NYLAG
New York Legal Assistance Group

December 4, 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:

Founded in 1990, the New York Legal Assistance Group (NYLAG) is a leading not-for-profit civil legal services organization advocating for adults, children, and families that are experiencing poverty or have low income. We tackle the legal challenges and systematic barriers that threaten our clients' economic stability, well-being, and safety. Access to health care through the Medicaid and Medicare programs for the aged and people with disabilities, as well as for children and families, is one of our priorities, with access to Medicaid home and community-based services a primary focus. We address these needs through comprehensive, free civil legal services, direct representation, impact litigation, policy advocacy, financial counseling, medical-legal partnerships, community education, and our website NYHealthAccess.org. Last year, we affected the lives of 90,800 people.

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 SUNSET 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.

The ill-conceived proposed SUNSET rule would undermine Medicaid, Medicare, and the marketplaces, as well as other core functions of government, such as Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The rule is totally unnecessary for these programs' proper administration. If finalized, the rule would require substantial agency staff time to implement, diverting key resources from responding to the COVID-19 crisis, other priorities, and day-to-day program administration. It has the potential to wreak havoc on HHS programs and harm the people who rely on them. This rule would also violate the Administrative Procedure Act (APA).

We also strongly 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 federal and state 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 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. 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 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, which could lead to great disparities among states.

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 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 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.

Additionally, 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.

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[1] 85 Fed. Reg. 70104.

[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.*

NYLAG is particularly concerned about highly regulated programs such as Medicaid and Medicare. Over **6.3 million New York residents** - nearly **one-third of the entire state population** -- depend on Medicaid for their health care for everything from preventative, primary and acute hospital care to long-term care both in the community and in nursing homes. The famously "Byzantine construction" of the federal Medicaid statute that "makes the Act 'almost unintelligible to the uninitiated,'"[4] makes the federal Medicaid regulations especially critical for the State Medicaid agency to interpret the statute. The regulations add flesh to the bones so that New York and other states have uniform federal guidance they need to implement it. Administration of a large State Medicaid program like New York's requires consistent, clear federal guidance, in order to program vast computer eligibility systems, to design procedures for and train the army of agency workers that determine eligibility, to establish standards, deliverables and rates for myriad managed care insurance and provider contracts, and to provide clear information for consumers.

For example, although the Medicaid statute mandates the inclusion of specified services in state Medicaid plans, rather than defining the minimum level of each service to be provided, the Medicaid Act requires states to establish reasonable standards for determining the extent of medical assistance, which must be comparable for all eligibility groups and consistent with the objectives of the Act. 42 U.S.C. § 1396a(a)(17). This broad mandate is fleshed out by a key federal regulation that has not substantively changed since 1981, which requires that services be "sufficient in amount, duration, and scope to reasonably achieve their purpose," and directs states not to "arbitrarily deny or reduce the amount, duration, or scope of such services to an otherwise eligible individual solely because of the diagnosis, type of illness, or condition." 42 C.F.R. 430.230(b) – (c). The same 1981 regulation permits states to place appropriate limits on a service based on such criteria as "medical necessity" or on utilization review criteria. Id. at 430.230(d). This federal regulation is the foundation upon which New York and other states have set standards for their benefits for nearly forty years – both in their state plans and in their contracts with managed care insurance plans. CMS also has relied on this regulation to further define services for benefits in guidance.[5] If this regulation lapsed, it would place in jeopardy the continued validity of this and other CMS guidance, as well as countless state standards for provision of Medicaid services, and would allow states to change their standards inconsistently and arbitrarily in ways that could violate the Medicaid statute. This could lead to extensive litigation, further wasting precious federal and state resources and hurting consumers.

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[4] Schweiker v. Gray Panthers, 453 U.S. 34, 43 (1981) (quoting Friedman v. Berger, 547 F.2d 724, 727, n. 7 (2d Cir. 1976)).

[5] See, e.g. CMS State Medicaid Director Letter Sept. 4, 1998 on Medical Equipment Coverage, available at https://www.medicaid.gov/federal-policy-guidance/downloads/SMD090498.pdf. This guidance, interpreting the above-referenced 1981 federal regulation, was the basis for the vacatur of the appellate decision by the U.S. Supreme Court in *Slekis v. Thomas*, 525 U.S. 1098, 119 S.Ct. 864 (1999), vacating and remanding *DeSario v. Thomas*, 139 F.3d 80 (2d. Circ. 1998).

Another example is 42 CFR 435.831, a Medicaid regulation relied on for the standards for determining eligibility for the "medically needy" – an optional category that in New York enables hundreds of thousands of aged, blind and disabled persons who have "excess income" above the Medicaid limits to qualify for Medicaid, if they incur certain medical expenses. The rule is complex, distinguishing treatment of paid and unpaid medical expenses, defining different "budgeting periods" each with different rules, and establishing other criteria. Since the rule was promulgated in 1994, it was amended only slightly in 2012 and 2016 to incorporate MAGI rules from the Affordable Care Act; those amendments did not change the decades-long rules for the non-MAGI population, which have long been incorporated in New York State regulations, guidance, and consumer-oriented web-based information.[6] If the regulation lapsed merely by the passage of 10 years, state eligibility systems based on these regulations would be thrown into chaos, having no clear federal standards. Consumers who depend on Medicaid by submitting proof of incurred medical expenses could lose vital coverage.

