

July 14, 2025

Robert F. Kennedy Jr. Secretary U.S. Department of Health and Human Services (HHS) Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

RE: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again

Dear Secretary Kennedy,

The American Academy of Physician Associates (AAPA), on behalf of the nearly 190,000 PAs (physician associates/physician assistants) throughout the United States, would like to provide comments on the Ensuring Lawful Regulation and Unleashing Innovation request for information (RFI). In the RFI, HHS reiterates its intention to implement deregulatory efforts to better promote the health and well-being of the American people. AAPA supports appropriate efforts to minimize burden, increase efficiency, and improve care outcomes. Any forthcoming deregulation should improve patient access and outcomes, and AAPA has identified several overburdensome policies that would benefit patients if they were modified or rescinded.

AAPA is aware of several overly burdensome restrictions that severely undercut HHS's efficiency and patient access goals by unduly restricting qualified health professionals, such as PAs, from providing care they are educated, trained, and qualified to provide. The Medicare Payment Advisory Commission (MedPAC) has noted that based on a "large body of research, including both randomized clinical trials and retrospective studies using claims and surveys" the quality of PA-provided care "produces health outcomes that are equivalent to physician-provided care."¹ Consequently, regulations restricting PAs from providing needed services may limit access to quality care,

¹ Medicare Payment Advisory Commission. Report to the Congress: Medicare and the health care delivery system. https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reportsjun19_medpac_reporttocongress_sec-pdf/. June 2019.

resulting in inefficiencies that can lead to higher costs for both patients and HHS. We discuss the issue of cost further at the end of our comments.

Below we have identified restrictions within HHS's purview to address as they are regulatory or sub-regulatory, with a particular focus on outdated restrictions under the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration jurisdictions. The regulations identified represent a mix of those that meet HHS's qualifications of being inefficient, unnecessary, inconsistent with the law, overly burdensome, and outdated. For these reasons, we urge HHS and CMS to address these policies in the department's forthcoming deregulatory efforts.

Regulations and Policies that Conflict with Underlying Statute

Below is a list of regulations and policies that meet the criterion expressed in the RFI as infringing upon statutory language. Specifically, these examples conflict with the statutory authority of section 1861(s)(2)(k)(i) of the Social Security Act (SSA) for PAs to provide "physicians' services" they are authorized to perform by the State. Many of these also meet other conditions expressed in the RFI, such as imposing significant costs that are not outweighed by the public benefit, imposing undue burdens, and hindering access to care. We have provided individualized justification for each regulation or policy included.

PAs are qualified and state-licensed to perform the services listed below. PAs have been demonstrated to improve access to care while providing high levels of quality and patient satisfaction similar to physicians.² The PA profession is one of the fastest growing occupations per the Bureau of Labor Statistics, with a projected 28% increase in PAs from 2023 to 2033.³ This growth projection, along with PAs' qualifications to provide the listed services, suggests that increasing PA utilization will be an effective way to enhance healthcare access and efficiency.

42 CFR §410.40(e)(2)(i)

Current Policy: This regulation requires a "physician certification statement" as a condition of payment for nonemergency, scheduled, repetitive ambulance services.

Change Request: Revise to remove the physician-centric language regarding the certification statement.

² Ibid

³ US Bureau of Labor Statistics, US Department of Labor. Occupational Outlook Handbook. Physician Assistants. 2024. https://www.bls.gov/ooh/healthcare/physician-assistants.htm

Reason for Change: Revising the regulation will increase efficiency by authorizing PAs caring for patients to provide certification and could decrease costs if patients have to have an encounter with a physician that would otherwise not be needed to obtain an order that their treating PA could provide. This restriction is arbitrary, as CMS previously extended the ability of PAs to sign a certification statement for other types of ambulance transfers (e.g., for unscheduled or scheduled but not repetitive).

42 CFR §483.30

Current Policy: This regulation restricts PAs from performing the initial comprehensive visit and alternate required visits for Medicare beneficiaries in Skilled Nursing Facilities (SNFs).

Change Request: Revise to authorize PAs to perform the initial comprehensive visit and all required visits in SNFs. Specifically, §483.30, §483.30(b) and §483.30(b)(1), §483.30(c) and §483.30(c)(1) and (2) should be revised to be inclusive of PAs. §483.30(c)(3) and (4) and §483.30(e)(1), (e)(1)(i), (e)(1)(ii), and(e)(1)(iii) should be rescinded. Additionally, §483.30(e)(2) and §483.30(e)(3) should be revised to be inclusive of PAs and §483.30(e)(4) should be rescinded.

