American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

December 4, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS-OS-2020-0012, Securing Updated and Necessary Statutory Evaluations Timely; Proposed Rule (Vol. 85, No. 214), November 4, 2020.

Dear Secretary Azar:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) proposed rule on regulatory review.

In this rule, HHS proposes to set expiration dates for its regulations (subject to certain exceptions), unless the department periodically assesses the regulations to determine if they are subject to review, and if they are, performs a review. Subject to this review, HHS would be able to unilaterally retain, modify or eliminate the regulation. **While we appreciate that this process has the potential to alleviate some regulatory burden for our hospital and health system members, we have substantial concerns that it does not provide an adequate mechanism for obtaining public input on the substance of regulations being reviewed.** HHS has approximately 18,000 regulations, the vast majority of which would be subject to review under this rule. They encompass a massive range of topics and affect a huge number of providers, beneficiaries and citizens; robust public input is critical. **As such, the AHA urges HHS to withdraw this rule.**

Under its proposal, HHS would be required to "assess" a regulation every 10 years to determine if it has a significant economic impact upon a substantial number of small entities. For regulations that have been in effect for more than 10 years at the time of the effective date of this proposed rule, HHS would have to undertake this assessment

within two years. If the regulation has a significant economic impact, the department would then "review" that regulation to determine if it should be retained, modified or eliminated. If HHS does not "assess" a regulation in a timely manner, it would automatically expire. However, despite these potentially drastic results, there would be limited opportunities for the public to provide input into HHS' assessments and reviews. Specifically, while the public would be able to comment on regulations that HHS states are in the process of assessment or review, it would not be in response to any proposal for action; thus, commenters would be without any context or indication of the department's thoughts on the substance of a regulation, any indication of what, if any, modifications it may be considering, or any indication of whether HHS is even considering modifications or deletion at all. Instead, the public would be commenting in a vacuum. This would not constitute a meaningful opportunity to comment.

As justification for this insufficient comment process, HHS states that "in this rulemaking process, which amends department regulations through the notice-and-comment rulemaking process, the department is considering the important factors" with regard to whether a regulation should be retained, modified or deleted. However, this claim is absurd on its face. The proposal sets forth a *process* for assessing and reviewing all of HHS' regulations, which is not a substitute for a thorough, public, transparent consideration of the *substance* of individual regulations. Thus, this rule does not constitute a meaningful opportunity to comment on potential changes to specific regulations. HHS cannot override the public's ability to meaningfully comment on regulations simply by creating another regulation that says it can do so. If notice-and-comment rulemaking was necessary to create a regulation, it also is necessary to modify or delete a regulation.

In addition, we have serious concerns about the proposal to remove any regulation for which an assessment is not completed in a timely manner. HHS states that the risk of a regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review. We strongly disagree. We also believe that the department's "risk mitigation" strategy – a website where, if the deadline for publishing an assessment or review is nearing, and HHS has not announced that it has undergone these activities, the public can submit a comment requesting that the assessment or review begin – is inappropriate and inadequate. It would be difficult, if not impossible, for the public to accurately determine whether a regulation is subject to assessment, and if so, the deadline for informing the agency and commenting. Thus, there very well may be scenarios where a regulation was not assessed, but it is unclear whether it has expired or was exempt from this regulatory review process and is still in place. At best, this would leave those subject to the regulation with no guidance on what is expected of them. At worst, there would be serious consequences of inadvertently removing rules, with negative impacts on beneficiaries, consumers and the public in general.

Examples of the above-mentioned confusion and consequence abound. First, CMS has recognized that under its alternative payment models, the waiver of certain payment

regulations is essential so that participants may coordinate care and ensure that it is provided in the right place at the right time. For example, regulations at 42 CFR 425.612 identify the circumstances under which specific payment regulations are waived under the accountable care organization (ACO) program. These include the skilled-nursing facility 3-day rule, and the telehealth originating site requirement. Payment waivers are valuable tools that help ACOs achieve success under the program – namely, increasing quality of their beneficiary care and reducing unnecessary costs for Medicare. If HHS unilaterally, and without public input, removed these waivers, modified them in an inappropriate manner, or let them inadvertently expire, it would cause confusion for participants and beneficiaries alike, and likely lead to failures of the program to achieve its goals.

Second, many Medicare Advantage (MA) and Part D marketing regulations protect Medicare beneficiaries from misleading and high-pressure marketing tactics that could result in enrollment in an inappropriate or inadequate health plan or result in the purchase of unnecessary ancillary products or services. A substantial number of these regulations were established shortly after the passage of the Medicare Modernization Act with the core marketing regulations finalized in 2008, well beyond the 10-year timeline contemplated by this rule, and remain just as vital today as when they were adopted. For example, regulations at 42 CFR 422.2268 establish standards for marketing by MA plans. Health plans may not, among other things, induce beneficiaries to buy their products through cash payments, discriminate against lower income beneficiaries by concentrating marketing in higher income areas only, or use aggressive outreach techniques, such as showing up at beneficiaries' homes unsolicited. If HHS unilaterally and without public input, removed any of these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it would be problematic. Beneficiaries would no longer enjoy these protections and the Centers for Medicare & Medicaid Services (CMS) would no longer be able to take any enforcement action against MA or Part D plans violating the rules. That is unacceptable.

In addition, each year, the agency issues updated MA and Part D marketing guidelines. This is subregulatory guidance that provides additional information on how to interpret and operationalize the regulations. It is unclear, however, whether this guidance suffices as "review" of the underlying regulations under this regulatory review proposal. Diverting agency attention to review each of these regulations would severely curtail agency resources for doing what matters: ensuring health plans are adhering to these regulations.

As another example, Medicare's quality measurement and value programs rely on regulations that have been implemented incrementally. For example, statutes do not require that CMS has an extraordinary circumstances exception (ECE) policy for natural disasters and other circumstances, but CMS has written such policies into all of its programs through regulation (for example, see 42 CFR 412.140(c)(2) for the inpatient quality reporting (IQR) program and 42 CFR 412.160(c)(1)-(4) for the value-based

purchasing program). There is good reason to have ECE policies – extraordinary circumstances can make it impossible for hospitals and other providers to submit quality data, or render the data they have unrepresentative of their true quality performance. In fact, that is precisely why CMS already has invoked ECE policies for its measurement programs during the COVID-19 pandemic. If HHS unilaterally removed these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it would remove critical certainty from hospitals' disaster planning. In fact, having the ECE policies stand unless and until there are revisions through a transparent rulemaking process gives the field important stability. The COVID-19 pandemic, and the numerous natural disasters like wildfires, hurricanes, tornadoes and floods that our nation has faced in recent years only underscore that hospitals need to be able to count on relief from reporting requirements, and not worry that an arbitrary timeline would simply wipe away the policies.

In addition, specific quality measures for Medicare programs have been implemented through regulation, such as 42 CFR.140(c)(1) for the IQR and 42 CFR 412.152 for the Hospital Readmissions Reduction Program. We have long urged Medicare to focus on using "measures that matter" in these programs, and believe all quality measurement program measures sets should be reviewed regularly to identify opportunities to streamline them. In fact, we have recommended a multi-factorial approach to decide when to remove measures from programs, including whether measure performance is topped out, has sufficient evidence to warrant its use, and has any negative unintended consequences. CMS has codified this approach in so-called "measure removal factors," as exemplified by policies adopted for the IQR (see 83 Federal Register 41540 through 41544). If HHS unilaterally, and without public input, removed these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it could set-back quality measurement by decades.

Regarding Medicaid and the Children's Health Insurance Program (CHIP), a combination of federal statute, regulations and subregulatory guidance outline parameters including who is eligible for benefits, what those benefits include, how the programs are administered and financed, and how beneficiaries are assured access to safe, quality care. Little of the law is "self-implementing," and the regulations and other guidance provide critical details – and even expand – on the requirements in the law. For example, section 1905(r) of the Social Security Act (the Act) establishes the requirement that state Medicaid programs cover periodic screening and treatment for Medicaid eligible children. Regulations at 42 C.F.R. § 441.62 require that states also assure transportation to this medically necessary care, and regulations at 42 C.F.R. § 440.170(a) provide the definition for what constitutes transportation services, e.g., ambulance, taxicab, common carrier or other appropriate means, as well as meals and lodging for both the child and necessary attendant. These particular regulations have stood the test of time since the early 1980s and continue to be entirely relevant today. If HHS unilaterally, and without public input, removed any of these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it would be

devastating – health care coverage would be on the line for the more than 70 million Medicaid enrollees and over 6 million CHIP enrollees, the preponderance of which are children.

Finally, legislation including the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and the ACA require parity between mental health or substance use disorder (SUD) benefits and medical/surgical benefits. Parity applies with respect to financial requirements and treatment limitations under group health plans and group and individual health insurance coverage. Essentially, plans and issuers are prohibited from imposing financial requirements or treatment limitations on mental health and SUD benefits that are more restrictive than those that apply to medical/surgical benefits. Examples of the regulations that help implement these provisions include 42 CFR Parts 146 and 147. These regulations go beyond the legislation to provide specific guidance on the application of non-quantitative treatment limitations (NQTLs) – which put limits on the scope or duration of treatment that are not expressed numerically, such as prior authorization. While the statutes prohibit payers from imposing NQTLs more stringently to mental health or SUD benefits than to comparable medical/surgical benefits, the regulations are necessary to clarify details around exactly how these NQTLs may and may not be imposed.

Despite the law and regulations, payers continue to struggle to operationalize these requirements and, therefore, we continue to urge for greater government oversight to ensure compliance. For example, we know both anecdotally and from independent studies that mental health and SUD services are often subject to NQTLs, especially prior authorization, more often than medical/surgical benefits. If HHS unilaterally, and without public input, removed any of these regulations, modified them in an inappropriate manner, or let them inadvertently expire, it would leave the department unable to pursue enforcement action, which could cause a drastic and devastating reduction in patient access to care.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at jkim@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President