American Academy of Physician Associates

April 4, 2025

Dr. Marty Makary, Commissioner, Food and Drug Administration

Robert F. Kennedy Jr., Secretary, Health and Human Services

Pam Bondi, Attorney General

Russell Vought, Director, Office of Management and Budget

Regarding Executive Order (EO), Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency"

President Donald J. Trump issued the Executive Order (EO), *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Regulatory Initiative*, on February 19, 2025, instructing the heads of agencies to identify regulations inconsistent with the law. Further, in consultation with the Attorney General, agency heads are to identify various classes of regulations within 60 days of the order. In this context, the American Academy of Physician Associates (AAPA), representing the 180,000 physician associates/physician assistants (PAs) in the United States, provides the following regulation that is not based on statutory authority and unjustly limits services for which PAs are trained, state licensed, and nationally certified to provide.

AAPA urges the agency to amend 21 § 606.160 to authorize PAs to sign for the emergency release of blood products. The current regulation requires that a physician sign for the emergency release of blood products before or after the release. A physician signature after administration is an administrative burden that does not benefit patient care. In addition, several large health systems require a signature before release to ensure the signature is obtained. This is problematic, especially in critical access hospitals and other underserved areas where a physician may not be readily available, thereby delaying access to life-saving treatment. The emergency release of blood products occurs in critical situations, including mass traumas, when clinical flexibility is most needed.

Amending this regulation and authorizing PAs to sign for the emergency release of blood products is consistent with the EO's goals of identifying regulations that do not represent the best reading of underlying statutory authority and harm the national interest by significantly and unjustifiably impeding disaster response.

AAPA appreciates the opportunity to provide recommendations for the Executive Order and welcomes further discussion with the Food and Drug Administration regarding these and other important issues. For any questions you may have, please do not hesitate to contact Sondra DePalma, AAPA Vice President of Reimbursement & Professional Practice, at sdepalma@aapa.org.

Sincerely,

Sondra M. DePalma, DHSc, PA-C

Vice President, Reimbursement and Professional Practice