November 19, 2021

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Submitted online via Regulations.gov

Re: Repeal of HHS Rules on Guidance, Enforcement and Adjudication Procedures; RIN: 0991-AC29

Justice in Aging appreciates the opportunity to comment on the above referenced notice of proposed rulemaking (NPRM). We strongly support the proposal of the Department of Health & Human Services (HHS) to repeal both the Good Guidance Practices (GGP) rule--which Justice in Aging had opposed when it was first proposed-- and the Civil Enforcement rule, which had been adopted without an opportunity for public comment.

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults nationwide. 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, particularly populations that have been marginalized and excluded from justice such as women, people of color, LGBTQ individuals, and people with limited English proficiency. We have decades of experience with Medicare and Medicaid and working with advocates who represent low-income older adults. Justice in Aging conducts trainings and engages in advocacy regarding Medicare and Medicaid, provides technical assistance to attorneys across the country on how to address problems that arise under these programs, and advocates for strong consumer protections at both the state and federal level.

Our comments focus primarily on the impact of these rules on administration of the programs that have the most impact on low income older adults, including Medicare, Medicaid, and programs of the Administration for Community Living.

The GGP and Civil Enforcement Rules Interfere with the Agency’s Mission to Improve Public Health and Protect Enrollee Rights

The GGP and Civil Enforcement rules divert the finite resources of HHS to burdensome and unnecessary activities. In so doing, they make it harder for the agency to timely respond to emergencies, to address the glaring disparities in provision of services that have been highlighted during the COVID-19 pandemic, and to respond to and help shape the rapid changes in the health care delivery system.
The GGP rule imposes a uniform set of additional complex steps for both the issuance of “significant” guidance and for determining whether guidance can be treated as insignificant. The procedures required by the rule are unworkable given the number, frequency, range and importance of guidance documents issued by the Centers for Medicare and Medicaid Services (CMS) alone.

The guidance that CMS issues in the Medicare program, for example, requires frequent updates. Some guidance such as the annual Call Letter, is updated annually on a tight timeline. Other guidance documents, like Medicare Advantage All-Plan Letters, are issued irregularly, sometimes to quickly address an abuse or problem that may hurt Medicare enrollees. Medicare Manuals provide detailed guidance to providers, Medicare insurers and contractors on payment, coverage of specific procedures, quality measure reporting and a wide range of topics too detailed for regulatory treatment but important to the proper functioning of the program and the protection of enrollees. The overly elaborate procedures required by the GGP rule would clog up the pipeline for these important documents, leaving important problems unaddressed for too long and making deadlines for the current set of annual updates impossible to meet.

The process for developing and releasing guidance is nimble by design—it is meant to allow HHS to respond quickly and provide additional important information to further clarify issues that could not be or were not addressed in formal rulemaking. The COVID-19 emergency has even more graphically demonstrated the importance of this ability to move quickly to protect enrollees. We have seen during the COVID-19 crisis that CMS and HHS have issued a torrent of guidance documents aimed at getting states and providers the information they need to respond as quickly as possible. This includes critical information about protocols for nursing facilities, bulletins that have reminded providers of their obligation to not discriminate in developing crisis care standards, and communications quickly informing providers about flexibilities in the delivery of care and services via telehealth. When the public health emergency unwinds, there is going to be a need for additional quick and responsive guidance as new challenges crop up that need prompt resolution.

The GGP also includes a requirement that all guidance documents be placed in a central HHS repository. While having a searchable central database could improve transparency, the GGP rule stated that any guidance HHS does not include in the repository (even inadvertently), is automatically rescinded without any analysis of its importance, of whether it is widely available through other channels, or of any other relevant factors. Like the rest of the GGP rule, this arbitrary approach undermines transparency and threatens to harm all stakeholders, leaving those regulated by the agencies and those who rely on the agencies for protection in uncertainty. The requirement could easily interfere with the smooth operation of the Medicare and Medicaid programs on which millions rely for delivery of health care.

\[1\] See, e.g., Letter to HCMS Medicare Managed Care Organizations re Third Party Marketing (Oct. 8, 2021) (addressing possible marketing abuses and providing Medicare Advantage plans with guidance on their responsibility to oversee brokers and other third parties).
The Civil Enforcement rule, like the GGP rule, interferes with the ability of CMS and other HHS agencies to exercise their enforcement authority. This is of particular concern to Medicare enrollees who rely on CMS to exercise its authority over suppliers, insurers and providers in the Medicare program. Weakened enforcement powers embolden bad actors and threaten the integrity of the Medicare program.

For these reasons, Justice in Aging supports repeal of both the GGP rule and the Civil Enforcement rule.

The Current Search Function of the HHS Repository is of Limited Value

The NPRM asked for feedback on the usefulness of the current repository. We have tested the search function and found it very unsatisfactory. It has not shown documents that we know exist and it shows too many documents that are irrelevant to the issues we are searching for. One challenge is the overly broad categories, like “health care.” We appreciate that there may be potential value in an HHS guidance repository, but significant effort may be needed to realize that potential.

Based on our limited, and negative, experience with the repository, we would urge CMS to focus its resources to improving the accessibility and search capability for the many specialized sites where it now posts important guidance. We have noted and appreciated recent improvements in some searchable CMS websites and encourage additional upgrades.

Conclusion

Justice in Aging strongly supports the proposal in the NPRM and urges the HHS to move expeditiously to repeal both the GGP rule and the Civil Enforcement rule. If any questions arise concerning this submission, please contact Georgia Burke at gburke@justiceinaging.org.

Amber Christ
Directing Attorney