WHITMAN-WALKER Institute

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U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: **Docket No, HHS-OS-2020-0012; RIN 0991–AC24; Securing Updated and Necessary Statutory Evaluations Timely; Comments of Whitman-Walker Health and the Whitman-Walker Institute**

Pursuant to the Notice of Proposed Rulemaking, 70096 Fed. Reg. 27846 (November 4, 2020), Whitman-Walker Health and the Whitman-Walker Institute (collectively referred to as Whitman-Walker) submit these comments on the Department of Health and Human Services (HHS) proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely" (referred to in these comments as the NPRM or proposed rule).

The proposed rule would 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. It 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 the Food and Drug Administration and the Centers for Disease Control and Prevention. 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.

INTEREST AND EXPERTISE OF WHITMAN-WALKER HEALTH

Whitman-Walker Health is a Federally Qualified Health Center serving the greater Washington, DC metropolitan area, with a particular mission to the lesbian, gay, bisexual, transgender, and queer (LGBTQ) community and to persons living with HIV of every sexual orientation and gender. Our more than 280 medical, behavioral health and dental professionals, lawyers and paralegals, support staff and administrators provide comprehensive primary and specialty HIV and LGBTQ care, including medical, dental, mental health, substance use disorder treatment, community health, legal and insurance navigation services, and youth and family health and wellness-related support services. In 2019, Whitman-Walker provided health care services to 20,760 individuals.

Whitman-Walker's patient population is quite diverse and reflects Whitman-Walker's commitment to being a health care home for individuals and families that have experienced stigma and discrimination, or have otherwise encountered challenges in obtaining affordable, high-quality health care. We are nationally known as experts in HIV and Hepatitis C specialty care and in gender-affirming care for transgender and gender nonconforming persons. Our patients reflect the diversity of the Washington, DC metropolitan area: they include a wide range of races and ethnicities, ages and income levels, sexual orientations and genders. Substantial numbers of our patients are lower-income, living with long-term disabilities, and/or elderly; they depend on Medicaid, Medicare, health insurance obtained under the Affordable Care Act (ACA), and many other programs administered by HHS. Moreover, substantial amounts of the health services we provide are paid for by Medicare, Medicaid, ACA health plans, and the Ryan White Care Act, all regulated by HHS.

Since the mid-1980s, Whitman-Walker has had an in-house Legal Services Department. Our attorneys and legal assistants provide information, counseling, and representation to Whitman-Walker patients, and to others in the community who are LGBTQ or living with HIV, on a wide range of civil legal matters that relate directly or indirectly to health and wellness – including access to health care and discrimination based on HIV, sexual orientation, or gender identity. Our legal staff includes nationally recognized experts in Medicaid, Medicare, the Affordable Care Act and health insurance law generally, HIV law, and LGBTQ law. In 2019, we provided legal assistance to over 2,600 clients. That year, our staff and volunteer attorneys and Public Benefits and Insurance Navigation staff handled more than 2,000 cases involving HHS-regulated health care programs. Moreover, Whitman-Walker lawyers and health care providers have been substantially involved in HHS regulatory proceedings over many years.

The Whitman-Walker Institute was established to consolidate our policy, research and educational activities in order to increase their impact and synergy with our health care services.

COMMENTS ON THE PROPOSED RULE

The proposed rule would create tremendous administrative burden for HHS and its many agencies. HHS asserts that the NPRM 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 NPRM 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.

In the midst of the crisis of the COVID-19 pandemic, the proposed rule detracts from HHS's ability to have the flexibility and bandwidth to shift focus and respond quickly to meet the immediate needs.

The current rule would wreak havoc across all HHS programs, and threaten the HHS-administered health benefits that our patients and legal clients desperately need. 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. In 2019, over 5,100 of Whitman-Walker's patients were beneficiaries of the Medicaid and Medicare programs, and of those 1,820 were participants in the Ryan White HIV/AIDS Program.

Many of our patients are beneficiaries of the programs administered by HHS, and Whitman-Walker is subject to many of the regulations which are the eventual target of the NPRM. A stable regulatory framework provides us with the clarity we need to run our programs on a day-to-day basis. Regulatory stability from HHS is also helpful to the health care providers and health insurance companies as guidance as to their obligations. Regulatory stability facilitates education to program beneficiaries of their rights and privileges. The NPRM would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process.

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[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.*

The bigger danger posed by the proposed 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. 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 NPRM 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, to "relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care."[7] The community of HHS program beneficiaries and participants, and their advocates also work to identify high-priority HHS regulations for revision. HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts.[8]

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[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.

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.

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 expired.[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' 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.

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[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).

[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.

CONCLUSION

The NPRM 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.

Respectfully submitted,

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