, states are already reporting an increase in returned mail due to the pandemic.[4] Serious health, economic,

or housing problems are expected to contribute to procedural problems for states but are not grounds for terminating coverage while receiving the enhanced federal funding under FFCRA. CMS should instead work with states and encourage states to work with each other to resolve any possible discrepancies on state residency.

The Lung Association urges CMS to rescind the harmful Medicaid provisions in the IFR and to reinstate the correct FFCRA interpretation as laid out in the April 2020 FAQ. It is clear from the statutory language that Congress intended to ensure Medicaid beneficiaries maintain coverage and eligibility group status and access to necessary services during the pandemic in exchange for the additional federal funding for the duration of the PHE.

Beneficiary Financial Liability
The IFR also reverses CMS' earlier guidance with respect to cost-sharing, in plain violation of the statute. In the COVID-19 FAQ first issued in early April 2020 and updated over the summer, CMS wrote that increasing cost-sharing amounts would violate the FFCRA continuous coverage provision. The FAQ also clearly prohibited changes to post eligibility treatment of income (PETI) rules, stating that, "Like cost-sharing increases, increasing a beneficiary's liability reduces the amount of medical assistance for which an individual is eligible and is therefore inconsistent with the requirement at section 6008(b)(3) of the FFCRA" (p. 30).

Even small increases in cost-sharing imposed on low-income populations are associated with reduced use of care, including necessary services.[5] Early on in the pandemic, outpatient visits declined precipitously; overall outpatient visits declined by about 60 percent with even bigger declines for children.[6] Even as some visits have returned to pre-pandemic levels, others still lag behind, including visits by Medicaid patients.[7] Moreover, the economic crisis brought on by the pandemic has made it increasingly hard for families to make ends meet. Even in the early weeks of the pandemic, over two-thirds (68.6 percent) of adults with family incomes below the federal poverty level and over 45 percent of black and Hispanic adults reported that their families could not pay the rent, mortgage, or utility bills, were food insecure, or went without medical care because of cost.[8] Allowing states to continue to receive the enhanced federal funding while imposing higher cost sharing not only violates the plain reading of the statute, it would exacerbate these problems for families and widen racial and ethnic inequities. The Lung Association urges CMS to return to its original guidance with respect to cost-sharing.

Validly Enrolled
CMS indicates that a state would not be out of compliance with the continuous coverage requirement if it disenrolls a beneficiary who was not "validly enrolled" in the first place (the eligibility determination was erroneous or the result of fraud and abuse). While CMS has indicated that generally beneficiaries are considered "validly enrolled," the IFR fails to explain how "invalidly" enrolled beneficiaries would be identified, nor does it provide for any protection against unreasonably requiring beneficiaries to document their valid enrollment repeatedly. The Secretary should limit any allowable disenrollment to only those beneficiaries who have been convicted of or pleaded guilty to fraudulent enrollment.

Maintaining coverage for lawfully residing immigrant children and pregnant women
Under the IFR, states that have opted to cover lawfully residing children and pregnant women would be required to limit their coverage to emergency services if individuals are found to no

longer meet the definition of such children and pregnant women. The IFR does not elaborate on how such children and pregnant women would be identified nor whether they would have a reasonable opportunity to provide any needed documentation of their ongoing eligibility. Under this misinterpretation of the statute, states must disenroll lawfully residing children who reach age 21 and lawfully residing women who are no longer pregnant, in contradiction to the plain reading of the statute requiring continuous coverage for all beneficiaries enrolled. CMS should rescind 42 CFR §433.400(d)(2).

Section 1332 Waivers

Under Section 1332 of the Affordable Care Act (ACA), states may apply for a State Innovation Waiver to alter key ACA requirements in the individual and small group health insurance markets. States must demonstrate compliance with four statutory requirements for Section 1332 waivers to be approved: (1) coverage that is at least as comprehensive in covered benefits and (2) at least as affordable, reaching (3) at least a comparable number of state residents and (4) without increasing the federal deficit. The statute also requires states and the federal government to provide the public with an opportunity to comment. To date, most states have used Section 1332 waivers to create reinsurance programs and improve affordability in the marketplace, but recent Section 1332 waiver proposals and approvals fail to meet the statutory requirements laid out above.[9]

Under the IFR, CMS would go even further by allowing the "modification" of 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 Lung Association relies on the public comment process to provide feedback on how waiver proposals will impact our patients and other key stakeholders and we urge the Administration to rescind these provisions of the IFR.

