JUSTICE IN AGING
FIGHTING SENIOR POVERTY THROUGH LAW

December 4, 2020

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

Submitted electronically via regulations.gov

Re: RIN 0991-AC24, Securing Updated and Necessary Statutory Evaluations Timely. Docket No. HHS-OS-2020-0012

Justice in Aging appreciates the opportunity to provide comments on the above-referenced Notice of Proposed Rulemaking (NPRM).

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income enrollees and populations that have been marginalized and excluded from justice such as women, people of color, people with disabilities, LGBTQ individuals, and people with limited English proficiency.

Our comments focus on the effects of the proposal on the 68 million Medicare enrollees and 69 million Medicaid enrollees who rely on HHS to ensure that those programs operate effectively to meet their needs. We primarily consider the impact of the proposal on the operations of the Centers for Medicare and Medicaid Services (CMS), which is responsible for both programs.

The HHS proposal

HHS proposes to assign high priority and strict deadlines to a retrospective review of nearly every regulation originally promulgated by HHS and its agencies over ten years ago, no matter how recently or how frequently the regulation has been amended. If the proposal were finalized in 2021, it would affect nearly every regulation promulgated in the Medicare and Medicaid program from the establishment of those programs in 1965 through 2010, a period of 45 years. The rule proposes a detailed assessment and review process for 12,400 regulations grouped into 2,400 rulemakings, with assessments and, where required, reviews all to be completed within two years. In any instance where the process has not been completed within the two year period, the affected regulation would automatically expire.

Justice in Aging urges HHS to withdraw the proposed regulation in its entirety. At a time when HHS is facing the most serious health care crisis since its inception and when the health care system in the United States is undergoing major transformations, HHS is proposing to launch and assign top priority to a vast retrospective exercise that ignores the current urgent needs of the 68 million Medicare enrollees and 69 million Medicaid enrollees who rely on CMS to ensure access to quality health care. The proposal is antithetical to a rational regulatory process and is not justified by the Department's own reasoning. The proposal is inconsistent with the core mission of CMS and irresponsible in the extreme.

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The proposal ignores the needs of individuals who rely on Medicare and Medicaid and is contrary to their interests

A marquee initiative of CMS over the last several years has been the Patients over Paperwork initiative meant to "improve the beneficiary experience."[1] The proposed regulation, however, would flip that initiative on its head by elevating the creation of a barrage of paperwork over the needs of Medicare and Medicaid enrollees. Under the guise of regulatory reform, it would divert resources and clog the CMS pipeline with regulatory reviews of questionable value in a time when the U.S. healthcare system is facing unprecedented challenges.

Despite the breadth of the proposal, the NPRM is virtually silent when it comes to analysis of its impact on Medicare and Medicaid enrollees. The closest it comes to addressing the issue is a perfunctory assessment of whether the proposal could affect "family well-being."[2] The only potential negative impact that HHS admits to is that a regulation might expire under the sunset provision, but even there, HHS asserts that the expiration "could have beneficial impact on family well-being."[3] The NPRM also dismisses concerns about the burden on the Department and its agencies of telescoping a review of 45 years of regulations into a two-year period: "The Department recognizes that this proposed rule requires the Department to undertake certain tasks. But the Department believes that retrospective review of regulations should be a priority and is willing to commit the necessary resources towards performing the Assessments and Reviews."[4] We urge HHS to reconsider this summary dismissal of the impact of its sweeping proposal.

The proposal would tie the hands of CMS at a time when the agency needs to be free to direct all its resources to the most pressing issues facing the Medicare and Medicaid programs

To prioritize this exercise, which HHS itself describes as clearing a backlog,[5] would divert critical resources of CMS when the agency must focus on addressing the COVID-19 pandemic and developing urgently needed Medicare and Medicaid policies and regulations to address inequities in health care that have come into stark focus during the public health emergency.[6] CMS plays a central role in the COVID-19 response.[7] That response needs to continue to be a high priority. Other high priority areas for regulations and policy development include: home and community-based services, nursing home reform, telehealth, and improvement in care for dual-eligible individuals, to name a few. CMS needs to prioritize matters that most affect Medicare and Medicaid enrollees in this time of radical change.

Pulling resources away from these priorities to address minor concerns such as outdated cross references or overestimated or underestimated cost determinations made years ago (all specifically

[1] See "Patients over Paperwork," available at www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.
[2] NPRM at 70118-70119.
[3] NPRM at 70119.
[4] NPRM at 70111.
[5] NPRM at 10115.
[6] See "Preliminary Medicare COVID-19 Data Snapshot," available at www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.
[7] See the CMS COVID-19 Response page at www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.

cited in the NPRM)[8] would be a shocking abdication of CMS's responsibility to prioritize the people depending on Medicare and Medicaid and ensuring that they have access to the services they rely on to maintain their health.

