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December 4, 2020

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

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

Dear Administrator Verma:

We appreciate the opportunity to provide comments on the Department of Health and Human Services (HHS) proposed rule, “Securing Updated and Necessary Statutory Evaluations Timely” (hereinafter referred to as the “Regulations Rule”). The proposed rule would retroactively impose an expiration provision on most HHS regulations, and establish “assessment” and “review” procedures to determine which, if any, regulations should be retained or revised.

Community Catalyst is a national non-profit health care advocacy organization dedicated to quality, affordable health care for all. Since 1998, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, along with policymakers and foundations, providing leadership and support to change the health care system so it serves everyone.

We feel strongly that the Regulations Rule is an ill-conceived proposal that would create tremendous administrative burden for HHS and would wreak havoc across a broad swath of department programs and regulated entities from Medicaid and Medicare to Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). We object to the truncated 30-day comment period which is insufficient for a rule of this broad scope with potentially harmful effects. **We urge HHS to immediately withdraw this proposed rule.**

The proposed rule would create tremendous administrative burden for HHS

HHS asserts that the Regulations Rule will promote “accountability, administrative simplification [and] transparency. . . .”¹ In fact, the proposed rule would create a significant administrative burden that would divert resources from critical work, including efforts to address the COVID-19 pandemic. HHS itself estimates that the proposed rule would cost nearly \$26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required

¹ 85 Fed. Reg. 70104.

reviews.² Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.³ However, these estimates likely underestimate the time and money involved in the review process, and do not accurately account for complications that may arise.

The Regulations Rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and appropriately review current regulations that need modification. In addition, several regulations implementing important parts of the Affordable Care Act are approaching their ten-year anniversary, like the Medicaid cost-sharing rule. Regulations like these would need to be reviewed within the next two years, or they would expire. However, the underlying law still exists, even if the regulations expire. Without the cost-sharing rule, states would not have clear guidance on how to implement cost-sharing amounts.

As an organization committed to high quality, equitable health care for all, specifically excluded populations, we are deeply concerned about regulations that are designed to protect the integrity of coverage and high-quality care delivery. Specifically, numerous regulations included in the scope of the proposed rule will affect all peoples' access to health care. Some examples of potential harm include:

- The EPSDT and CHIP coverage rules ([42 CFR 441](#)), including cost-sharing for well child care ([42 CFR 457.520](#)), that provide coverage and access to robust and vital health services for over 36 million children who would be at risk under the proposed rule. These are longstanding and important regulations that protect the nation's youngest lives.
- The essential health benefits (EHBs) ([45 CFR Subpart B](#)) play a vital role in maintaining access to health coverage and provide access to critical services such as substance use disorder and mental health services. [According to the Centers for Disease Control \(CDC\)](#), the rates of both substance use disorders and mental health challenges continue to rise during the pandemic, generating an additional crisis that reinforces the importance of these EHBs.
- Regulations ([45 CFR 146.136](#)) that apply the federal law requiring parity between private health insurance coverage for physical ailments and for mental illness and substance use disorders would be at risk. These federal regulations are important because they provide stronger tools for ensuring private health insurers don't discriminate against people with substance use disorders and mental illness.
- The federal regulations regarding application of parity requirements ([42 CFR Parts 438, 440, 456, and 457](#)) would also be at risk. These regulations are important because they build on earlier parity rules for private insurance, and apply parity rules to Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans.
- The Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule ([42 CFR 438](#)) – which regulates the delivery system through which the majority of Medicaid enrollees receive care. The 2016 final rule (CMS 2390-P) increased and

² 85 Fed. Reg. 70116.

³ 85 Fed. Reg. 70112. To be specific, HHS states that “because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.” *Id.*

strengthened many consumer protections for Medicaid managed care enrollees regarding choice counseling supports, provider access, language access and grievance/appeal rights, and it specifically strengthened many of these protections for individuals receiving long-term services and supports. If this rule were to expire, individuals receiving LTSS would be at risk of losing access to their preferred providers and would not receive as much support with choosing a health plan that best meets their needs.

The annual updates to the Notice of Benefits and Payment Parameters for marketplaces that revise requirements based on new information and data and the 2016 Medicaid managed care final rule mentioned above are both key examples of HHS taking steps to review and update regulations. Ironically, the SUNSET rule would likely impede HHS efforts to meaningfully update regulations where needed, since it would force HHS to devote staff time to the unnecessary reviews it would mandate. Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs.

