Comments of Melanie Buzzelli
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On
The U.S. Department of Health and Human Services Notice of Proposed Rulemaking
Securing Updated and Necessary Statutory Evaluations Timely

Docket ID No. HHS-OS-2020-0012

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Good morning. My name is Melanie Buzzelli, and I am a National Director of Advocacy at the American Lung Association. Thank you for the opportunity to speak to you today regarding the Department of Health and Human Services' Notice of Proposed Rulemaking entitled "Securing Updated and Necessary Statutory Evaluations Timely."

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 chronic obstructive pulmonary disease or COPD, lung cancer, asthma, cystic fibrosis, 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.

Much of what we work on in our advocacy is touched by federal regulations. In a sense, regulations are to laws as air is to lungs, as they give laws life. Every aspect of public health, including those aspects critical to lung health, are impacted by federal regulations. Were this proposal to proceed, existing federal regulations would be put at risk, and the ability for agencies to thoughtfully promulgate new rules to protect our health would be hampered. For this reason, and those that I will subsequently articulate, the American Lung Association strongly opposes this proposal and urges HHS to withdraw it.

We also note that this proposal is being rushed through during the COVID-19 pandemic. We reiterate our request for a consolidation of the deadlines with a 60-day extension of the comment period to February 4.

Requiring agency officials to assess and likely review nearly all of HHS' regulations will quickly become an all-consuming task, and one for which there will have been no additional appropriations. Even if this were the sole job of those working underneath HHS' umbrella, there still would not be enough time to carry out this gargantuan task with due diligence. Consequently, in the most ideal of circumstances, certain regulations important to health would be at risk of expiring simply due to a lack of resources. A concept that is anathema to good governance and to the health safeguards required by law that such regulations implement.

Yet, this is not the sole job of HHS. The agencies impacted by this proposal, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and more, are responsible for orchestrating an immense number of programs and activities that impact the lives of every single individual in the United States. Responsibilities that will be gravely strained by this proposal. During the current COVID-19 pandemic these resources are already stretched and rightfully focused on the current public health emergency.

Were the proposal to advance, agencies would struggle to efficiently administer their existing functions let alone make progress with new regulations, and the consequence of this struggle would be actual pain for individuals in this country, whether through a loss of coverage, a delay of innovative therapies, exposure to harmful products, or a worsening of a calamitous pandemic that has already taken the lives of more than quarter million in the United States.

This proposed rule would have profound implications on FDA's ability to protect public health from tobacco products. The Family Smoking Prevention and Tobacco Control Act became law in 2009, and a number of critical rules have since been promulgated, including the "deeming" rule that gives FDA authority over e-cigarettes. Currently one in five kids use e-cigarettes, and it is clear more rules are needed to protect the public health – not just from e-cigarettes but other tobacco products, including menthol cigarettes. FDA has been tasked by Congress with protecting the public health. Using the latest science, FDA must be able to build on its existing regulatory framework to issue new rules that help it better meet its mandate.

Further, several millions of individuals across the United States rely on Medicaid and the Children's Health Insurance Program, or CHIP, for healthcare. Almost one-fifth of people with COPD are enrolled in Medicaid or qualify as dual eligible, close to half of all children with asthma receive their healthcare coverage through Medicaid and CHIP, and Medicaid enrollees smoke at a rate over twice as high as privately insured individuals. These individuals, the people we represent, are at risk of being harmed by this proposal.

Implementation of the Medicaid and CHIP programs is heavily reliant on regulations. All who interact with these programs, states, providers, patients, managed care plans, rely on existing regulations to interpret existing statue and to perform their jobs. These programs depend on predictability and certainty. This proposal would not only call into question CMS' ability to administer the programs, but it would jeopardize the very certainty necessary for proper implementation. Were a regulation regarding eligibility or benefits to slip through the cracks, chaos would ensue, and innocent beneficiaries would bear the brunt.

So why proceed with such a proposal? With the nation still in the grips of a devasting pandemic that has taken so many, there is no possible justification for enacting a proposal that would hamstring our public health agencies and place our nation at greater risk of harm.

Consequently, on behalf of the American Lung Association, I wish to again urge HHS to withdraw this proposal. Thank you again for the opportunity to speak with you all today.