American Academy of PAs

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

Re: Centers for Medicare and Medicaid Services (CMS) proposed Conditions of Participation (CoP) for Rural Emergency Hospitals (REH) and Critical Access Hospital (CAH) Updates

Dear Secretary Becerra,

The American Academy of PAs (AAPA), on behalf of the more than 159,000 PAs (physician assistants) throughout the United States, appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed Conditions of Participation (CoP) for Rural Emergency Hospitals (REH) and Critical Access Hospital (CAH) Updates. PAs are committed to increasing access to high-quality care for Medicare beneficiaries and seek to work in partnership with CMS in developing and advancing healthcare policies that achieve that goal. To attain this objective, it is essential that Medicare's policies authorize PAs to practice to the fullest extent of their education and expertise and not impose arbitrary, unnecessary barriers to care.

PAs have an increasingly important role in the U.S. healthcare delivery system and currently provide hundreds of million patient visits each year[1], many of which are for Medicare beneficiaries. PAs provide cost-effective, quality care with high levels of patient satisfaction.[2, 3] The care and quality of care PAs provide is similar to that provided by physicians.[4] More than fifty years of evidence, research, and beneficiary experience demonstrate that PAs are effective healthcare practitioners and a valuable resource to the U.S. healthcare system.

---

[1] National Commission on Certification of Physician Assistants. *2021 Statistical Profile of Certified Physician Assistants: An Annual Report of the National Commission on Certification of PAs*. 2022. https://www.nccpa.net/wp-content/uploads/2022/08/2021StatProfileofCertifiedPAs-A-3.2.pdf
[2] Hartsell Z, Rumans M, Boman J, Muenzer JT. Advanced Practice Providers Optimize Efficiency and Improve Financial Performance. *Healthcare Financial Management Association*. 2019. https://sullivancotter.com/wp-content/uploads/2019/02/HFMA-APPs-Optimize-Efficiency-andImprove-Financial-Performance.pdf
[3] Cipher CJ, Hooker RS. Sekscenski E. Are Older Patients Satisfied with Physician Assistants and Nurse Practitioners? *JAAPA*. 2006;19(1):36, 39-40, 42-44. doi: 10.1097/01720610-200601000-00007
[4] Medicare Payment Advisory Commission. *Report to the Congress. Medicare and the Health Care Delivery System. June 2019*. http://www.medpac.gov/docs/defaultsource/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0

AAPA agrees with CMS that "many rural populations suffer from limited access to care due to a shortage of health care professionals . . .". Therefore, CMS must eliminate barriers and unnecessary administrative burdens when PAs provide needed care to rural populations to improve access and decrease disparities in care. The PA profession remains committed to working with the administration to develop effective policies that are not administratively burdensome. It is within this context that we draw your attention to our comments.

Surgical Services

The standards proposed in the rule for outpatient surgical services in REHs authorize only a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, or a doctor of podiatric medicine to perform surgery. Based on this restrictive standard, PAs would not be authorized to provide surgical services to Medicare beneficiaries in REHs. Limiting PAs from providing surgical services they are qualified by training and authorized to provide by national certification and state licensure would significantly hinder the purpose of REHs, which is to ensure people in rural communities receive critical outpatient services, including surgical services.

Such a limitation would be contrary to Medicare policy and the express authority that "the types of services that PAs may provide include services that traditionally have been reserved to physicians", including "minor surgery".[5] Such an arbitrary limitation would significantly limit access to minor surgical procedures that PAs are otherwise qualified and authorized to provide in outpatient offices, inpatient and outpatient hospital facilities, and other places of service. It would create a further disparity between access to care, patient choice, and other factors adversely affecting people living in rural areas compared to urban and suburban settings.