Reason for Change: Such restrictions are not based on medical evidence but on outdated policies that should be modernized to reflect current medical practice and bring greater efficiency to the system. During the COVID-19 public health emergency, CMS authorized the delegation of "physician-only" visits in SNFs to PAs if there was no conflict with state law or facility policy. This authorization allowed additional qualified health professionals to provide care they are competent to provide and was based on the recognition of the years of experience that demonstrated that PAs offer high-quality care in SNFs. In a recent report by CMS⁴, the agency acknowledged the benefit of this waiver, indicating that it helped address workforce shortages, increased the provision of care, and protected the health and safety of residents by maximizing the use of available personnel. Unnecessary regulatory requirements in SNFs necessitate physician involvement that may not be readily available in rural settings or in a timely fashion in high-demand settings. Allowing PAs to provide these services will ensure the flexibility for SNFs to determine which care delivery processes would most efficiently meet current patient needs and ensure that patients will not have to wait to see a physician when a PA is available.

42 CFR §412.622(a) and §412.29

Current Policy: Regulations §412.622(a)(3)(iv) and §412.29(e) identify the need to conduct face-to-face visits with an Inpatient Rehabilitation Facility (IRF) patient three days a week to assess medical status and functionality and to modify the course of treatment as necessary. However, language contained in these sections of the CFR also requires that for the first week, a physician must do all three visits, and in each subsequent week, a non-physician

⁴ Centers for Medicare & Medicaid Services. *COVID-19 Public Health Emergency Response and Use of Section 1135 Waivers and Other Flexibilities: Report to Congress, Fiscal Year 2023.* U.S. Department of Health & Human Services; January 2025. Accessed June 26, 2025. https://www.cms.gov/files/document/covid-19-phe-report-congress.pdf

health professional, such as a PA, may only do one of the three visits per week. §412.29(h) indicates that a physician must establish, review, and revise a plan of treatment in an IRF. §412.622(a)(4)(ii), requires a rehabilitation physician to develop a plan of care for a patient within four days of admission. §412.29(d) requires that a patient's preadmission screening be reviewed and approved by a physician.

Change Request: Revise sections §412.622(a)(3)(iv), §412.29(e), §412.29(h), §412.622(a)(4)(ii), §412.29(d) to include PAs.

Reason for Change: Requiring a physician to perform these duties is inefficient and may impact patient treatment if a patient must wait to see a physician for care that another health professional is qualified to provide. To address concerns of regulatory burdens in IRFs and ensure an adequate healthcare workforce in these settings, CMS had previously expressed interest in amending requirements under §412.622(a)(3)(iv) and §412.622(a)(4)(ii) to permit PAs to fulfill many of the medical responsibilities previously assigned only to rehabilitation physicians. AAPA supported CMS's proposal to expand the role of PAs in IRFs by authorizing PAs to fulfill many of the CMS "physician-only" requirements currently in place. Unfortunately, CMS did not choose to finalize the flexibilities as initially proposed, maintaining much of the physician-centric requirements. AAPA requests that CMS revisit removing these inefficient barriers to care. CMS should authorize PAs to perform medical duties that are currently only allowed to be performed by a rehabilitation physician when those services are within the PA's scope of practice under applicable state law. Granting an expanded authorization in this setting would not impose a requirement on IRFs. Rather, it would give rehabilitation facilities maximum flexibility by allowing them to utilize appropriately qualified PAs in the same manner as rehabilitation physicians to ensure a robust rehabilitation workforce that provides patients with timely access to care. Each IRF would continue to be able to determine which health professionals have the necessary education, training, and experience to meet the care needs of their patients. Decisions regarding which qualified health professional provides care for a patient should be made according to the IRF's patient and staffing needs rather than limited by arbitrary restrictions.

42 CFR § 418.106(b)(1)(iii)

Current Policy: This regulation indicates that PAs must be a patient's attending physician and must not be employed by a hospice to order medications for hospice patients.

Change Request: Rescind §418.106(b)(1)(iii)(A) and (B) and revise the language in §418.106(b)(1)(iii) to remove any notion of qualifiers to authorize PAs employed by the hospice to order medications for hospice patients. **Reason for Change:** This restriction prevents PAs from providing needed treatments to hospice patients, which may result in inefficiency. Removing this restriction will improve patient access to medications, increase healthcare efficiency for this population, and reduce administrative burden.

Section 40.1.3.3, Chapter 9 of the Medicare Benefit Policy Manual

Current Policy: This section of the manual contains a policy whereby if a beneficiary does not have a physician, nurse practitioner (NP), or PA who provided primary care to them before, or at the time of, terminal illness, the beneficiary is given the choice of having either a physician or NP (but not a PA) who works for the hospice as an attending physician.

Change Request: Revise Section 40.1.3.3 of 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.

