



December 4, 2020

The Honorable Alex M. Azar, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Securing Updated and Necessary Statutory Evaluations RIN 0991–AC24

Dear Secretary Azar,

The American Academy of PAs (AAPA), on behalf of the more than 140,000 PAs (physician assistants) throughout the United States, appreciates the opportunity to provide comments on the Department of Health and Human Services' (HHS) proposal to create a process for the periodic review of regulations under the agency's purview. Regulations having a significant economic impact on a substantial number of small entities would undergo a formal review and evaluation based on a pre-established timetable to determine their current relevance and effectiveness. Following that review, regulations would either be retained, revised, or allowed to expire. This retrospective review would consider, among other factors, whether regulations overlap, duplicate, or contradict with other federal and state rules.

The concept of a proactive, periodic review of existing regulations to facilitate the removal of outdated policies which fail to align with the efficient delivery of healthcare services has merit. The PA profession has often experienced the negative impact of archaic federal healthcare regulatory policies that limit their ability to deliver the full range of medical care to patients. Certain outdated regulatory policies have and continue to restrict PA practice by failing to align with and account for the high level of PA education, clinical competency, and state-authorized scope of practice. Ultimately, the result of such out-of-date policies is delayed patient access to care and the existence of unnecessary and costly administrative burdens. However, while pursuing regulatory reviews HHS must be especially mindful of the potential for adverse and unintended consequences of such a process.

If the proposed rule is finalized AAPA believes there must be:

- Full and complete transparency for any regulations identified for review. HHS, the Centers for Medicare and Medicaid Services and other federal agencies should engage in a process that obtains early and significant feedback from the health professionals and stakeholder groups most directly affected by the regulation being reviewed. Ensuring such interaction and communication will provide HHS with a real world understanding of the impact of regulations on actual clinical practice, and specific examples of the implications on patient care.

- A process established to remedy a situation in which a regulation is mistakenly not identified for review during the required time frame. With the myriad of existing regulations, one can imagine the possibility of a regulation being missed. It would be inappropriate and unfair for an existing regulation to automatically expire simply because it was erroneously not identified for review and evaluation.
- A commitment for the review and evaluation of regulations to be conducted with an evidence-based, data driven approach that seeks to increase competition in healthcare. Timely and appropriate patient access to quality care, patient satisfaction, and the effective use of resources should be the requisite key evaluation metrics. Any efforts aimed at protecting professional turf only serve to hinder competition and efficiency.


Only when the above listed concerns can be appropriately acknowledged and accepted should the proposed rule be finalized.

AAPA also urges the agency to avoid using the proposed rule, if finalized, as the only method or justification to review or seek comments on outdated regulatory language. Doing so could cause the department to fail to consider worthwhile and necessary regulatory changes or updates that could provide increased patient access to care and greater efficiencies if enacted before a required, pre-determined evaluation date. Health professionals, medical professional societies and other stakeholders have traditionally been able to engage HHS and CMS in discussions related to the impact and assessment of existing regulations. It is imperative for those opportunities for interaction to remain available.

Finally, the serious challenges of the COVID-19 Public Health Emergency (PHE) further emphasize the need for maximum regulatory flexibility to support and strengthen our nation's healthcare workforce. The department has made significant progress in this area. AAPA appreciates HHS' efforts, through waivers, proposed rules and interim final rules, to update and revise regulatory policies to enhance patient-centric care delivery. We believe the need for regulatory flexibility to meet current and future patient care needs will not stop when the PHE ends. If the agency is committed to the idea of modernizing regulatory policies, AAPA strongly urges HHS to maintain and not eliminate the beneficial flexibilities enacted during the COVID-19 PHE which have led to decreased administrative burden and expanded patient access to vital healthcare services.

Thank you for the opportunity to provide feedback on the proposed rule. AAPA welcomes further discussion regarding this issue. For any questions you may have please do not hesitate to contact Michael Powe (michael@aapa.org), AAPA Vice President of Reimbursement & Professional Advocacy.

Sincerely,



Beth R. Smolko, DMSc, MMS, PA-C, DFAAPA
President and Chair of the Board