

December 2, 2020

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The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**RE: RIN 0991-AC24 (HHS-OS-2020-0012) Securing Updated and Necessary Statutory Evaluations Timely**

Dear Secretary Azar:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) proposed rule: Securing Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70096 (November 4, 2020).

MACPAC is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide range of topics related to Medicaid and the State Children's Health Insurance Program (CHIP). As described in its authorizing statute, MACPAC is required to review and make recommendations regarding policies affecting access to covered items and services (§ 1900(b)(1) of the Social Security Act). The comments provided below stem from this obligation.

Under the proposed rule, subject to certain exceptions, all regulations issued by the Secretary of HHS in Titles 21, 42, and 45 of the Code of Federal Regulations would expire at the later of (1) two calendar years after the year in which the proposed rule becomes effective, (2) 10 calendar years after the year of the regulation's promulgation, or (3) 10 calendar years after the last year in which HHS assessed, and if required, reviewed the regulation.

The proposed rule would affect nearly all Medicaid and CHIP regulations, as it would require HHS to assess all regulations to determine whether or not each regulation has a significant economic impact upon a substantial number of small entities.<sup>1</sup> If the Department assesses that a regulation has such an impact, it must review the regulation to determine whether it should be continued without change, amended, or rescinded, to minimize this impact.



When a review determines that a regulation should be amended or rescinded, the Department would, on a case-by-case basis, use enforcement discretion to not enforce the rule or part of a rule until it is amended or rescinded.

## Comments on Proposed Rule

The Commission generally supports a retrospective review of regulations to ensure that they remain necessary and current. However, Congress has already established procedures for regulatory promulgation, review, and public comment through the Administrative Procedure Act (APA, 5 U.S.C. §§551-559) and the Regulatory Flexibility Act (RFA, 5 U.S.C. §§600-612). With these laws in place, MACPAC questions the need for a proposed rule that creates a duplicative and administratively burdensome new process that is likely to create confusion for beneficiaries, states, providers, and managed care plans. In addition, the new requirements will create additional unnecessary work that will distract the Department and CMS from the critical roles they play in our health care system, Medicaid and CHIP amid the pandemic and its resulting economic challenges. We further describe our concerns below.

### Duplication of existing processes

While the Commission recognizes the value of retrospective review of regulations, particularly for rules that have been in effect for decades, a review process covering the stated purpose of the proposed rule is already in place. Since 1980, the RFA has required federal agencies to conduct reviews every 10 years of regulations that have a significant economic impact on a substantial number of small entities. HHS posted its final plan for retrospective review of existing regulations in 2011, with a stated purpose to “identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined” (HHS 2011). From 2012 to 2016, HHS provided semi-annual updates on its website listing the rules undergoing or scheduled for review (HHS 2016). While the website has not been updated recently, we encourage the Department to continue to conduct retrospective reviews using its already established process and to provide regular updates to the public.

### Administrative burden

The Commission is concerned that the proposed rule’s automatic expiration mechanism places an immediate and unduly high administrative burden on the Department, and the Centers for Medicare & Medicaid Services (CMS) specifically.

In the proposed rule’s regulatory impact analysis, HHS indicates that the vast majority of its roughly 18,000 regulations would need to be assessed. Approximately 12,400 of those regulations were promulgated more than 10 years ago and would potentially need to be reviewed within the two years following the proposed rule’s finalization (85 FR 70112). Given that many of these rules are administered by CMS, the Commission is concerned that the administrative burden created by the new review process would divert staff resources and limit the agency’s ability to oversee the day-to-day operation of Medicaid and CHIP. No



provision is made for extenuating circumstances, such as responding to the COVID-19 pandemic, that would create new urgent priorities on CMS staff.

## Use of reviewers who are not responsible for implementing the regulations to perform the initial assessment

The proposed rule notes that, as an initial matter, the review would not necessarily be conducted by individuals in the Department who implement the regulation. The use of reviewers who are not responsible for implementing the regulations to perform the initial assessment may lead to the expiration of rules essential to the successful operation of both programs. As noted above, a retrospective regulatory review process is already in place that gives the Department adequate time to assess, review, and potentially propose new or amended rules through notice and comment rulemaking. This process also ensures a level of expertise and transparency that review by unknown or inexperienced staff cannot provide.