Reason for Change: In addition to the conflict with Section 1861(s)(2)(k)(i) of the SSA, mentioned previously, this policy also conflicts with the statutory authority of the Section 1861(dd)(3)(B) of the SSA that authorizes PAs to serve as "attending physicians" for hospice. This policy omits PAs who are otherwise authorized to serve in the role of a hospice attending physician when not employed by a hospice.

42 CFR §424.13

Current Policy: This regulation contains policies that require physician certification/recertification of need for acute care hospital services that are 20 inpatient days or more, and continued hospitalization if a SNF bed is not available.

Change Request: Revise sections §424.13(a), §424.13(c)(1) and (2), and §424.13(d)(1) to include PAs. **Reason for Change:** These restrictions present a significant barrier to coordination of care and ensuring that patients receive a duration of care that is sufficient to meet health objectives. Such certifications should be performed by the health professional most familiar with the needs of the patient in order to confirm the appropriateness of extended care scenarios.

42 CFR §424.14

Current Policy: This regulation contains policies that require physician certification/recertification of need for inpatient psychiatric services

Change Request: Revise section §424.14(a) and (b) to include PAs.

Reason for Change: These restrictions present a significant barrier to timely access and coordination of care, especially in rural and underserved areas where psychiatrists are in short supply. PAs are trained and authorized to diagnose and manage behavioral and mental health conditions, including determining medical necessity for psychiatric hospitalization. They perform psychiatric evaluations, manage medications, and develop treatment plans in collaboration with psychiatrists and other clinicians. The inability to certify care they are already delivering undermines both patient access and the efficiency of psychiatric facilities.

National Coverage Determination (NCD) 40.2 re: Home Blood Glucose Monitors

Current Policy: This NCD indicates that coverage of home blood glucose monitors is limited to patients who have either a) been determined by a physician to be capable of or b) can be monitored by a person determined capable of being trained to use the equipment. Further, special glucose monitors are covered only when a physician certifies that a patient has a severe visual impairment that requires this monitoring system.

Change Request: The NCD should be revised to authorize PAs to certify the need for coverage of this durable medical equipment (DME).

Reason for Change: In addition to the conflict with Section 1861(s)(2)(k)(i) of the SSA, mentioned previously, this NCD also conflicts with the regulatory authority of 42 CFR § 410.38(C)(2) for PAs to order/prescribe/certify DME. Revising the NCD will improve chronic disease management, reduce administrative burden of requiring an otherwise unnecessary physician order for patients cared for by PAs, and could improve program integrity by reducing waste if patients do not have to have an encounter with a physician to obtain an order/certification that their treating PA could otherwise provide.

National Coverage Determination (NCD) 210.3 re: Colorectal Cancer Screening Tests

Current Policy: This NCD indicates that Fecal Occult Blood Tests (FOBT) and Blood-based Biomarker Tests (BBT) for colorectal cancer screening are only covered when ordered by a physician.

Change Request: The NCD should be revised to authorize payment for FOBT and BBT for colorectal cancer screening ordered by PAs.

Reason for Change: In addition to the conflict with Section 1861(s)(2)(k)(i) of the SSA, mentioned previously, this NCD also conflicts with the regulatory authority of 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 and detection of colorectal cancer, promote disease prevention, reduce the administrative burden of requiring an otherwise unnecessary physician order for patients cared for by PAs, and could improve program integrity by reducing waste if patients do not have to have an encounter with a physician to obtain an order that their treating PA could otherwise provide.

42 CFR § 410.37(f)

Current Policy: This regulation authorizes coverage of screening colonoscopies only when performed by a physician.

Change Request: §410.37(f) should be rescinded to authorize coverage of screening colonoscopies performed by PAs.

Reason for Change: A study⁵ indicated no significant differences in cecal intubation time or success, adenoma detection rate, or adverse reactions reported related to the endoscopic procedure up to 30 days post-colonoscopy for PAs compared to gastroenterologists. The researchers, who included five allopathic physicians, concluded that the findings support the use of trained PAs to perform average-risk screening colonoscopies and that "this approach may be particularly relevant to underserved populations and resource-poor areas where access to and cost of colonoscopy limits the optimization of colorectal cancer screening strategies."

Local Coverage Determination (LCD) L34353 re: Outpatient Psychiatry and Psychology Services

Current Policy: This LCD indicates that only physicians may prescribe and establish an individualized treatment plan for outpatient psychiatry and psychology services and bill for electroconvulsive therapy.
Change Request: The LCD should be revised to authorize PAs to prescribe and establish individualized treatment plans for outpatient psychiatry and psychology services and bill for electroconvulsive therapy.
Reason for Change: Removing these limitations would improve access to behavioral and mental health services and could improve program integrity by reducing waste if patients do not have to have an encounter with a physician to obtain services and treatment plans that their PA could otherwise provide.

