American Academy of Physician Associates

May 12, 2025

Russell Vought
Director
Office of Management and Budget
725 17th Street NW Washington, DC 20503

Regarding: Office of Management and Budget Request for Information for Deregulation
[FR Doc. 2025-06316]

Dear Director Vought,

The American Academy of PAs (AAPA), on behalf of the approximately 190,000 PAs (physician assistants/physician associates) throughout the United States, would like to provide comments on the Office of Management and Budget Request for Information for Deregulations. There are numerous regulations, noted below, that unjustly limit the services PAs are state-licensed and authorized by section 1861(s)(2)(k)(i) of the Social Security Act to provide. These regulations create unnecessary inefficiencies in care delivery, increasing costs to patients and the federal government, and hindering access to high-quality care. The Medicare Payment Advisory Commission 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".

PAs practice medicine in every medical and surgical specialty in all 50 states and the District of Columbia, U.S. territories, and the uniformed services. PAs undergo rigorous education and training to become board-certified and licensed to practice. With thousands of hours of medical education, PAs are highly qualified, capable, and versatile healthcare providers. PAs obtain medical histories, perform physical examinations, diagnose and treat illnesses, order and interpret diagnostic tests, prescribe medications, perform procedures, assist at surgery, coordinate care, provide patient education and counseling, and perform other medical services. PAs often serve as a patient's principal healthcare practitioner. It is within this context that we provide the following recommendations.

Regulations Promulgated by the Centers for Medicare and Medicaid Services that Should be Rescinded or Revised

Centers for Medicare and Medicaid Services
Dr. Mehmet Oz, Administrator
7500 Security Boulevard, Baltimore, Maryland 21244-1850

Regulation 42 CFR § 410.37

Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998 or 42 CFR § 410.37(f): *Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 410 Supplementary Medical Insurance (SMI) Benefits, Subpart B Medical and Other Health Services, § 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.37

Title, parts, and/or sections of the C.F.R.

42 CFR § 410.37(f) should be rescinded as an Interim Final Rule. Alternatively, it should be revised to authorize coverage of screening colonoscopies performed by physician assistants.

Text of the relevant C.F.R. after the rescission or revision.

42 CFR § 410.37 is amended by deleting paragraph (f).

Alternatively, 42 CFR § 410.37 is amended by revising paragraph (f)

42 CFR § 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

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(f) *Condition for coverage of screening colonoscopies.* Medicare Part B pays for a screening colonoscopy if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) or a physician assistant (as defined in section 1861(aa)(5) of the Act).

Short summary of the justifications for the rescission or revision.

42 CFR § 410.37(f), which authorizes coverage of screening colonoscopies only when performed by a physician, conflicts with the statutory authority of Section 1861(s)(2)(k)(i)) of the Social Security Act for physician assistants (PAs) to provide "physicians' services" they are authorized to perform by the State. Further, the regulation is not necessary because the Social Security Act and other regulations already limit the coverage of services to physicians and PAs when performed in accordance with state law. Authorizing payment for colonoscopies that PAs have statutory authority and state licensure to perform, and for which they have been demonstrated to perform with similar outcomes as physicians, will improve screening, detection, disease prevention, and wellness.

Reasons for the rescission or revision.

The regulation dictates that payment for colonoscopies only be made when performed by a doctor of medicine or osteopathy, which conflicts with the statutory authority of section 1861(s)(2)(k)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. Further, PAs have been demonstrated to perform colonoscopies comparable to gastroenterologists in technical performance and quality metrics. Specifically, a study (https://journals.lww.com/jaapa/Fulltext/2020/04000/Quality_metrics_of_screening_colonoscopies.8.aspx) 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." This is especially important because it has been estimated that initiating colonoscopy screenings at age 45 rather than 50 years, which has recently been done, will increase demand for colonoscopies by 22% and add 21 million people to the previous 94 million eligible people (https://www.cghjournal.org/article/S1542-3565(20)30917-4/fulltext).

Background for the regulation.

42 CFR § 410.37 specifies conditions for coverage for screening colonoscopies. The Centers for Medicare and Medicaid Services (CMS) proposed in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) proposed rule to expand coverage for colorectal cancer screening. In public comments, the American Academy of Physician Associates requested that the agency revise regulations to further expand access to colorectal cancer screening by authorizing PAs to perform colonoscopies. CMS noted in the Calendar Year (CY) 2023 PFS final rule (see page 1048 of https://public-inspection.federalregister.gov/2022-23873.pdf) that although a request regarding the furnishing of colonoscopies by PAs was outside the scope of the proposals made in the CY 2023 PFS proposed rule, the agency would consider the request for possible future rulemaking. However, no further rulemaking has occurred.

Agency Contact(s)

Division of Practitioner Services and Regina Walker-Wren for issues related to billing for services of physician assistants and Kimberly Long for issues related to expanding colorectal cancer screening.

