December 1, 2020

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

Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

The National Health Law Program (NHeLP) has worked to improve health access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals for over 50 years. 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"), which 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.[1] This ill-conceived proposal is unlawful, burdensome, and would wreak havoc on Department programs and regulated entities. We also strongly object to the truncated, 30-day comment period, which is insufficient for a proposal rule with such far-reaching and potentially harmful effects. HHS should immediately withdraw the Regulations Rule.

Retroactively imposing blanket expiration date on duly promulgated regulations is unlawful

In the Regulations Rule, HHS seeks to retroactively impose a mandatory expiration date on an estimated 18,000 duly promulgated regulations.[2] Even long-standing rules would be automatically rescinded unless they survive a complex process of assessment and review.

HHS cites to the Regulatory Flexibility Act (RFA), which requires executive agencies to periodically review current rules.[3] 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."[4] However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations.

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.[5]

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expired.[6] 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.

Under the plain language of the APA and affirmed in well-established case law, a final agency rule promulgated through notice and comment can only be revised or rescinded through an additional notice and comment rulemaking process.[7] The plain language of the APA states that

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[1] U.S. Dept. of Health and Human Srvs., *Securing Updated and Necessary Statutory Evaluations Timely*, RIN 0991–AC24 (Notice of Proposed Rulemaking), 85 Fed. Reg. 70096-70124 (Nov. 4, 2020), https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-23888.pdf (hereinafter "Regulations Rule"). *See also* U.S. Dept. of Health and Human Srvs., *Securing Updated and Necessary Statutory Evaluations Timely*, RIN 0991–AC24 (Proposed rule; public hearing) 85 Fed. Reg. 73007 (Nov. 16, 2020), https://www.govinfo.gov/content/pkg/FR-2020-11-16/pdf/2020-25246.pdf.
[2] 85 Fed. Reg. 70112.
[3] Regulatory Flexibility Act (RFA), Pub. Law 96–354, 94 Stat. 1164 (Sept. 19, 1980), https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg1164.pdf; 5 U.S.C. § 610(a).
[4] 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).
[5] 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).
[6] 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.
[7] *See Motor Vehicles Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983) ("We believe the recession or modification of an [agency rule] is subject to the same test.").

notice and comment rulemaking is required for "amending, or repealing a rule."[8] In addition, the case law clearly anticipates that amending an existing rule take place on an individual basis, requiring specific fact-finding relevant to the individual rule that the agency wants to amend, and not as HHS proposes, via universal, wholesale revisions.

When an agency seeks to change an existing policy promulgated by notice and comment rulemaking, that agency must "at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'"[9] In addition, agency action is arbitrary and capricious, in violation of the APA, if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choices made.'"[10] The Supreme Court has made clear that "[i]t would be arbitrary and capricious to ignore" factual findings which underlay a prior policy.[11] The blanket amendment of 18,000 regulations that HHS is currently attempting does not meet the fact-finding requirements mandated by the APA for amendment of existing regulations.

Even more troubling, in the Regulations Rule, HHS has arbitrarily chosen to reject the APA's definition of regulation and instead claims that "for the purposes of this rule" regulation is defined as "a section of the Code of Federal Regulations."[12] HHS seeks to justify this by claiming that the APA's definition could create confusion "in certain circumstances about what needs to be reviewed."[13] HHS provides no further explanation regarding why it rejects the well-established definitions and procedures from the APA. Moreover, HHS provides no statutory basis for redefining "regulation" here.

In an attempt to further justify this extraordinary regulatory action, HHS cites to select law review articles and the practices in a handful of U.S. states, the European Union, and the Republic of Korea.[14] These examples have no bearing or authority over federal rulemaking in the United States, where Congress, through the APA, has established procedures and standards for promulgating, updating, and rescinding regulations. HHS also cites to a string of executive actions reviewing regulations dating back to the Carter Administration.[15] These examples underscore that executive agencies do not need the Regulations Rule to compel

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[8] 5 U.S.C. §§ 553(a)(2); 551(5).
[9] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2126 (2016) (citations omitted).
[10] *State Farm*, 462 U.S. at 42 (quoting *Burlington Truck Lines v. U.S.*, 371 U.S. 156, 68 (1962)).
[11] *F.C.C. v. Fox Television Stations, Inc.*, 555 U.S. 502, 515-16 (2009).
[12] 85 Fed. Reg. 70104-70105. *See also* 5 U.S.C. § 551(4) (stating that " 'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing. . . .").
[13] 85 Fed. Reg. 70105.
[14] 85 Fed. Reg. 70102.
[15] 85 Fed. Reg. 70098-70099.

periodic regulatory review. Rather than a good faith effort to improve regulatory practices, the Regulations Rule seems designed to hamstring the incoming administration.