The current rule would wreak havoc across all HHS programs

Regulations play an important role in implementing HHS policies and programs including safety net programs such as Medicare, Medicaid and the Children's Health Insurance Program (CHIP), which provide health coverage for over 75.5 million people, including 36.6 million children and 12 million low-income older adults and people with disabilities. A strong regulatory framework provides states the clarity they need to run these programs on a day-to-day basis, gives providers and managed care plans guidance as to their obligations, and explains to beneficiaries what their entitlement means. The Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

The bigger danger posed by the Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time-consuming review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

Rules that govern affordability and access to health coverage are at-risk of expiration and are core to consumers accessing needed care, especially during a pandemic. Specifically, the Public Health Services (PHS) Act section 2707(b), as added by the Affordable Care Act, provides that a non-grandfathered group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under sections 1302(c)(1) and (c)(2) of the Affordable Care Act. Section 1302(c)(1) limits out-of-pocket costs and, for small group market plans, section 1302(c)(2) limits deductibles as outlined in [45 CFR 156.410](#). In addition, the cost-sharing protections applied to dental plans in marketplace ([45 CFR 156.150](#)) protect consumers and is an example of where regulations shape how states implement the law and in the case of dental coverage, provide robust and consistent protections from potential medical debt.

In addition, multiple insurance affordability programs including Medicaid and CHIP rely on regulations ([42 CFR 435.603](#)) to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. If this regulation were to simply disappear, programs would be free to redefine MAGI household and income counting rules, with no standards, consistency, or accountability. **Arbitrarily rescinding large swaths of regulations would wreak havoc in HHS programs, leading to untold harm to the millions of people who rely on those programs.**

The proposed rule is unnecessary and contrary to requirements established by Congress.

The Regulations Rule claims that automatic expiration dates give HHS the incentive necessary to conduct regular assessments of existing regulations and comply with the Regulatory Flexibility Act (RFA). First, HHS agencies already commonly update regulations when needed. For example, in 2002 the Centers for Medicare & Medicaid Services (CMS) promulgated new regulations implementing statutory changes to Medicaid managed care.⁴ In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.⁵ CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.⁶ This administration undertook further rulemaking to revise Medicaid managed care regulations; “relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care.”⁷ HHS’ contention that it needs to “incentivize” regulation review by imposing a mandatory rescission is simply not supported by the facts.⁸

Further, the RFA requires each agency to publish “a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”⁹ However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

⁴ CMS, *Medicaid Program; Medicaid Managed Care: New Provisions*, RIN 0938–AK96, 67 Fed. Reg. 40989 – 41116 (June 14, 2002), <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf>.

⁵ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules*, RIN 0938–AS25, 80 Fed. Reg. 31098–31296 (June 1, 2015), <https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

⁶ CMS, *Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Final Rule*, RIN 0938–AS25, 80 Fed. Reg. 27498–27901 (May 6, 2016), <https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

⁷ CMS, *Medicaid Program; Medicaid and Children’s Health Insurance Program (CHIP) Managed Care (Final Rule)*, RIN 0938–AT40, 85 Fed. Reg. 72754–72844, 72754 (Nov. 13, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-11-13/pdf/2020-24758.pdf>.

⁸ 85 Fed. Reg. 70099, 70106.

⁹ 5 U.S.C. 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years).

In fact, this proposal is contrary to the Administrative Procedure Act's (APA) requirements for rulemaking. In the APA, Congress established clear procedures and standards for agencies seeking to modify or rescind a rule. The APA requires agencies to go through the same rulemaking process to revise or rescind a rule as they would for a new rule, with public notice and the opportunity to comment.¹⁰

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expire.¹¹ We do not dispute that federal agencies can later amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS in a single stroke, in violation of the APA. HHS's attempt to apply a blanket amendment to 18,000 regulations violates the APA's requirements that review of an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend.

Conclusion

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations by retroactively imposing an arbitrary end date. This rule is unnecessary, will wreak havoc in current HHS programs, and will tie the hands of the incoming administration by detracting from critical issues like the COVID-19 pandemic. We strongly oppose this rule, and urge HHS to withdraw it immediately. Thank you for the opportunity to comment on this important issue. If you have further questions, **please contact Eva Stahl, Associate Director of Policy, Community Catalyst (emstahl@communitycatalyst.org).**

Thank you for this opportunity to comment.

Respectfully submitted,



Emily Stewart
Executive Director

¹⁰ 5 U.S.C. § 551(5); *see also* Maeve P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration's Regulations?*, Congressional Research Service (Nov. 21, 2016), <https://fas.org/sgp/crs/misc/IN10611.pdf> ("In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule."); Office of Information and Regulatory Affairs, Office of Management and Budget, *The Reg Map 5 (2020)* (noting that "agencies seeking to modify or repeal a rule" must follow the same rulemaking process they would under the APA).

¹¹ 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively.