



December 3, 2020

VIA ELECTRONIC SUBMISSION

Department of Health and Human Services

Attention: RIN 0991-AC24, Docket No. HHS-OS-2020-0012

Securing Updated and Necessary Statutory Evaluations Timely

Dear Madam or Sir:

Thank you for the opportunity to comment on proposed rule, Docket No. HHS-OS-2020-0012, "Securing Updated and Necessary Statutory Evaluations Timely," RIN 0991-AC24. We believe that the proposed rule should be withdrawn because it would disrupt the ability of the Centers for Medicare & Medicaid to efficiently administer the Medicaid and CHIP programs on which tens of millions of children and their families rely.

The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005 with a mission to expand and improve high-quality, affordable health coverage for America's children and families. As part of the McCourt School of Public Policy, Georgetown CCF provides research, develops strategies, and offers solutions to improve the health of America's children and families, especially those with low and moderate incomes. In particular, CCF examines policy development and implementation efforts related to Medicaid, the Children's Health Insurance Program (CHIP), and the Affordable Care Act.

The Department should withdraw the proposed rule and instead conduct periodic review of significant regulations by continuing to implement its August 2011 Final Retrospective Review Plan. The proposed rule contemplates using a "forcing mechanism"—automatic expiration—to compel, within the next two years, the "Assessment" and, if applicable, the "Review" of nearly all Departmental regulations that have been in force for more than 10 years. The imposition of such a "forcing mechanism" would disrupt the ability of the Centers for Medicare & Medicaid Services (CMS) to administer the Medicaid and CHIP programs over the next two years. Instead of undermining the operation of the two health insurance programs that are essential to tens of millions of low-income children and families, the Department should continue to implement its existing Final Retrospective Review Plan, adopted in August 2011 and posted on the Department's website here: <https://www.hhs.gov/open/retrospective-review/index.html>.

Federal regulations are an essential tool for the management of Medicaid and CHIP, which are the source of health insurance coverage for over 75 million Americans, including 36 million children.

Medicaid and CHIP are large, complex, federal-state health insurance programs that affect not only all of the states and territories, but also millions of beneficiaries, tens of thousands of providers, and hundreds of managed care plans. Each of these stakeholders has an interest in—and legitimate expectation of—stability in the federal regulatory guidance on which they rely in administering or participating in these programs at the state level. By providing for automatic expiration if CMS does not conduct timely “Assessments” and “Reviews,” the proposed rule’s “forcing mechanism” would unnecessarily and illegally create uncertainty on the part of stakeholders as to whether they should continue to rely on federal regulations for policy and operational guidance.

The Department has an existing mechanism for periodic review of significant regulations: its Final Retrospective Review Plan (August 22, 2011).

In August 2011, the Department issued a [Final Retrospective Review Plan](#) to implement EO 13563. The Plan has five goals: (1) streamline or eliminate unjustified costs and burdens; (2) increase transparency in the retrospective review process; (3) increase opportunities for public participation; (4) set clear retrospective review priorities; and (5) strengthen analysis of regulatory options. Between January 2012 and February 2016 the Department issued [ten updates](#) on the regulatory reviews it conducted. The preamble to the proposed rule does not contain any reference to the Department’s August 2011 Plan or to any of the updates, much less explain why the Plan is ineffective or why the updates were discontinued in 2016.

The Department does not have the authority to place almost all Medicaid and CHIP regulations at risk of automatic expiration as a means of forcing retrospective review.

The authority for issuing Medicaid and CHIP regulations is found in section 1102 of the Social Security Act, which expressly directs the Secretary of HHS to issue regulations “not inconsistent with this Act, as may be necessary to the efficient administration of the” functions with which [he] is charged under this Act.” This section does not give the Secretary the authority to write automatic expiration dates into regulations. In fact, the risk of automatic expiration if an “Assessment” and “Review” are not conducted within a specified time frame is flatly inconsistent with the “efficient administration” of Medicaid and CHIP. It would force CMS to engage in an endlessly repeating and highly inefficient cycle of “Assessments” of all regulations and “Reviews” of those determined to have a significant economic impact upon a substantial number of small entities.

The preamble to the proposed rule repeatedly cites the Regulatory Review Act at 5 U.S.C. 610 as authority for this “forcing mechanism.” This is a clear misreading of the statute. Section 610 does not require, much less authorize, the blanket imposition of automatic expiration dates on almost all regulations, as the proposed rule would do. Section 610

only requires that agencies have a “plan for the periodic review of rules that have or will have a significant economic impact upon a substantial number of small entities.” That is exactly what the Department already has in the form of its August 2011 Final Retrospective Review Plan.

The proposed rule will force CMS to divert limited staff resources to reviewing long-standing regulations over the next two years, disrupting its administration of Medicaid and CHIP during the coronavirus pandemic.

If the proposed rule is issued in final form in January 2021, any Medicaid or CHIP regulation issued before 2013 would have to be “Assessed” and, if applicable, “Reviewed” before the end of 2023, or it would automatically expire. The proposed rule would define “regulation” as a section of the Code of Federal Regulations. It does not explain how many Medicaid and CHIP “regulations” CMS would need to “Assess” and, if necessary “Review” over the next two years. Nor does it explain how many CMS staff would be required to carry out these activities.

The regulations implementing the Medicaid program are found at 42 CFR Parts 430 to 436, 438, 440-442, 447, and 455-456. These 14 Parts contain 1,044 separate CFR sections. Most of those sections are at least ten years old—Medicaid was enacted in 1965—which means that they would each have to be “Assessed” and if necessary, “Reviewed” before 2023, or they would expire. The regulations implementing the CHIP program are found in 42 CFR Part 457. That Part has over 155 separate sections, the large majority of which were promulgated over ten years ago. *In short, the proposed rule would require that, over the next two years, CMS “Assess” and, if necessary, “Review” in the neighborhood of a thousand Medicaid and CHIP “regulations” in order to avoid or postpone their automatic expiration.*

This would be a colossal and indefensible waste of resources. The preamble states at p. 70111: “The Department recognizes that this proposed rule requires the Department to undertake certain tasks. But the Department believes that retrospective review of regulations should be a priority, and is willing to commit the necessary resources towards performing the Assessments and Reviews.” In the midst of a pandemic, when Medicaid and CHIP coverage are so important to the communities of color most at risk, “performing the Assessments and Reviews” of hundreds and hundreds of current program regulations “should be a priority” for CMS?

The priority for CMS over the next two years should be ensuring Medicaid and CHIP coverage is as effective as possible in making COVID-19 testing, treatment, and vaccinations available to all low-income Americans. Moreover, as our recent [report](#) documents, the number of uninsured children is on the rise, and the majority of these children are eligible but unenrolled in Medicaid or CHIP. The Department has made no public acknowledgement of any efforts to ensure that these children obtain or regain coverage, and this situation is no doubt worsening as a consequence of job losses associated with the current recession. This should be a priority for CMS as well.

Conclusion

The Department should withdraw this proposed rule and continue the periodic review of regulations it conducted between 2012 and 2016. The proposed “forcing mechanism” would disrupt the operation of Medicaid and CHIP by creating regulatory uncertainty for states and other stakeholders, and it would divert CMS resources from what should be the highest priority: ensuring that these programs respond as effectively as possible to the pandemic, the growing number of uninsured children, and the many other public health challenges our country faces, including the opioid epidemic and the maternal mortality crisis.

Thank you again for the opportunity to comment on the proposed rule. Please contact Andy Schneider at Andy.Schneider@georgetown.edu if you have any questions or if we can be of further assistance.

Respectfully submitted,

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