Moreover, HHS agencies 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.[16] In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.[17] As CMS noted:

> Because the health care delivery landscape has changed substantially […] this rule proposes to modernize the Medicaid managed care regulatory structure to facilitate and support delivery system reform initiatives to improve health care outcomes and the beneficiary experience while effectively managing costs.[18]

CMS took nearly a year to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.[19] This administration undertook further rulemaking to revise Medicaid managed care regulations, to "relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care."[20] HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts.[21]

The APA also provides that each "agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."[22] However, the APA does not specify the process for receiving petitions. As a result, "[h]ow petitions are received and treated varies

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[16] 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.

[17] 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.

[18] *Id*. at 31101.

[19] 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.

[20] 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.

[21] 85 Fed. Reg. 70099, 70106.

[22] 5 U.S.C. § 553(e).

across—and even within—agencies."[23] To date, HHS has "not adopted any particular regulations concerning the form that petitions under § 553(e) must take."[24] Nor has HHS adopted recommendations by the Administrative Conference of the United States for receiving, processing, and responding to petitions.[25]

Finally, we note that HHS has chosen to impose an automatic expiration date on thousands of regulations under the rationale that reviewing and updating regulations is critically important. Yet, HHS also specifically decided to exempt the Regulations Rule from the assessment and review process. This is at best disingenuous, and at worst an attempt to permanently impose a rigid review structure on the Department that would severely hamper its ability to carry out critically important work.

The rule would create tremendous administrative burden

HHS asserts that the Regulations Rule will promote "accountability, administrative simplification and transparency."[26] In fact, the 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, representing 90 full-time staff positions.[27] Within the first two years, HHS estimates the need to assess at least 12,400 regulations that are over 10 years old.[28] However, these estimates are likely a minimum assessment of the time and money involved in the review process, and do not accurately account for complications that may arise. HHS also does not account for the costs that will be passed along to states, providers, and beneficiaries who rely on regulations that are arbitrarily rescinded if they are not properly assessed and reviewed.

The Regulations Rule would adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, and to appropriately review current regulations that need modification. It would drain critical resources that are needed to address current challenges in the health care landscape. Especially during crisis situations, like the COVID-19 pandemic, it is important that agencies have the flexibility and resources to shift their focus and

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[23] Admin. Conf. of the U.S., *Recommendation 2014-6, Petitions for Rulemaking*, 79 Fed. Reg. 75,117-75120, (Dec. 17, 2014), https://www.govinfo.gov/content/pkg/FR-2014-12-17/pdf/2014-29546.pdf.
[24] *Minuteman Health, Inc. v. United States Dep't of Health & Human Servs.*, 291 F. Supp. 3d 174, 194 (D. Mass. 2018) (holding that mere public comment to CMS regarding benefit and payment parameters could not be construed as a petition for rulemaking, even where agency did not have rules clearly describing process for petitioning the agency).
[25] Admin. Conf. of the U.S., Recommendation 2014-6, note 23 *supra*, at 75117.
[26] 85 Fed. Reg. 70104.
[27] 85 Fed. Reg. 70116.
[28] 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.*

respond quickly to immediate needs. The Regulations Rule would create an administrative burden that makes such a response nearly impossible.

The rule would wreak havoc on HHS programs

Regulations play an important role in implementing HHS policies and programs, including safety net programs such as Medicaid and the Children's Health Insurance Program (CHIP), which provide health coverage for over 75.5 million people, including 36.6 million children. 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 makes clear to beneficiaries what their entitlement means.

The Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations and would wreak havoc in HHS programs. The Regulations Rule would create a kind of regulatory purgatory, in which regulations identified during the review process as needing to be amended or rescinded would continue to be in effect for up to two years. HHS admits that "enforcing a Regulation deemed to require amendment or rescission in some cases raises concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the Regulation (or portions thereof) would arguably 'run […] counter to the evidence before the agency.'"[29] However, HHS provides no insight or explanation on how it would address this conundrum.

The bigger danger posed by the Regulations Rule is that important regulations will likely slip through the cracks of this complicated and time-consuming assessment and review process. Such regulations would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies. For example, multiple insurance affordability programs including Medicaid and CHIP rely on regulations at 42 C.F.R. § 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.

Conclusion

The Regulations Rule is simply an attempt to sabotage and destroy duly promulgated regulations by retroactively imposing an arbitrary end date. We strongly oppose this rule, and urge HHS to withdraw it immediately.

Finally, we have included citations to research and other materials, including direct links to those materials. We request that the full text of material cited, along with the full text of our

[29] 85 Fed. Reg. 70108, quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

comment, be considered part of the formal administrative record for purposes of the APA. If HHS is not planning to consider these citations part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

If you have questions, please feel free to contact me at (202) 289-7661 or turner@healthlaw.org or my colleague Dania Douglas, douglas@healthlaw.org.

Yours truly,

Wayne Turner
Senior Attorney