Section 290, Chapter 15 of the Medicare Benefit Policy Manual

Current Policy: This section contains exceptions to the routine foot care exclusion (see Section 290 C), systemic conditions that might justify coverage (see Section 290 D), and presumption of coverage (see Section 290 F) that require patients to have been evaluated and treated by a physician.

Change Request: These policies should be revised to authorize coverage of podiatry services for beneficiaries with certain conditions when under the care of a PA.

Reason for Change: These requirements may result in patients receiving care from a PA needing to schedule a separate visit with a physician to document a need for podiatric care that PAs are qualified to determine, potentially increasing costs and burdens to patients. Revising the policy will improve chronic disease management, reduce administrative burden, and could improve program integrity by reducing waste if patients do not have to have otherwise unnecessary physician care when already being evaluated and treated by PAs.

42 CFR §416.42, §416.48, §416.52

Current Policy: These regulations contain physician-centric language regarding the provision of services in Ambulatory Surgical Centers (ASCs).

⁵ Kern LM, Zhou Y, Rajendran N, et al. Quality metrics of screening colonoscopies. *JAAPA*. 2020;33(4):35–41. https://journals.lww.com/jaapa/Fulltext/2020/04000/Quality_metrics_of_screening_colonoscopies.8.aspx

Change Request: §416.42 should be revised to authorize PAs to perform surgical procedures in ASCs, §416.42(a)(1)(i) and (ii) should be revised to authorize PAs to evaluate the risk of the procedure to be performed and the risk of anesthesia in ASCs, §416.48(a)(1) should be revised to authorize PAs to receive reporting of adverse reactions, §416.48(a)(2) should be revised to authorize PAs to administer blood and blood products, §416.48(a)(3) should be revised to authorize PAs to order drugs and biologicals in ASCs, §416.52(c)(1) should be revised to authorize PAs to provide follow up appointments, §416.52(c)(2) should be revised to authorize PAs to discharge patients (and issue and sign discharge orders), and §416.52(c)(3) should be revised to authorize PAs to determine if patients are exempted from being discharged in the presence of a responsible adult.

Reason for Change: States authorize PAs to perform minor surgeries, risk assessments, and other medical services. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

42 CFR §485.639(a)

Current Policy: This regulation uses physician-centric language regarding who may perform surgery for patients in Critical Access Hospitals (CAHs).

Change Request: §485.639(a) should be revised to authorize PAs to perform surgical procedures in CAHs. **Reason for Change:** Amending these regulations will increase workforce adequacy and improve efficiency.

42 CFR §485.524(d)(1)

Current Policy: This regulation uses physician-centric language regarding who may perform surgery for patients in Rural Emergency Hospitals (REHs)

Change Request: §485.524(d)(1) should be revised to authorize PAs to perform surgical procedures in REHs. **Reason for Change:** Amending these regulations will increase workforce adequacy and improve efficiency.

21 CFR §606.110, §606.151, §606.160

Current Policy: These regulations contain physician-centric language relating to the manufacturing and administration of blood and blood products.

Change Request: §606.110(a)(1) and (2) should be revised to authorize PAs to determine when a recipient must be transfused with the leukocytes or platelets from a specific donor and supervise the procedure, §606.151(e) should be revised to authorize PAs to expedite transfusion in life-threatening emergencies and complete and sign documentation justifying the emergency action, §606.160(b)(1)(iv) should be revised to allow records to include signed requests from PAs for therapeutic bleedings, and §606.160(b)(3)(v) should be revised to authorize PAs to order and sign for the emergency release of blood.

Reason for Change: Arbitrary obstacles to the administration of needed care by qualified professionals, especially in geographic areas where a physician may not be readily available can potentially harm patient health if access to life-saving treatments is delayed. Additionally, a physician determination and signature after administration are an administrative burden that does not benefit patient care.

Regulations and Policies that Result in Undue Burden

Below is a list of regulations and policies that meet the criterion expressed in the RFI of imposing undue burden on parties involved. The examples demonstrate increased burdens on physicians and PAs for outdated and unnecessary oversight requirements and potentially harm patients through inefficiency of care.

42 CFR § 485.631(b)

Current Policy: This regulation requires physician co-signature of medical records for patients not cared for by a physician in Critical Access Hospitals (CAHs) and a periodic physician presence at CAHs.

Change Request: §485.631(b)(1)(iv) and (v) should be rescinded to remove the requirement of physician cosignature for medical records of patients cared for by PAs and other non-physician practitioners in CAHs and §485.631(b)(2) should be revised to remove the requirement that a physician be present at a CAH for "sufficient periods of time."