We ask, for example, whether it makes sense to require staff managing the Medicare Part C and D programs to spend significant time in the next two years on a retrospective review of more than 2,000 Medicare Part C regulations (42 C.F.R. §§ 422.1-422.2615) and more than 2,000 Part D regulations (42 C.F.R. §§ 423.1-423.2615) when they need to focus their limited resources on the complex challenges around how plans will coordinate distribution of COVID-19 vaccines to plan members, how changes in telehealth affect network adequacy, particularly for plan members who do not have reliable internet access, how to measure the impact of the recent addition of supplemental benefits in Part C on social determinants of health and other immediately critical matters. In our view, it does not make any sense at all.

The negative impacts the proposal would be far reaching and similarly hamstring other parts of the agency that are essential to making Medicare, Medicaid and other programs work for older adults. In particular, we note the detrimental impact of this rule on divisions such as the Administration for Community Living, which has limited staff and relies on partnerships with the local and state "small entities" within aging and disability network. Together, ACL and the aging and disability network help to ensure older adults and people with disabilities have access to the broad range of supports and services they need to live safely in their communities. Under this rule, ACL would have to review and assess extensive, longstanding regulations, such as those implementing the Older Americans Act and the long-term care ombudsman program, at a time when ACL and the aging and disability network are grappling with ways to deliver their services during the public health emergency. ACL should be prioritizing the COVID crisis and assessing how to reinvent and restart programs once the emergency has ended. Diverting resources away from such critical operational issues, particularly for a smaller division of HHS like ACL, impedes the ability of HHS to perform its core missions, missions that affect the everyday lives of millions of older adults and people with disabilities.

The NPRM does not address the impact of the proposal on the health care system as a whole.

Medicare and Medicaid enrollees receive their services from small entities: home health providers, physician offices, DME suppliers, transportation providers, to name a few, all of which are regulated by CMS either directly or indirectly. All of these entities will be operating in limbo while CMS attempts to race through the assessment/review/regulatory process to meet the artificial and extreme deadlines imposed by these proposed regulations.

The U.S. health care system is a complex organism with thousands of interlocking moving parts. As Medicare is by far the largest payor of health care in the nation, the entire health care system touches the Medicare program in some way and therefore relies on Medicare regulations to function. Yet HHS proposes to put the future of that regulatory structure in doubt for at least two years while the agency assesses the impact of almost every regulation and then reviews what to do about those that impact small entities, which is most of them. This period of uncertainty is bound to affect decisions in the provider community to move forward with innovation when they do not know what the regulatory landscape will be. Instead of innovation, this rule could easily lead to stasis, a result that does not serve the interests of Medicare and Medicaid enrollees, particularly at this moment when the health care

[8] See discussion in NPRM at 70100.

delivery system is under extreme stress. The proposal would mean that nearly every Medicare regulation concerning hospitals, managed care, prescription drug coverage, skilled nursing facilities, durable medical equipment, home health agencies, hospice, dialysis, transplants and on and on would be under scrutiny, leaving the 68 million older adults and people with disabilities who rely on Medicare without clear protections and the entire web of providers without a clear path. Nowhere does the NPRM acknowledge this reality. Instead HHS asserts that the proposed rule will not have significant impact on the operations of a substantial number of small entities and does nothing to address the impact on the health care system as a whole.[9]

The authorities cited by HHS do not support its proposal

The NPRM includes a long review on executive orders and other policy directives relating to retrospective review of regulations and use of sunset measures. While the value of an agency reviewing whether its regulations are achieving their intended purpose is beyond dispute, the documents cited in the NPRM in no way support what HHS is proposing: cramming a review of 45 years' worth of regulations into two years in the midst of the most significant health care crisis in the last 100 years. HHS does not point to any. To the contrary, in setting a ten-year lookback, HHS asserts: "The Department has many Regulations, some of which are complex, so having to perform the Assessment and Review more than once every ten years could unduly burden the Department and increase the likelihood that a Regulation inadvertently expires because it is not Assessed or Reviewed."[10] Yet HHS finds no contradiction between this statement and its decision to compress thousands of reviews of regulations older than ten years into a two-year window.

Finding no support for a two-year deadline in prior orders or literature, HHS instead asserts--without any reference to impact of the COVID-19 public health emergency--that, because any individual rulemaking generally takes less than two years, it is reasonable to review 2,400 rulemakings addressing 12,400 regulations in that same time frame.[11] Further, HHS offers no support for why regulations that have been recently amended through a thorough rulemaking process should also be included in the two-year assessment requirement.

The fact that agencies can and should do better in reviewing regulations is adequately supported by the authorities cited in the NPRM. The proposed implementation—which is akin to deciding to rearrange the closets while the house is on fire—has no such support.

Conclusion

Justice in Aging reiterates its request that HHS withdraw this proposed regulation in its entirety. Thank you again for the opportunity to submit comments. If any questions arise concerning this submission, please contact Amber Christ, Directing Attorney, at achrist@justiceinaging.org.

Sincerely,

Jennifer Goldberg
Deputy Director

[9] NPRM at 70118.
[10] NPRM at 70106.
[11] NPRM at 70106.