COVID-19 Vaccine Coverage

The IFR takes a number of important steps to implement provisions in the Coronavirus Aid, Relief and Economic Security (CARES) Act that require coverage of COVID-19 vaccinations by Medicare and most private insurance plans. The Lung Association supports CMS' determination that a COVID-19 vaccine licensed by the Food and Drug Administration (FDA) under an emergency use authorization should be covered for Medicare enrollees without cost-sharing. Additionally, the Lung Association supports the requirements in the IFR for 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.[10]

However, critical gaps in vaccine coverage still remain. For example, patients 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 plans, healthcare sharing ministries and farm bureau plans – may not have coverage for a COVID-19 vaccine or may be charged significant copays.

The Lung Association is extremely concerned about the provisions in the IFR that relate to COVID testing, treatment, and vaccine coverage in Medicaid. In the IFR, 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. For example, beneficiaries enrolled in programs focused on the treatment of breast and cervical cancer and tuberculosis, family planning programs, and some programs provided under Section 1115 waiver authority, would not have access to COVID-19 vaccines even as the state continues to draw down the additional federal funding. The FFCRA makes no such distinction between full and limited Medicaid benefit categories, and specifically applies the requirement to Section 1115 waiver programs. The Lung Association urges CMS to revise its policy to include vaccine coverage for all Medicaid enrollees. Additionally, COVID-19 vaccine coverage for adults in the traditional Medicaid population will still be optional for state Medicaid programs after the end of the public health emergency.[11] The Lung Association urges the Administration to work with Congress on closing this gap.

Finally, the Lung Association remains concerned about access to vaccines for the 30 million Americans without health insurance. Millions of Americans have lost employer-sponsored health insurance coverage as a result of the COVID-19 pandemic and its economic impact.[12] Ensuring that the uninsured can access COVID-19 vaccines at no cost will also be critical to addressing disparities, as about half of the 30 million Americans without insurance are people of color.[13] There are also many undocumented individuals who lack access to insurance but who are disproportionally employed in many essential industries where they have a higher risk of exposure to COVID-19, such as agriculture and home health.[14] The Lung Association urges the Administration to support and strengthen existing public health systems providing free vaccines to the uninsured to ensure that lack of insurance coverage and costs are not barriers.

COVID-19 Diagnostic Tests

The Lung Association appreciates CMS' efforts to provide additional clarity around the provisions in the FFCRA, and then amended in the CARES Act, that provide for coverage of testing for COVID-19. Testing, when utilized appropriately, is a key aspect of containing and controlling a pandemic. The provisions within FFCRA requiring coverage of COVID-19 testing represented an essential step, but they cannot meet their potential if not implemented properly. Despite passage of the FFCRA and these provisions along with it, many individuals have continued to receive enormous and damaging bills associated with COVID-19 testing.[15] Not only are these bills harmful to those who incur them, they also create harm by instilling fear in those who might otherwise seek out testing.

Accordingly, the Lung Association supports the language within the IFR aimed at further implementing existing law pertaining to COVID-19 testing. In particular, the Lung Association believes that CMS should adopt as inclusive a definition of provider as possible to cover all who may be involved in the process and to avoid any charges from falling outside the scope of the statute and subsequent regulations. Similarly, CMS should clarify that, as stated in the FFCRA and amended in the CARES Act, all items and services received during an office visit in which a COVID-19 test is administered should be covered without cost-sharing, including if the provider is outside of a health plan's network. These items and services should be incorporated into a provider's "cash price" as much as is feasible. Finally, in requiring providers to publicly post their cash price, CMS should also require providers to include simple and straightforward language explaining that, by law, patients receiving COVID-19 tests are not liable for any cost-sharing. The Lung Association is concerned that the public posting of a cash price without such a disclaimer could further disincentive individuals from seeking testing.

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Conclusion

The Lung Association urges CMS to rescind the harmful Medicaid provisions in the IFR and reinstate the policies as laid out in earlier guidance, enforce the public notice and comment period requirements for Section 1332 waivers, and make the additional changes outlined above to ensure access to COVID-19 testing and vaccines without cost-sharing. Thank you for the opportunity to provide comments.

Sincerely,

Harold P. Wimmer
National President and CEO
American Lung Association

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