Reason for Change: At nearly all other sites of service under Medicare, PAs are authorized to provide inpatient care without a physician's presence. Meanwhile, the requirement for physician co-signature of medical records for services PAs are qualified to provide compromises facility efficiency by placing an unnecessary administrative burden on physicians. To meet these requirements, physicians must take time from patient care to perform an administrative requirement that does not improve quality of care.

42 CFR §485.528(c)

Current Policy: This regulation requires physician co-signature of medical records for patients cared for by PAs if required by state law in rural emergency hospitals (REHs) and periodic physician presence at REHs.

Change Request: §485.528(c)(1)(iv) should be rescinded to remove the requirement of a physician co-signature of records in REHs, and §485.528(c)(2) should be revised to remove the requirement that a physician be present at an REH for "sufficient periods of time."

Reason for Change: At nearly all other sites of service under Medicare, PAs are authorized to provide inpatient care without the need for a physician to be present. Meanwhile, a hypothetical requirement for physician co-

signature of medical records that is generally not required by state law is confusing and could create administrative burdens if misinterpreted.

Hospital Inpatient Admission Order and Certification Statement – Jan 30, 2014⁶

Current Policy: CMS stated in a 2014 document that a PA may write an inpatient admission order if the physician responsible for the patient's care "accepts responsibility for the admission decision by counter-signing the order prior to discharge."

Change Request: CMS should remove all outdated guidance documents suggesting a physician must co-sign an admission order issued by a PA and clearly state that a physician co-signature is not needed when a PA issues an inpatient order.

Reason for Change: The status of this requirement, due to conflicting guidance documents, has resulted in a lack of clarity. CMS relaxed⁷ the time frame for critical access hospitals, requiring that co-signature be obtained one day prior to the submission of the claim as opposed to prior to the patient discharge. A 2017 transmittal⁸ indicated that an order for admission could be furnished by a physician or other qualified practitioner if that practitioner is: (a) licensed by the state to admit inpatients to hospitals, (b) granted privileges by the hospital to admit inpatients to that specific facility, and (c) knowledgeable about the patient's hospital course, medical plan of care, and current condition at the time of admission. As of January 1, 2019, CMS no longer requires a written inpatient admission order from a physician as a specific condition of Medicare Part A payment. However, CMS never clarified if an admission order from a PA or other non-physician practitioner that a physician did not co-sign would be afforded the same waiver of not being required as a condition of payment. Clarifying that a physician co-signature for hospital admissions is no longer necessary would decrease the physician documentation burden of co-signing an order after a determination of inpatient medical care has already been made.

⁶ Centers for Medicare & Medicaid Services. *Hospital Inpatient Admission Order and Certification*. U.S. Department of Health & Human Services; January 30, 2014. Accessed June 26, 2025. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf

⁷ Centers for Medicare & Medicaid Services. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; and Other Revisions. *Fed Regist.* 2014;79(163):49853-50536. Published August 22, 2014. Accessed June 26, 2025. https://www.govinfo.gov/content/pkg/FR-2014-08-22/pdf/2014-18545.pdf

⁸ Centers for Medicare & Medicaid Services. Clarification of Admission Order and Medical Review Requirements. *Transmittal 234, Medicare Benefit Policy Manual (Pub. 100-02).* Issued March 10, 2017. Accessed June 26, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R234BP.pdf

State Operations Manual, Appendix Z⁹, Page 234

Current Policy: This sub-regulatory guidance document indicates that a physician must "authenticate" (e.g, cosign) a discharge summary written by PAs and other non-physician practitioners.

Change Request: The language on page 234 regarding discharge authentication should be revised. Specifically, the following sentence should be deleted: "Whether delegated or non-delegated, 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."

Reason for Change: CMS staff have indicated in private written communication that the guidance is sub-regulatory and not enforceable. However, many hospitals require a physician co-signature based on this guidance. This revision would decrease the physician documentation burden of co-signing a discharge summary after a patient has already been discharged.

Sections 40.6 and 40.8 of Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

Current Policy: The current guidance indicates that a request for an expedited determination under Part C may only be made by a physician or on a physician's behalf.

Change Request: Sections 40.6 and 40.8 of the guidance document should be revised to authorize PAs to request an expedited determination under Part C.

Reason for Change: As Federal law authorizes PAs to own their own practice, PAs may practice without a physician to request an expedited determination on behalf of. This would disadvantage Part C patients who are seen by PAs.

