

April 4, 2025

Amy Gleason, Acting Administrator, Department of Government Efficiency 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 a list of regulations that meet one or more of these classifications.

The below listed regulations are based on a faulty reading of underlying statutory authority and unjustly limit services for which the Social Security Act (SSA) authorizes Medicare payment. They create unnecessary red tape and inefficiencies in care delivery, increasing costs to patients and the federal government, and hindering access to high-quality care. Specifically, Sec. 1861(s)(2)(k)(i) of the SSA clearly authorizes coverage of services furnished by physician assistants/physician associates (PAs) when the services "would be physicians' services" and "which the physician assistant is legally authorized to perform by the State in which the services are performed."

Removing anti-competitive barriers to PAs as a method of improving healthcare was identified during President Trump's first term and highlighted in *Reforming America's Healthcare System Through Choice and Competition*, a publication jointly authored by the Department of Health and Human Services, the Department of the Treasury, and the Department of Labor. Specifically, the publication, which was also in response to an Executive Order by President Trump, stated that "states should consider eliminating requirements for rigid collaborative practice and supervision agreements" between physicians and PAs or other practitioners "that are not justified by legitimate health and safety concerns." These recommendations were built on the foundation that PAs provide safe and effective care on the level of physicians. PAs are state-licensed and nationally certified to provide medical and surgical services. PAs diagnose and treat illnesses, order and interpret diagnostic tests, prescribe medications, perform procedures, assist at surgery, and perform other medical services. PAs often serve as a patient's principal healthcare practitioner.

Addressing these regulations would not only achieve the stated goals of the current EO, but would fulfill the recommendations of the previous publication.ⁱ Additionally, the below regulations undermine President Trump's recent Executive Order on *Establishing the President's Make America Healthy Again Commission*, which strives to re-direct our national focus toward understanding and drastically lowering chronic disease rates. Several of the below regulations hinder access to critical chronic disease screening and treatment.

As part of the administration's efforts to reduce burdensome and unnecessary regulations, we urge the administration to consider the below revisions to enable PAs to practice to the full extent of their license, improve the delivery of healthcare in the US, and reduce federal spending on healthcare.

Regulatory changes to promote wellness and chronic disease management.

- Revise 42 CFR § 410.37(f) to authorize Medicare payment for screening colonoscopies performed by
 PAs. 42 CFR § 410.37(f) conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to
 provide "physicians' services" they are authorized to perform by the State. Amending the regulation
 to authorize payment for colonoscopies that PAs have statutory authority to perform, and for which
 they have been demonstrated to perform with similar outcomes as physicians, will improve screening,
 detection, disease prevention, and wellness.
- Revise 42 CFR § 410.40(e)(2) to authorize PAs to certify nonemergency, scheduled, repetitive ambulance services. 42 CFR § 410.40(e)(2) conflicts with the statutory authority of SSA

Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State. Further, PAs are authorized to certify non-emergency ambulance services that are unscheduled or scheduled on a non-repetitive basis. Amending this regulation will improve chronic disease management (e.g., improve access to dialysis and chronic wound care) for patients who otherwise would not be able to access care without non-emergency, scheduled, repetitive ambulance services.

Regulatory changes to ensure access to quality post-acute care.

- Revise 42 CFR § 483.30 to authorize PAs to perform the initial and all required visits in a skilled nursing facility and approve in writing a recommendation that an individual be admitted to a facility. 42 CFR § 483.30 conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State. Additionally, PAs have been demonstrated to provide care that is comparable to physicians in quality, outcomes, and patient satisfaction. Amending these regulations will ensure access to quality post-acute care.
- Revise 42 CFR § 412.29, 42 CFR § 412.622 (a)(4)(i)(D), and 42 CFR § 412.622 (a)(4)(ii)(A) to authorize
 PAs to provide all required face-to-face visits, review and improve the preadmission screening, and complete the plan of care in inpatient rehabilitation facilities. These regulations conflict with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State. Additionally, PAs have been demonstrated to provide care that is comparable to physicians in quality, outcomes, and patient satisfaction. Amending these regulations will ensure access to quality post-acute care.

Regulatory changes to increase efficiency, improve workforce adequacy, and reduce administrative burden.

 Revise 42 CFR § 418.106(b)(1)(iii) to authorize hospice-employed PAs to order medications for hospice patients. 42 CFR § 418.106(b)(1)(iii) conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State. Further, non-hospice-employed PAs are authorized to order medications for hospice beneficiaries. Amending this regulation will improve efficiency and reduce administrative burden.