Regulations 42 CFR § 410.40

Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID-19 Interim Final Rules or 42 CFR § 410.40(e)(2)(i) and 42 CFR § 410.40(e)(2)(ii): *Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 410*

Supplementary Medical Insurance (SMI) Benefits, Subpart B Medical and Other Health Services, § 410.40 Coverage of Ambulance Services, Special Rule for Nonemergency, Scheduled, Repetitive Ambulance Services.

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.40

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

42 CFR § 410.40(e)(2)(i) should be revised through an Interim Final Rule to remove a "physician certification statement" as a condition of payment for nonemergency, scheduled, repetitive ambulance services to authorize physician assistants to provide the certification.

42 CFR § 410.40(e)(2)(ii) should be rescinded through an Interim Final Rule. Alternatively, it should be revised.

Text of the relevant C.F.R. as they will exist after the rescission or revision.

42 CFR § 410.40 is amended by revising (e)(2)(i) to read as follows:

42 CFR § 410.40 Coverage of ambulance services

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(e) ***

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.*

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a certification statement dated no earlier than 60 days before the date the service is furnished.

42 CFR § 410.40 is further amended by deleting paragraph (e)(2)(ii).

Alternatively, 42 CFR § 410.40 is amended by revised (e)(2)(ii) to read as follows:

42 CFR § 410.40 Coverage of ambulance services

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(e) ***

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.*

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a certification statement (CS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the CS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The CS and additional documentation must provide detailed explanations, that are consistent with the

beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at § 410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in § 410.41(b).

Short summary of the justifications for the rescission or revision.

42 CFR § 410.40(e)(2)(i) conflicts with the statutory authority of section 1861(s)(2)(k)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. 42 CFR § 410.40(e)(2)(ii) is unnecessary because medical necessity and the documentation of that necessity is a general requirement for coverage of services.

Reasons for the rescission or revision.

The regulation that requires a "physician certification statement" as a condition of payment for nonemergency, scheduled, repetitive ambulance services conflicts with the statutory authority of Section 1861(s)(2)(k)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs are state-licensed to determine medical necessity and complete medical forms and certification statements. Further, PAs are authorized to certify non-emergency ambulance services that are unscheduled or scheduled on a non-repetitive basis. Revising this regulation will improve chronic disease management (e.g., access to dialysis and chronic wound care) for patients who would otherwise be unable to access care without non-emergency, scheduled, repetitive ambulance services. These changes will also increase healthcare efficiency and reduce administrative burdens.

Background for the regulation.

The CMS CY 2023 PFS proposed rule sought to clarify medical necessity and documentation requirements for nonemergency, scheduled, repetitive ambulance services. In public comments, the AAPA requested that the agency revise regulations to authorize PAs to complete the required certification statement. CMS stated in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule (see page 1758 of https://public-inspection.federalregister.gov/2022-23873.pdf) that the request to extend authorization to PAs was outside the scope of the rule.

Agency Contact(s) – Katie Parker and Thomas Kessler.

Regulations 42 CFR § 418.106

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule or 42 CFR § 418.106(b)(1)(iii)(A) and 42 CFR § 418.106(b)(1)(iii)(B): *Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 418 Hospice Care, Subpart D Conditions of Participation: Organizational*

Environment, § 418.106 Condition of Participation: Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment.

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-418/subpart-D/section-418.106

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The conditional requirements on physician assistants (i.e., that they must be the patient's attending physician and not employed or under arrangement with the hospice to order medications) at 42 CFR § 418.106(b)(1)(iii)(A) and 42 CFR § 418.106(b)(1)(iii)(B) should be rescinded through a Direct Final Rule.

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

42 CFR § 418.106 is amended by deleting paragraphs (b)(1)(iii)(A) and (B).

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(b) *Standard: Ordering of drugs.*

(1) Drugs may be ordered by any of the following practitioners:

(i) A physician as defined by section 1861(r)(1) of the Act.

(ii) A nurse practitioner in accordance with state scope of practice requirements.

(iii) A physician assistant in accordance with state scope of practice requirements and hospice policy.

Short summary of the justifications for the rescission or revision.

42 CFR § 418.106(b)(1)(iii)(A) and 42 CFR § 418.106(b)(1)(iii)(B) conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for physician assistants (PAs) to provide "physicians' services" they are authorized to perform by the State. The CFR also conflicts with sections 1861(dd)(2)(B) and 1861(dd)(3)(B) of the Social Security Act, which do not preclude a PA from being a member of a hospice's interdisciplinary group and expressly authorize PAs to serve as an "attending physician" and be employed by a hospice program. Amending this regulation will improve patient access, increase healthcare efficiency, and reduce administrative burdens.

Reasons for the rescission or revision.