Requirements to List Home Address When Providing Telehealth Services

Current Policy: During the COVID-19 public health emergency, CMS authorized health professionals who provided telehealth services from home to list their previously enrolled location, instead of using their home address on their enrollment. In response to overwhelming concern expressed by the provider community regarding the expiration of this authorization, CMS continued to permit distant site providers to use their business practice location when providing telehealth services from their home, as opposed to the practitioner's home address, first under the 2024 Physician Fee Schedule final rule, through 2024, and then under the 2025 Physician Fee Schedule final rule, through 2024.

⁹ Centers for Medicare & Medicaid Services. *State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.* U.S. Department of Health & Human Services; Revised April 19, 2024. Accessed June 26, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_a_hospitals.pdf

Change Request: CMS should make permanent a process that would allow health professionals to avoid using their home addresses when providing telehealth services from their home.

Reason for Change: The intention of the flexibility, and the reason it should be made permanent, is to protect the privacy of health professionals. Otherwise, the public reporting of this practice location, in this case a home address, could be accessed by patients and other entities.

Regulations and Policies that are Unnecessarily Complicated

Below is a list of regulations and policies that meet the criterion expressed in the RFI of fostering unnecessarily complicated requirements. Such requirements often provoke confusion due to conflicting authorizations, flexibilities that apply to certain groups and not similar ones, and antiquated policies that obscure when health professionals, such as PAs, provide services to patients.

Variations in Medicare Administrative Contractor (MAC) Policy

Current Policy: Currently, in implementing federal Medicare policy, MACs may have conflicting policies and requirements that cause confusion. For example, at least one MAC¹⁰ has a policy that only a physician may bill an initial hospital visit (CPT codes 99221-99223) or discharge day management service (CPT codes 99238 and 99239). This contradicts the statutory authority for PAs to provide these services based on section 1861(s)(2)(k)(i) of the SSA, which allows PAs to provide "physicians' services" they are authorized to perform by the State and Medicare policy¹¹, which indicates this includes "all levels of CPT evaluation and management codes". **Change Request:** Medicare should ensure that MACs do not develop and maintain policies that are more restrictive than or inconsistent with federal regulations and national policies. There should also be an efficient method to report any inconsistencies.

Reason for Change: These MAC requirements, which may conflict with federal Medicare policies or the policies of other MACs, provoke confusion. Examples such as the one identified above are particularly egregious as they prohibit qualified health professionals like PAs from providing a service, potentially delaying patient care and costing the Medicare program more money for comparable care.

¹⁰ National Government Services. Evaluation and Management Services. Accessed June 26, 2025. https://www.ngsmedicare.com/web/ngs/evaluation-and-

management?selectedArticleId=3855826&lob=96664&state=97118&rgion=93623

¹¹ Centers for Medicare & Medicaid Services. *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services.* U.S. Department of Health & Human Services; Revised May 2, 2024. Accessed June 26,

^{2025.} https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

Variations in Medicaid Policies that Undercut Federal CMS Policies and Goals

Current Policy: Medicaid programs may promulgate their own policies regarding coverage and which services health professionals, such as PAs, are authorized to provide. However, some are unduly restrictive, limiting PAs and other health professionals from providing needed services they are qualified to provide. In 2021, AAPA surveyed all 51 fee-for-service Medicaid agencies. The results confirmed variations in authorizations for PAs to provide certain services. While not the case in most states, some state Medicaid agencies restricted PAs from ordering DME, providing psychiatric services, ordering home health, or first assisting at surgery.

Change Request: While AAPA supports deferring to state Medicaid programs to make coverage decisions that are legally within their purview, we request that CMS disseminate best practices regarding the elimination of policy barriers that prohibit PAs from providing and patients from receiving essential services.

Reason for Change: Patients seeking services in states where PAs have practice restrictions have fewer options for receiving care. Consequently, geographic inequities brought about by unduly restrictive coverage policies may contribute to an inequitable landscape of access to care and inefficient systems of care provision if physicians are instead required to provide services that PAs are qualified to provide.

42 CFR §485.914(e)(3)(iii) and §485.916(a)(3)

Current Policy: These regulations use physician-centric language regarding Community Mental Health Centers, including a requirement for the inclusion of only physician orders on a discharge summary and the lack of explicit inclusion of PAs on the interdisciplinary treatment team.

Change Request: §485.914(e)(3)(iii) and §485.916(a)(3) should be revised to be inclusive of PAs. **Reason for Change:** Physician-centric language regarding "physician orders" on a discharge summary may be strictly interpreted in a manner that would result in only a subset of orders related to a patient's care (i.e., those issued by a physician) being included in the summary, and omit orders made by non-physician health professionals. This may then provide patients with incomplete information regarding the care received. Meanwhile, the omission of PAs by name in the list of those who may participate in an interdisciplinary team starkly conflicts with §485.916(a)(1), which authorizes PAs to lead such teams.

