September 16, 2020

The Hon. Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 713F
Washington, DC 20201

RE: Comments on RIN 0991–AC17
Department of Health and Human Services Proposed Rule:
Good Guidance Practices

Submitted electronically: www.regulations.gov

Dear Secretary Azar:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates on behalf of long-term care consumers across care settings. Our membership consists primarily of consumers of long-term care and services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has more than 40 years' experience advocating for quality nursing home care.

The Long Term Care Community Coalition (LTCCC) is a nonprofit organization dedicated to improving quality of care, quality of life, and dignity for elderly and disabled people in nursing homes, assisted living, and other residential settings. LTCCC's work is grounded in its organization as a New York State based coalition of consumer, community, civic, and professional organizations, bringing together these different stakeholders to identify the systemic issues that affect quality of care and dignity in long term care.

The focus of this rule - agency guidance - is a valuable tool that allows executive branch agencies to help clarify policy issues and explain ambiguities raised by the laws and rules they are tasked with implementing and enforcing. Guidance also provides important information to long-term care providers to help them interpret and carry out regulations.

The Department of Health and Human Services (HHS) states that the proposed rule, Good Guidance Practices, is designed to increase accountability. While Consumer Voice and LTCCC support measures that increase transparency and accountability, the rule has significant problems and would not achieve HHS' stated goals. Instead, the net effect of this rule would be to undermine, weaken and even eliminate helpful guidance. This rule is overly burdensome to agencies and requires unnecessary procedures that serve no purpose except to substantially delay or prevent the issuance of new guidance and even do away with existing guidance.

Further, the truncated 30-day comment period provides insufficient time to fully consider this complex proposal that would have far-reaching, harmful consequences on the individuals whom the regulations and guidance ultimately serve.

We strongly urge HHS to withdraw the proposed rule. Our comments are below.

The creation of "significant guidance" is unwarranted and places an undue burden on agencies.

The new rule creates a new category of guidance, "significant guidance," that would be subject to the same procedural requirements as regulations. Specifically, HHS would be required to analyze the proposed guidance and OIRA to review it. In addition, such guidance would have to go through a notice and comment process that lasts at least 30 days. These required procedures mean that HHS is, in essence, creating a new, legally ambiguous category somewhere between guidance and a rule.

We oppose establishing this new administrative category for a number of reasons. First, any guidance that would have the kind of economic impact or adverse material effect on areas such as public health or safety as described in the definition of significant guidance should be classified as a regulation given its potential consequences.
[We do question, however, how any potential consequences can be reasonably anticipated if the guidance does not have the force of law and does not direct parties to take or refrain from taking any action.]

Second, significant guidance would have to go through all the hurdles of a proposed rule, (e.g. OIRA review and public comment), without the guardrails of a rule (e.g. can generally only be modified or withdrawn through public rulemaking).

Third, instead of going into effect immediately, any guidance deemed "significant" would face a long, burdensome process, delaying its implementation. This delay could cost lives. As an example, on March 13, 2020, CMS issued QSO-20-14-NH: (revised) Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes. This guidance laid out steps to control and prevent the spread of COVID-19 in facilities. Given how quickly the virus can spread in a facility and how vulnerable nursing home residents are to the virus, it was critical that the guidance be issued very quickly in order to assist nursing home providers in taking appropriate measures. Had the guidance been subject to the additional burdens and time constraints called for in the proposed rule, it would have taken longer for providers to act, placing at risk the lives of both residents and staff.

The procedure to petition for review of guidance creates uncertainty and is onerous.

We are also opposed to the provision in the proposed rule that allows any interested party to petition HHS to withdraw or modify any particular guidance. Permitting such petitions would impact the ability of the regulated party to operationalize the guidance by creating uncertainty and unpredictability. It is extremely difficult to implement guidance that could be changed or eliminated at any time.

Additionally, “any interested party” gives almost anyone who objects to the guidance the opportunity to undermine it or have it thrown out. For instance, QSO-20-25-NH: 2019 Novel Coronavirus (COVID-19) Long-Term Care Facility Transfer Scenarios is guidance that provides key information and directions for cohorting and moving residents based on their COVID-19 status. In this instance, any interested party could have included providers, residents, family members, companies involved in transport, and staff, among many others.

Creating a petition review process would place an enormous burden on agencies. In the case of CMS, staff would be forced to devote a tremendous amount of time, resources, and effort to processing these petitions. Such a process would needlessly hamstring CMS and impact its ability to carry out other essential functions, like survey and enforcement. During the COVID-19 crisis, had such a process already been in place, it would have diverted CMS staff at a time when they needed to remain focused on the pandemic and public safety.

The proposed guidance repository is deeply problematic.

HHS’ proposal includes creation of a guidance repository with a highly troubling provision - guidance omitted from the repository would be automatically rescinded. This would place an overwhelming administrative burden on agencies since all guidance currently in effect must be moved into the repository by November 16, 2020. There is no rationale for such haste. If guidance is left out of the repository for any reason, it will be considered rescinded, even if that is not the intention of the agency.

The repository also creates a burden on the many regulated parties, including nursing facilities, that have reliance interests based on current guidance that may not end up in the repository. Based on guidance from CMS that could suddenly cease to be applicable, nursing facilities have spent money and developed processes over the years to protect residents, such as those relating to infection control.

Further, several provisions in the proposed rule would violate the Administrative Procedure Act (APA). The Supreme Court has ruled that, while agencies have the right to rescind a guidance document, the APA requires them to do so in a matter that evidences “reasoned decision-making” to prove that the decision is not “arbitrary and capricious.”[1] Neither the automatic rescission of guidance not included in the repository by the deadline, nor the intentional, permanent rescission due to administrative error or carelessness are a reasonable basis for eliminating guidance. Such action also fails to give adequate consideration to the value and necessity of guidance. Any decision about including guidance in the repository should be carefully considered with input from key stakeholders.

The repository is also likely to confuse members of the public if a guidance document appears on an HHS website, but is not included in the repository. It would not be apparent that such guidance is considered rescinded under this rule. Even if stakeholders petition to

[1] *Citizens to Preserve Overton Park, Inc v. Volpe, 401 U.S. 402, 416 (1971).*

reinstate guidance omitted from the repository, such a process would be time-consuming, burdensome, and cause uncertainty among the public and regulated entities.

We oppose the recission of guidance not transferred to the repository by early November.

Conclusion

We urge HHS to withdraw this proposed rule, which serves only to increase administrative burden, add unnecessary complexity, and delay and/or eliminate guidance that is important to guiding the behavior of regulated parties. Based on our decades of advocacy, this proposal would have a detrimental impact on our nation's nursing home residents.

Consumer Voice and LTCCC thank HHS for consideration of these comments.

Sincerely,

Lori Smetanka, Executive Director
The National Consumer Voice
for Quality Long-Term Care

Richard Mollot, Executive Director
Long Term Care Community Coalition