## Potential impact on beneficiaries, states, providers, and managed care plans

The proposed rule creates undue risk that rules essential to the successful operation of both programs may expire. States, providers, and managed care plans rely on stable and consistent regulatory guidance to meet their obligations under Medicaid and CHIP. Beneficiaries' access to care could also be affected by this uncertainty, particularly if rules related to eligibility or cost sharing limits were to expire.

The proposed rule also increases the likelihood for confusion by creating a new definition of regulation as a section of the Code of Federal Regulations.<sup>2</sup> As a result, each section of a rule would be treated as a separate rule for retrospective review purposes, while the implementing language and rationale included in the preamble to the rule could be lost altogether. For example, 42 CFR 438.4, which defines actuarial soundness for the determination of Medicaid managed care capitation rates, would be treated as a separate regulation from 42 CFR 438.5, which describes rate development standards. While these sections, and the overall managed care rule were originally designed and drafted to work together, they could be reviewed and expire separately, undermining the established rate setting process for states and plans.

The rule's proposed assessment and review process under which HHS would, on a case-by-case basis, exercise discretion to not enforce a rule or part of rule until it is amended or rescinded, would also create considerable uncertainty and undue harm. For example, millions of beneficiaries could lose eligibility for Medicaid if the section of the rules implementing the modified adjusted gross income eligibility standard (42 CFR 435.603) is either not enforced while under review, or allowed to expire because a review has not been conducted within the prescribed timeframes.



## Diminished opportunity for public comment

The notice and comment rulemaking process established in the APA enables the public to comment on proposed rules and requires federal agencies to meaningfully respond to those comments (5 U.S.C. §§552-553). The APA also includes a process for the public to petition for retrospective review of existing rules (5 U.S.C. §553(e)). Although HHS proposes to create a website to enable the public to comment and request a review when the deadline for assessing a rule is approaching, this website would not be governed by APA rules and the Department would not be required to meaningfully respond to those comments. As a result, rules that govern the administration of Medicaid and CHIP and affect access to care for millions of beneficiaries could automatically expire without public comment. As noted above, notice and comment rulemaking is an established process that ensures a level of public input and transparency that is vital to the effective operation of Medicaid and CHIP. The Commission does not see how the public or the regulatory review process benefits from a considerably less robust approach.

Again, we appreciate the opportunity to provide comments on this proposed regulation.

Sincerely,



Melanie Bella, MBA  
Chair

cc:

The Honorable Chuck Grassley, Chairman, Committee on Finance, U.S. Senate

The Honorable Ron Wyden, Ranking Member, Committee on Finance, U.S. Senate

The Honorable Frank Pallone Jr., Chairman, Committee on Energy and Commerce, U.S. House of Representatives

The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives

The Honorable Anna Eshoo, Chairwoman, Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives

The Honorable Michael Burgess, Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives

Seema Verma, Administrator, Centers for Medicare & Medicaid Services

Anne Marie Costello, Acting Deputy Administrator and Director, Center for Medicaid and CHIP Services



## Notes

<sup>1</sup> The Regulatory Flexibility Act (RFA) defines a “small entity” as 1) a propriety firm meeting the size standards of the Small Business Administration; 2) a nonprofit organization that is not dominant in its field; or 3) a small government jurisdiction with a population of less than 50,000. Except for such small government jurisdictions, neither state nor local governments are “small entities” (5 U.S.C. 601(3)-(6)).

<sup>2</sup> The Administrative Procedure Act (APA) defines a rule as “the whole or part of agency statement of general or particular applicability and future of effect or policy designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency...” (5 U.S.C. §551(4)).

## References

U.S. Department of Health and Human Services (HHS). 2016. Retrospective Review of Existing Rules. Washington, DC: HHS. <https://www.hhs.gov/open/retrospective-review/index.html>

U.S. Department of Health and Human Services (HHS). 2011. Plan for Retrospective Review of Existing Rules. Washington, DC: HHS. [https://wayback.archive-it.org/org-745/20141203143033/http://www.hhs.gov/open/execorders/13563/hhs\\_final\\_retrospective\\_review\\_plan\\_8-19-11\\_4.pdf](https://wayback.archive-it.org/org-745/20141203143033/http://www.hhs.gov/open/execorders/13563/hhs_final_retrospective_review_plan_8-19-11_4.pdf)