Similarly, 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.

The proposed rule is unnecessary and HHS does not have the authority to propose automatic expiration dates on almost all regulations.

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.[7] In 2015, CMS published a Notice of Proposed Rulemaking to update and modernize Medicaid managed care regulations.[8] CMS took nearly a year

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[6] New York Code of Rules & Regulations Title 18, Section 360-4.8(c), NYS Dept. of Health 96-ADM-015 - *Excess Income Program Clarifications/Prepayment of Client Liability (Pay-In) Program (*Aug. 13, 1996), https://www.health.ny.gov/health_care/medicaid/publications/pub1996adm.htm; also see consumer-oriented FAQ at https://www.health.ny.gov/health_care/medicaid/excess_income.htm.

[7] 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.

[8] 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.

to review and consider the 875 comments submitted, publishing the final rulemaking in May 2016.[9] 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."[10] HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts.[11]

The proposed rule will unduly burden State and Local governments that administer the Medicaid program as well as health insurers and providers that contract to provide Medicaid services – resulting in harm to consumers

The burden on states from unnecessarily frequent and arbitrary changes in regulations cannot be overstated. When CMS amended the Medicaid managed care regulations in May 2016 (discussed above), it wisely gave states time to implement the myriad changes; New York had two years to implement them by May 1, 2018. Even two years was barely enough time, despite diligent work by New York's Medicaid agency, which convened a stakeholder workgroup composed of representatives of managed care plans, consumers, and state and local Medicaid agencies. The workgroup, in which NYLAG participated, convened in numerous meetings over a year to provide input to the State on how to implement just *one* the many changes in this massive revision -- the new requirement that managed care enrollees "exhaust" their internal plan appeal when appealing an adverse plan determination, before requesting a fair hearing. 42 C.F.R. 438.402(c). With nearly five million Medicaid recipients in managed care plans, this change required huge systems changes – for plan call centers, plan grievance and appeal units, the State fair hearing agency, and more. The State Medicaid agency invited NYLAG and other stakeholders to propose suggested language for model notices to consumers of their appeal rights, procedures to protect consumers who had difficulty requesting a plan appeal or who have cognitive impairments, and myriad other policies and procedures. The State agency administrators considered all of this stakeholder input when it finalized the procedures, and conducted numerous webinars and issued numerous FAQ's to roll out the final changes implemented in 2018. The State agency just recently published proposed state regulations to codify the policies and procedures by which it implemented the 2016 changes in 2018.[12]

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[9] 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.

[10] 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.

[11] 85 Fed. Reg. 70099, 70106.

[12] See NYS Dept. of Health webpages with guidance and model notices implementing the "exhaustion" requirement, at https://www.health.ny.gov/health_care/managed_care/plans/appeals/index.htm; proposed State regulations at https://regs.health.ny.gov/sites/default/files/proposed-regulations/Medicaid%20Managed%20Care%20State%20Fair%20Hearings%20and%20External%2

That New York's implementation of this one regulatory change – the exhaustion requirement in appeals of managed care determinations -- is still being fine-tuned four years later illustrates the complex job states have in administering this huge program. All of these systems cannot simply change on a dime. In the stakeholder workgroup, the managed care insurance plans emphasized the lead time they needed to amend all of their form notice templates, translate them into multiple languages, train all of their call center, appeals, and case management staff, amend member handbooks, etc. If such changes are made more frequently because federal regulations are subject to arbitrary review requirements, this drains states of their own limited resources needed for COVID-19 and many other demands, and burdens local governments and health insurers as well. All of this, of course, detrimentally impacts consumers when resources that should be used to provide medical care are diverted to the cost of administration.

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."[13] However, nothing in this forty year-old law authorizes agencies to retroactively impose a blanket expiration date to rescind duly promulgated regulations. Ironically, it is the periodic review itself that would cause a significant economic impact on small entities – providers, insurers that must adapt to ever-changing regulations, more than the regulations themselves.

The Proposed Rule Violates the Administrative Procedure Act (APA)

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.[14]

HHS states it has authority under the APA to add end dates, or conditions whereby a previously promulgated rule would expired.[15] We do not dispute that federal

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0Appeals%20Processes%20and%20Standards.pdf (notice of rulemaking published in NYS Register, Vol. XLII Issue 27 (July 8, 2020), available at https://www.dos.ny.gov/info/register/2020/070820.pdf.

[13] 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).

[14] 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).

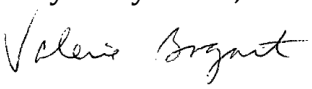
[15] 85 Fed. Reg. 70104, fn 85 & 86, citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively.

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' 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 to duly promulgated regulations. 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, to undertake this time-consuming process. We strongly oppose this rule, and urge HHS to withdraw it immediately. Thank you for the opportunity to comment on this important issue.

Very Truly Yours,



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