Medicare Claims Manual Part 3 – Claims Process – Transmittal 1780

Current Policy: There is no authorization, as there is for "teaching physicians" and medical residents, for billing and payment of minor surgical procedures performed by PA students or other students under the direct supervision of a licensed practitioner.

Change Request: Policies should be revised to include, "For minor procedures that take a few minutes to complete (e.g., simple suture, excisional biopsy, injection) and involve relatively little decision making once the need for the

procedure is determined, the billing practitioner (e.g., physician and PA) must be present for the entire procedure performed by a student (e.g., PA student) to bill for the procedure."

Reason for Change: PAs and other healthcare practitioners need adequate, hands-on, supervised training opportunities that prepare them to perform medical procedures safely. Without the ability to bill for PA student-performed procedures, and because PA education is not supported by graduate medical education funding, health systems have limited the performance of procedures by PA students they are otherwise able to provide under supervised clinical practice experience.

Restrictions on Services Provided by Health Professionals of the Same Specialty

Current Policy: Due to all PAs being recognized by the same taxonomy code (i.e., CMS specialty code '97') and Medicare policy related to new versus established patients and same-day services, claims are denied for services under certain circumstances that would otherwise have been appropriate and are often overturned on appeal. The first issue is that CMS allows one evaluation and management service per beneficiary, per day, per provider specialty type. Because PAs are enrolled in Medicare under a single specialty taxonomy rather than the specialty in which they practice, when services are provided by two PAs (e.g., primary care and orthopaedics) on the same day, one of the visits is often not paid due to the assumption that practitioners of the same specialty performed both visits. The second issue occurs with Medicare's new versus established patient policy, which recognizes a new patient as someone who has not received professional services from a clinician or another provider within a group practice within the same specialty in the previous three years. Because PAs all have the same specialty code (97), this has led to claims denials when more than one PA, but in different specialties within a multi-specialty practice, sees a patient for an initial encounter within three years.

Change Request: A national Medicare policy allowing PAs to use a secondary specialty code on claims should be implemented. Alternatively, Medicare policies related to new versus established and same-day services should be modified to avoid this problem.

Reason for Change: The single specialty code for PAs has become more of a problem as many practices are consolidating into larger, multi-specialty practices and commonly have patients seeing multiple PAs in different specialties on the same day or having PAs in one specialty referring patients to PAs in other specialties. This has led to a high number of claims denials and overturns on appeal, resulting in several Medicare Administrative Carriers (including NGS¹²) creating a workaround of including a secondary specialty on the claims form to reduce otherwise unnecessary and costly appeals that result in significant administrative burden and unnecessary documentation and reporting.

¹² National Government Services. Evaluation and Management Services. Published September 30, 2024. Accessed June 26, 2025. https://www.ngsmedicare.com/web/ngs/evaluation-and-

management? selected Article Id = 768586 & art fid = 2072831 & lob = 96664 & state = 97118 & region = 93623 e region = 9362

Direct Supervision by Electronic Means

Current Policy: During the COVID-19 public health emergency, CMS indicated through IFC 1744 that direct supervision (the requirement that a supervising health professional be immediately available on site but not in the room) could be met by the supervising clinician being available via audiovisual (real-time, interactive) communication. Through the annual Physician Fee Schedule rules, CMS has repeatedly extended the flexibility for additional years beyond the end of the public health emergency.

Change Request: Direct supervision by audiovisual communication should be authorized only for the supervision of health professionals who are not authorized to bill Medicare for their services.

Reason for Change: While originally necessary to minimize exposure to COVID-19 and reduce the detrimental impacts of the pandemic on the timely provision of care, AAPA has expressed concern that repeated extension of this authorization, as it pertains to billing for PAs and NPs, puts priorities of CMS at risk, such as appropriate attribution of services. Direct supervision is required for "incident to" billing, and making this supervision easier in these instances may expand the use of the billing mechanism, which has detrimental effects for patients, health policy researchers, the Medicare program, and PAs and NPs, due to resulting flawed data collection. PAs and NPs can provide and bill for services under their own names instead of a physician's, and at a lower cost of care (reimbursement rate) to the Medicare program. Any further extension of direct supervision by audiovisual communication for PAs and NPs would only serve to increase costs and further impair data transparency through the potential proliferation of "incident to" billing. However, AAPA supports permanently extending direct supervision by audiovisual communication for health professionals who are not authorized to submit claims for their services, such as registered nurses and pharmacists. This will allow for expanded patient access to care while not adversely affecting transparency.