The long-standing Medicare policy that authorizes PAs to perform minor surgery recognizes PA program accreditation standards[6] that require all PAs to have completed medical and surgical training that includes a surgery rotation, during which PAs obtain clinical practice experience in pre-, intra-, and postoperative care. In addition, up to 20% of the content of the required certification examination that PAs must pass as a condition of state licensure is related to general surgical topics.[7] Published studies also support the ability for

[5] Centers for Medicare & Medicaid Services. *Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services. Rev. 10639 & Rev. 10573*. Accessed August 25, 2022. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
[6] Accreditation Review Commission on Education for the Physician Assistant. *Accreditation Standards for Physician Assistant Education. 5 th Ed*. 2019. http://www.arc-pa.org/wpcontent/uploads/2021/03/Standards-5th-Ed-March-2021.pdf
[7] Commission on Certification of Physician Assistants. *PANCE Content Blueprint. 2019*. https://www.nccpa.net/wp-content/uploads/2020/09/PANCE-Content-Blueprint-5-21.pdf

PAs to safely perform minor surgery, including cardiac catheterizations, thoracostomies, sigmoidoscopies, colonoscopies, and other procedures with similar skill, safety, and outcomes as physicians.[8, 9, 10, 11]

AAPA strongly encourages CMS to revise the proposed standard for outpatient surgical services at §485.524(d)(1)(i) to include PAs among the qualified practitioners who may perform surgery in an REH. AAPA also recommends in future rulemaking that CMS revise similar restrictive language from §416.42 that limits PAs from providing surgical services in an ambulatory surgery center.

Patient Rights

The agency proposes to codify patient rights in REH CoPs to prevent harm to patients. However, as the proposed regulations are written, certain rights would only be protected if a patient were receiving care from a physician. For example, the proposed rule would require an REH to provide discharge planning evaluation upon the request of a patient, patient representative, or physician, but not upon the request of a PA. In addition, a patient would have the right to have a treating physician notified of the patient's admission to the REH, but a patient would not be ensured the same right to have a treating PA notified.

PAs strongly support the rights of each patient but do not believe that certain rights should be predicated on a patient having a treating physician.[12] An REH's discharge planning process is designed to "identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning". Patients receiving care from PAs should not be subject to potential disparities and inequities by not having protected access to discharge planning. Patients receiving care from PAs should also be afforded the transmission of prompt and accurate information about their medical condition and the care they receive. Otherwise, delayed, inaccurate, or omitted information can further limit access to equitable care among rural residents who already face disparities in access and outcomes.

AAPA recommends that CMS revise § 485.532(a) to include PAs, expressly stating that a patient may receive a discharge planning evaluation upon the request of a PA. The CoP § 485.614(b)(4) should also be amended to ensure that patients have the right to have their practitioner, whether that practitioner is a PA or physician, promptly notified of an admission to an REH.

---

[8] Krasuski RA, Wang A, Ross C, et al. Trained and Supervised Physician Assistants Can Safely Perform Diagnostic Cardiac Catheterization with Coronary Angiography. *Catheter Cardiovasc Interv.* 2003;59(2):157–160. doi: 10.1002/ccd.10491
[9] Bevis LC, Berg-Copas GM, Thomas BW, et al. Outcomes of Tube Thoracostomies Performed by Advanced Practice Providers Versus Trauma Surgeons. *Am J Crit Care*. 2008;17(4): 357–363. from http://ajcc.aacnjournals.org
[10] Horton K, Reffel A, Rosen K, Farraye FA. Training of Nurse Practitioners and Physician Assistants to Perform Screening Flexible Sigmoidoscopy. *J Am Assoc Nurse Pract*. 2001;13(10): 455–459. http://www.aanp.org/publications/jaanp
[11] Fejleh MP, Shen CC, Chen J, Bushong J, Dieckgraefe B, Sayuk GS. Quality Metrics of Screening Colonoscopies Performed by PAs. *JAAPA*. 2020; 33(4): 43-48. doi: 10.1097/01.JAA.0000657192.96190.ab
[12] American Academy of Physician Associates. *2022-2023 Policy Manual*. 2022. https://www.aapa.org/download/100415/

Ordering Outpatient Medical and Health Services

The agency proposes standards for ordering medical and health services that could only be ordered by a practitioner who is "responsible for the care of the patient". This provision could limit access to medical and health services that PAs are authorized to order but who practice in states where physicians are expressly or implied to be responsible for the care of a patient.