- Revise 42 CFR § 485.631(b)(1)(iv) and 42 CFR § 485.631(b)(1)(v) to remove requirements that a physician periodically review and sign records of all inpatients seen by PAs in Critical Access
 Hospitals (CAHs). Physician co-signature requirements are not generally required by state law and create inefficiencies and administrative burdens without benefiting patients.
- Revise 42 CFR § 485.639(a) to authorize PAs to perform surgical procedures by including them in the list of "qualified practitioners" in CAHs. 42 CFR § 485.639(a) conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery. Amending this regulation will increase workforce adequacy and improve efficiency.
- Revise 42 CFR § 485.524(d)(1) to authorize PAs to perform surgical procedures by including them in the list of "qualified practitioners" in Rural Emergency Hospitals. 42 CFR § 485.524(d)(1) conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery. Amending this regulation will increase workforce adequacy and improve efficiency.
- Revise regulations to authorize PAs to provide services in Ambulatory Surgical Centers (ASCs).
 - Revise_42 CFR § 416.42 to authorize PAs to perform surgical procedures by including them in the list of "qualified practitioners" in ASCs. 42 CFR § 416.42 conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery. Amending this regulation will increase workforce adequacy and improve efficiency.
 - Revise 42 CFR § 416.42(a)(1)(i) and 42 CFR § 416.42(a)(1)(ii) to authorize PAs to evaluate risk in ASCs. These regulations conflict with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

- Revise_42 CFR § 416.48(a)(3) to authorize PAs to order drugs and biologicals in ASCs. This regulation conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State, which includes prescriptive authority. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.
- Revise 42 CFR § 416.52(c) to authorize PAs to perform essential discharge functions in ASCs.
 This regulation conflicts with conflicts with the statutory authority of SSA Sec. 1861(s)(2)(k)(i))
 for PAs to provide "physicians' services" they are authorized to perform by the State.
 Amending this regulation will increase workforce adequacy, improve efficiency, and decrease administrative burden.

As mentioned, the listed regulations are consistent with *class iii*, as defined in the EO, as they do not represent the best reading of the underlying statutory authority. In addition, many of the regulations are also consistent with *class v* because they impose significant costs upon private parties that are not outweighed by public benefits and *class vi* because they harm the national interest by significantly and unjustifiably impeding innovation, economic development, and disaster response. Further, many of the listed regulations are consistent with *class vii* because they impose on small businesses and entrepreneurs who would benefit from the suggested regulatory revisions.

The identified regulations impose significant costs that are not outweighed by public benefits. The increased utilization of PAs could save the Medicare program millions of dollars annually, because PAs are reimbursed at 85% of what a physician would be reimbursed for the same services. State Medicaid programs and commercial payers could incur similar savings. These savings would not adversely affect public benefit, as the Medicare Payment Advisory Commission concluded in a 2019 Report to Congress that "both randomized clinical trials and retrospective studies using claims and surveys, suggests that care provided by . . . PAs produces health outcomes that are equivalent to physician-provided care."ⁱⁱ

The listed regulations also threaten the national interest, especially the nation's disaster response. President Trump's first administration agreed with this assessment, waving some of these unduly restrictive regulations during the initial phases of the COVID-19 pandemic, such as authorizing a physician to delegate previously "physician only" tasks in skilled nursing facilities to PAs and other qualified health professionals.ⁱⁱⁱ

In addition to the identified regulations, many sub-regulatory policies (see the addendum below) further limit the statutory authority for Medicare coverage of services provided by PAs. The AAPA would be happy to work with the corresponding agencies to remove these policies, which create inefficiency and an administrative burden and harm patient access to high-quality, affordable healthcare.

AAPA appreciates the opportunity to provide recommendations for the Executive Order and welcomes further discussion with the Centers for Medicare and Medicaid Services regarding these 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,

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Addendum of Sub-Regulatory Policies That Should be Addressed

Although the Office of the Attorney General issued a <u>memorandum</u> under President Trump's first term indicating that guidance documents "do not have the force and effect of law", many healthcare facilities rely on guidance documents to inform work practices. Sub-regulatory policies and guidance documents that are more restrictive than regulations and statutes can lead to inefficiencies, administrative burdens, and workforce inadequacies that adversely affect health and wellness. Therefore, AAPA urges the administration to consider the revisions below to sub-regulatory documents to enable PAs to practice to the full extent of their license, improve the delivery of healthcare in the US, and reduce federal spending on healthcare.