Regulatory and Policy Changes and Their Effects on Cost of Care

The efficient use of health professionals, like any resources, can potentially reduce costs. Requiring a physician to provide services that PAs are qualified to perform is an inefficient use of practitioners, time, and money. These concerns are magnified in rural or underserved areas if a physician is unavailable to provide the required services. Patients may have to travel further to receive appropriate care, or they may have to delay or forgo care. Any of these scenarios may exacerbate a patient's medical condition and result in the need for more intensive and high-cost interventions such as emergency care or hospitalization. Even when a physician is available, limiting the services a PA may perform or order, and for which they are otherwise qualified and authorized to provide, may result in the patient having an additional and unnecessary encounter with a physician to obtain the service or

order and increasing costs to Medicare. In addition, equivalent services provided by physicians, as opposed to PAs, come at a higher cost to the Medicare program.

Similarly, oversight requirements, such as a physician co-signature on services PAs are qualified to provide or a physician's presence when PAs provide services, are burdensome and inefficient, and inefficiency can increase healthcare service costs. Medicare's restrictive policies identified in these comments are outdated and not based on medical evidence. They should be modernized to reflect current medical practice and improve the system's efficiency. In 2018, HHS expressed similar concerns when, in conjunction with the US Department of the Treasure and US Department of Labor, it released a report titled "Reforming America's Healthcare System Through Choice and Competition." This report conveyed the importance of removing scope-of-practice barriers and superfluous supervisory requirements on health professionals such as PAs, noting that such restrictions may increase costs.¹³ We encourage HHS to adhere to its previously stated positions and take the appropriate actions identified in these comments to address them.

Title Change

AAPA requests that all references to PAs in regulations and policies be listed as "Physician Assistants/Physician Associates", as recognized in 20 CFR § 220.46 (a)(9).¹⁴ This accurately reflects PAs who currently graduate with degrees as either "physician assistant" or "physician associate" and are state-licensed as a "physician assistant" or "physician associate," but who all graduate from programs accredited by the same accrediting organization (Accreditation Review Commission on Education for the Physician Assistants), are certified by the same certifying organization (National Commission on Certification of Physician Assistants), and have the same scopes of practice. Although the profession has been known as "physician assistant," the official title of the profession is now recognized as "physician associate" to more accurately reflect the breadth of education, training, experience, and services of PAs. This is reflected in the title of the AAPA, other professional organizations¹⁵, professional training

¹³ U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor. *Reforming America's Healthcare System Through Choice and Competition*. Published December 2018. Accessed June 26,

^{2025.} https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf ¹⁴ Code of Federal Regulations: Medical evidence. 20 CFR § 220.46 . 2025. https://public-inspection.federalregister.gov/2025-00515.pdf

¹⁵ Several Constituent Organizations, which are independent organizations affiliated with AAPA, have reflected the title Physician Associate in their professional organization's legal name. Examples: Connecticut Academy of Physician Associates https://connapa.org/aboutconnapa, Kansas Academy of Physician Associates https://kansaspa.mypanetwork.com, Academy of Physician Associates in Cardiology https://www.cardiologypa.org, and Association of Physician Associates in Obstetrics and Gynecology https://apaog.wildapricot.org.

programs¹⁶, and several state and territory laws and licensures.¹⁷ Despite the recognized title of "physician associate," it is anticipated to take some time for the title change from "physician assistant" to occur in all states and jurisdictions in which PAs practice. Therefore, a dual reference to "physician assistant" and "physician associate" is recommended to avoid confusion. AAPA urges all agencies to reference the profession by the dual title "physician assistant/physician associate."

Thank you for the opportunity to provide comments regarding the Ensuring Lawful Regulation and Unleashing Innovation RFI. AAPA welcomes further discussion with HHS regarding these important issues. For any questions you may have please do not hesitate to contact Sondra DePalma, Vice President of Reimbursement and Professional Practice, at <u>sdepalma@aapa.org</u>.

Sincerely,

Tlickard

Todd Pickard, DMSc, PA-C, DFAAPA, FASCO President and Chair, Board of Directors

¹⁶ Several universities, which are accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA), have Physician Associate Programs and graduate students in Physician Associate Studies. Examples: Yale School of Medicine, Physician Associate Program, https://medicine.yale.edu/pa, Wichita State University, Physician Associate Program https://www.wichita.edu/academics/health_professions/pa/, Alvernia University, Physician Associate Program https://www.alvernia.edu/academics/ug/bio-pa.

¹⁷ Or. Rev. Stat. § 677, MN Stat. 316, Wis. Stat. § 448.974(1)(a)(2)-(6), 185 N. MAR. I. ADMIN. CODE § 185-10-4101(p).