Some outdated state law provisions and/or regulations assign responsibility of care for services provided by PAs to physicians. Furthermore, the theory of respondeat superior in states with supervisory requirements may be interpreted to imply that a PA, otherwise treating a patient and authorized to order services, would not be considered "responsible for the care of a patient" and be precluded from ordering appropriate services. This could inappropriately disadvantage patients receiving care from PAs. Furthermore, patients are often cared for by teams of healthcare professionals, all of whom may appropriately order needed medical and health services without being considered individually "responsible" for the overall care of the patient.

AAPA encourages CMS to remove from § 485.524(c)(1) the proposed requirement that outpatient medical and health services can only be ordered by a practitioner who "is responsible for the care of the patient", as this provision is unnecessary and could limit or delay access to needed services. An alternative option would be to change the wording to require that a diagnostic test be ordered by a "treating practitioner", similar to diagnostic regulations at § 410.32(a), or a practitioner knowledgeable about the patient's condition and treatment.

Staffing and Staff Responsibilities

CMS proposes to include PAs among the practitioners who can provide staffing and care at an REH. Such inclusion of PAs is supported by the Social Security Act, existing Medicare policy, established practices at CAHs and other places of services, and evidence best summarized by the Medicare Payment Advisory Commission, that "a large body of research, including both randomized clinical trials and retrospective studies", demonstrates that care provided by PAs "produces health outcomes that are equivalent to physician-provided care".

AAPA encourages CMS to continue to support regulations and policies that authorize PAs to provide services to the full extent of their training, certification, and licensure and minimize administrative burden imposed on PAs and healthcare professionals, including physicians, with whom PAs collaborate.

CMS also proposes to include practitioners other than physicians in developing policies at REHs. Specifically, CMS proposes that policies be developed by staff that include "one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists".

AAPA supports and encourages CMS to adopt regulations that expressly state that PAs should participate in the governance and policy development at REHs. Representative inclusion of all practitioners providing services will ensure that policies are developed that are supported by state law, appropriate scopes of practice, and other important requirements to ensure the provision of safe and effective care. However, the

inclusion of PAs should not substitute for the inclusion of nurse practitioners or clinical nurse specialists, or vice versa, as could occur with the proposed standard as written.

AAPA recommends that § 485.514(b) be revised to include that "one or more doctors of medicine or osteopathy, one or more physician assistants, and one or more nurse practitioners or clinical nurse specialists" be included in developing policies if those professions are on staff under the provisions of § 485.528(b)(1).

AAPA also supports the reduction of administrative burdens that do not demonstrate a benefit in care quality or improved outcomes. Specifically, AAPA supports the proposal that a physician co-signature should not be required on outpatient records of patients cared for by PAs. Similarly, a physician co-signature should not be required on inpatient records.

CMS proposes language that would only require a physician to periodically review and sign outpatient records of patients cared for by PAs and advanced practice registered nurses *if* and *to the extent* required by state law. This provision does not need to be stated because Medicare already requires that state laws and regulations be followed. Furthermore, stating a hypothetical requirement that is not required by most states could create confusion.

AAPA encourages CMS to delete § 485.528 (c)(iv) that a physician periodically review and sign a sample of outpatient records of patients cared for by PAs and advanced practice nurses to the extent required by state law.

Similar problematic language exists in regulations related to critical access hospitals.

AAPA recommends that § 485.631(b)(v) be deleted for the same reason as stated above. In addition, AAPA recommends removal of the* requirement at *§ 485.631(b)(iv) that a physician "review and sign the records of all inpatients" cared for by PAs and advanced practice registered nurses.

AAPA is not aware of any evidence indicating a difference in quality or outcomes related to whether a physician co-signs a medical record; as such, co-signature requirements create administrative burden without providing a known benefit. Furthermore, no such review and co-signature is required in acute care hospitals, inpatient or outpatient facilities, or other places of service. Requiring or implying a need for a physician review and co-signature creates a disparity in care at locations that are already struggling to improve equity and access.