Sub-regulatory changes to promote wellness and chronic disease management.

- Revise the National Coverage Determination (NCD) for Colorectal Cancer Screening to authorize payment for Fecal Occult Blood Tests and Blood-based Biomarker Tests for colorectal cancer screening ordered by PAs. The NCD is in direct conflict with the statutory authority of SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services" they are authorized to perform by the State, 42 CFR § 410.37(b) authorizing payment of FOBT ordered by PAs, and 42 CFR § 410.32 authorizing payment for diagnostic laboratory tests ordered by PAs. Revising the NCD will improve screening, detection, disease prevention, and wellness.
- Revise the NCD for home blood glucose monitors to authorize PAs to certify the need for coverage. The NCD is in direct conflict with the statutory authority of SSA Sec. Sec. 1834 for PAs to order/certify durable medical equipment. Revising the NCD will improve chronic disease management.
- Revise Section 290 of Chapter 15 of the Medicare Benefit Policy Manual to authorize coverage of
 podiatry services for beneficiaries with certain metabolic, neurologic, and peripheral vascular diseases
 when under the care of a PA. The current policy requires patients to have been evaluated and treated by
 a physician. This requirement is not based on statute. Revising the policy will improve chronic disease
 management.

Sub-regulatory changes to increase efficiency, improve workforce adequacy, and reduce administrative burden.

- Revise Section 40.1.3.3 Chapter 9 of the Medicare Benefit Policy Manual to authorize PAs employed by
 a hospice to serve in the role of a patient's attending physician if an "attending physician" was not
 previously selected by the patient. The current policy requires a beneficiary who does not have a
 physician, nurse practitioner (NP), or PA who provided primary care to them prior to or at the time of
 terminal illness to select an "attending physician" who is a physician or NP (but not a PA). This policy
 conflicts with the statutory authority of the SSA Sec 1861(dd)(3)(B) that authorizes PAs to serve as
 "attending physicians" for hospice and SSA Sec. 1861(s)(2)(k)(i)) for PAs to provide "physicians' services"
 they are authorized to perform by the State. Revising this policy will improve workforce adequacy,
 increase efficiency, and reduce administrative burden.
- Revise the State Operations Manual Appendix Z to remove unnecessary physician co-signatures on discharge summaries. The language in the manual (page 234) stating "Whether delegated or nondelegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content" should be removed. Physician co-signature requirements are not generally required by state law and create inefficiencies and administrative burdens without benefiting patients.
- Revise Section 30.6.9.2 B and E of Chapter 12 of the Medicare Claims Processing Manual to indicate that
 PAs may perform and bill for hospital discharge management and death pronouncements. Physiciancentric language should be modified to indicate that PAs can pronounce death and are authorized to bill
 discharge management services (CPT 99238 or 99239) to Medicare. PAs have the statutory authority in
 SSA Sec. 1861(s)(2)(k)(i)) to provide "physicians' services" they are authorized to perform by the State.
 Modifying the language will improve workforce adequacy, decrease inefficiencies, and remove
 administrative burden.
- Revise Section 30.6.7 of Chapter 12 of the Medicare Claims Processing Manual and/or claims processing methods to improve the efficiency of payment for Office or Other Outpatient Evaluation and Management Services. Medicare policy related to "new versus established patients" and "same day

services", as well as all PAs being recognized by the same taxonomy on claims forms, leads to the inappropriate denials of claims and subsequent overturning of those denials through the appeals process. Policies and/or processes should be modified to improve efficiency and administrative burden.

 Revise policies to allow for the payment of minor procedures performed by PA students under the direct supervision of a billing practitioner (e.g., a PA or physician). There is no authorization for the payment of minor procedures (e.g., sutures, excisional biopsy, and injections) performed by PA students under the direct supervision of a licensed practitioner (after the need for the procedure is determined appropriate by a licensed practitioner) as there is for minor procedures performed by medical residents under the direct supervision of "teaching physicians". Policies should be amended to ensure appropriate training for PAs to improve workforce adequacy.

ⁱⁱ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/defaultsource/reports/jun19_medpac_reporttocongress_sec.pdf

ⁱ https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf

iii https://www.cms.gov/files/document/long-term-care-facilities-cms-flexibilities-fight-covid-19.pdf