AAPA also cautions against creating arbitrary administrative requirements for physicians and PAs. Specifically, AAPA opposes the following proposed CoPs

- § 485.528(d)(ii), which would require that PAs "participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records".
- § 485.528(e)(1), which states "the quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH".

- § 485.528(c)(2), which would require that "a doctor of medicine or osteopathy . . . be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH".
- § 485.528(d)(3), which would require that "whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status".

These are outdated requirements that may have been useful in the past. They are not reflective of how efficient medicine is currently practiced. The listed requirements will cause a burden to physicians and REHs without adding known benefits to patient care, create a regulatory burden when trying to ensure compliance with the standards, and detract from meaningful collaboration and quality assurance based on individual circumstances and situations.

***PAs should be included as part of the REH medical staff and held to the same standards as physicians*.**

An REH governing body is accountable for ensuring the quality of care that members of the medical staff provide. An REH governing body should similarly be accountable for the quality of care provided by all practitioners, including PAs. Allowing an REH to use the same credentialing, privileging, and competency/quality assessment processes for PAs as physicians would be more efficient and reduce administrative burdens.

CMS indicates in the proposed rule that an REH "could *choose* to grant medical staff privileges to nurse practitioners and physician assistants if this is allowable under state law". CMS has similar but stronger language for including PAs in medical staff membership but has indicated the information may not be cited.[13] This has led to confusion and misinformation about the ability for PAs and other non-physician practitioners to be included in the medical staff. Medical staff governance is important, as is the ability for all practitioners to participate in policies, self-governance, and other of attributes medical staff membership.[14]

AAPA strongly believes that CMS should state that an REH should grant medical staff privileges to PAs if this is allowable under state law and should encourage states to remove any barriers under state law to PA membership in the medical staff.

***AAPA strongly encourages CMS to remove any language from the CoPs that require a specified type of physician oversight of PAs or actions that physicians must undertake when care is provided by PAs other than what is required by state law and facility bylaws and policies. AAPA also believes that PAs should be assessed for competency and quality in the same manner as physicians through the medical staff process and not through arbitrary requirements that impose an administrative burden*.**

---

[13] Centers for Medicare and Medicaid Services. *Revised Guidance Related to New & Revised Regulations for Hospitals, Ambulatory Surgical Centers (ASCs), Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).* 2015. https://www.cms.gov/Medicare/Provider-Enrollment-andCertification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-22.pdf

[14] DePalma SM. The Value of PAs in Hospital Medical Staff Governance. *JAAPA*. 2019; 32(1): 41-43. doi: 10.1097/01.JAA.0000550288.09145.7e

Pharmaceutical Services

CoPs related to the provision of pharmaceutical services at § 485.522 propose to require that adverse reactions be documented in the medical record and reported to "the physician responsible for the patient". AAPA recognizes the importance of healthcare practitioners being aware of adverse reactions from medications; however, the requirement as proposed will not be able to be met if care is provided by a PA. This could cause REHs to create burdensome processes or duplicative work to require a "responsible physician" be identified or that a physician participate in all care provided by PAs. Otherwise, the regulation as written could put REHs at risk of being non-compliant if they do not ensure that adverse reactions are reported to a physician.

AAPA encourages CMS to revise § 485.522(c)(1) to state that any adverse reactions "be reported to a practitioner treating the patient and documented in the record".

Additional Outpatient Medical and Health Services

CMS proposes standards related to patient services and the qualifications of personnel providing those services. For any specialty services offered at an REH, proposed regulations state that a practitioner must have "experience and training in the specialty service area". As stated, it could be construed that a PA must complete a formal training program or have specified experience in a given specialty.

PAs are trained, certified, and licensed to practice medicine in all medical and surgical specialties. Most PAs work in specialties without having completed formal specialty training programs but have repeatedly demonstrated high-quality care with favorable patient outcomes. Evidence shows that PAs provide comparable care to physicians when working in specialties like primary care, cardiology, pulmonology, orthopaedics, surgery, neonatal intensive care, and others.[15, 16, 17, 18, 19, 20] Implying or requiring that a practitioner have training beyond what is required by national certification and state licensure will reduce the availability of practitioners who are otherwise qualified to provide specialty services at an REH, limit patient access, and adversely affect patient care and health outcomes. Furthermore, the qualifications and

---

[15] Jackson GL, Smith VA, Edelman D, et al. Intermediate Diabetes Outcomes in Patients Managed by Physicians, Nurse Practitioners, or Physician Assistants: A Cohort Study. *Ann Intern Med*. 2018;169(12): 825- 835. doi: 10.7326/M17-1987

[16] . Virani SS, Maddox TM, Chan PS, et al. Provider Type and Quality of Outpatient Cardiovascular Disease Care: Insights from the NCDR PINNACLE Registry. *J Am Coll Cardiol*. 2015;66(16):1803-1812. doi: 10.1016/j.jacc.2015.08.017

[17] Agarwal A, Zhang W, Kuo Y, Sharma G. Process and Outcome Measures Among COPD Patients with a Hospitalization Cared for by an Advance Practice Provider or Primary Care Physician. *Plus One.* 2016. doi: 10.1371/journal.pone.0148522

[18] Anderson TJ, Althausen PL. The Role of Dedicated Musculoskeletal Urgent Care Centers in Reducing Cost and Improving Access to Orthopaedic Care. *J Orthop Trauma*. 2016;30(5):s1-s2. doi: 10.1097/BOT.0000000000000712

[19] Miller W, Riehl E, Napier M, Barber K, Dabideen H. Use of Physician Assistants as Surgery/Trauma House Staff at an American College of Surgeons-Verified Level II Trauma Center. *J Trauma*. 1998;44(2):372-376. doi: 10.1097/00005373-199802000-00025.

[20] Carzoli RP, Martinez-Cruz M, Cuevas LL, Murphy S, Chieu T. Camparison of Neonatal Nurse Practitioners, Physician Assistants, and Residents in the Neonatal Intensive Care Unit. *Arch Pediatr Adolesc Med*. 1994; 148(12): 1271-1276. doi: 10.1001/archpedi.1994.02170120033005

competency of a practitioner are already ensured by the required hospital credentialing and privileging process. Requiring training in a specialty area should not be required to demonstrate competency and should not be a substitute for individual competency assessment.

AAPA recommends that CMS revise § 485.524(b)(3) and authorize specialty services offered at an REH to be provided by practitioners, including PAs, in accordance with their scope of practice and granted privileges.

Maternal Health Workforce Shortage

CMS states they would expect that an REH would "leverage clinicians other than only physicians so that a variety of trained professionals or support persons could help to address barriers to access to care and the maternal health workforce shortage in rural areas by utilizing nurse practitioners, nurse midwives, and doulas as allowed by state law". AAPA appreciates that CMS recognizes the vital role healthcare professionals other than physicians play in addressing barriers to access to care. However, the statement as written by CMS undervalues the contribution of PAs to maternal and fetal health. Additionally, the statement could inadvertently cause REHs to erroneously think that PAs are not qualified, licensed, and authorized to provide these and other needed services in rural areas.

AAPA encourages CMS to include PAs in all language and policies related to physician-services that authorized Part B providers may provide. The exclusion of PAs in language such as this, in waivers related to the ACO REACH Model[21], and other policies can negatively affect access to care, especially among rural and underserved populations.

Thank you for the opportunity to provide feedback on the proposed Conditions of Participation for Rural Emergency Hospitals and Critical Access Hospital Updates. AAPA welcomes further discussion with CMS regarding these issues. For any questions you may have please do not hesitate to contact Michael Powe, AAPA Vice President of Reimbursement & Professional Advocacy, at michael@aapa.org.

Sincerely,

Lisa M. Gables, CPA
Chief Executive Officer

[21] Centers for Medicare and Medicaid Services. *ACO Realizing Equity, Access, and Community Health (REACH) Model: Request for Applications*. 2022. https://innovation.cms.gov/media/document/aco-reach-rfa