The regulations limiting PAs from prescribing medications for hospice beneficiaries unless they are formally recognized as the patient's "attending physician" and not employed by the hospice conflict with statutory authorizations in the Social Security Act. They are also conditions that are not imposed on physicians and nurse practitioners. This unjustified limitation significantly limits a PA's ability to provide needed services to hospice beneficiaries. Hospice care is recognized as an underutilized service (https://www.jpsmjournal.com/article/S0885-3924(18)30414-7/fulltext), which CMS concurred in the 2024 and 2025 Hospice Wage Index. Underutilization of hospice can lead to prolonged patient usage of expensive and ineffective care. While the causes of underutilization are multifactorial, unnecessary regulatory barriers create additional challenges. The subsequent improved utilization of PAs by removing these barriers can improve access to hospice services. The effective use of PAs will also help ensure that

hospice organizations are appropriately staffed with health professionals, increasing workforce capacity and improving efficiency.

Background for the regulation.

Section 51006 of the Bipartisan Budget Act of 2018 added PAs to the statutory definition of the hospice "attending physician" for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician as part of the "Medicare Program; FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements" final rule, which was published in the August 6, 2018 Federal Register (83 FR 38622, 38634). Despite this, the CFR regarding the ordering of medications for hospice patients was not updated until the following year. In a final rule (RIN 0938-AT72) effective January 1, 2020, CMS expressed that although there is no preclusion of PAs serving on the hospice interdisciplinary team, the fact that a PA was not a required member led them to create different policies for PAs compared to physicians and nurse practitioners (https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list). During subsequent meetings with the American Academy of Physician Associates, CMS staffed acknowledged that this was an arbitrary and unnecessary restriction but that they needed to wait for proposed rulemaking to revise the regulations. However, no further rulemaking related to this has occurred.

Agency Contact(s) – Mary Rossi-Coajou for Hospice or Regina Walker-Wren for issues related to billing for services of physician assistants.

Regulation 42 CFR § 483.30

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities or 42 CFR § 483.30: *Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter G Standards and Certification, Part 483 Requirements for States and Long Term Care Facilities*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-483/subpart-B/section-483.30

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The following should be revised and/or rescinded through an Interim Final Rule:

42 CFR § 483.30 should be revised to include physician assistants (PAs). This includes the following:

42 CFR § 483.30 should be revised to be inclusive of PAs.

42 CFR § 483.30(b) and 42 CFR § 483.30(b)(1) should be revised to be inclusive of PAs.

42 CFR § 483.30(c) and 42 CFR § 483.30(c)(1) and (2) should be revised to be inclusive of PAs.

42 CFR § 483.30(c)(3) and (4) should be rescinded.

42 CFR § 483.30(e)(1), (e)(1)(i), (e)(1)(ii), and(e)(1)(iii) should be rescinded.

42 CFR § 483.30(e)(2) should be revised to be inclusive of PAs.

42 CFR § 483.30(e)(3) should be revised to be inclusive of PAs.

42 CFR § 483.30(e)(4) should be rescinded.

Describe the text of the relevant C.F.R. provisions as it will exist after the rescission. – 42 CFR § 483.30 is amended to read as follows:

42 CFR § 483.30 *Practitioner services*. A physician or physician assistant must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

42 CFR § 483.30 is amended by revising paragraphs (b) and (b)(1) to read as follows

42 CFR § 483.30 Practitioner services.

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(b) *Practitioner visits.* The physician or physician assistant must

> (1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;
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> ***

42 CFR § 483.30 is amended by revising paragraphs (c), (c)(1), and (c)(2) to read as follows:

42 CFR § 483.30 Practitioner services.

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Frequency of practitioner visits.

(1) The resident must be seen by a physician or physician assistant at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A practitioner visit is considered timely if it occurs not later than 10 days after the date the visit was required.

42 CFR § 483.30 is amended by deleting paragraphs (c)(3) and (4).

42 CFR § 483.30 is amended by deleting paragraphs (e)(1), (e)(1)(i), (e)(1)(ii), and(e)(1)(iii).

42 CFR § 483.30 is amended by revising paragraph (e)(2) and (e)(3) to read as follows:

42 CFR § 483.30 Practitioner services.

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(e) ***

(2) A physician or physician assistant may delegate the task of writing dietary orders, consistent with § 483.60, to a qualified dietitian or other clinically qualified nutrition professional who —

(3) A physician or physician assistant may delegate the task of writing therapy orders, consistent with § 483.65, to a qualified therapist who—

42 CFR § 483.30 is amended by deleting paragraph (e)(4).

Short summary of the justifications for the rescission or revision.

The stated provisions conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. The current regulatory requirements in SNFs necessitate physician involvement that is unnecessary, does not contribute to quality care, and may not be readily available in rural settings. Allowing PAs to provide these services will expand patient access to needed care and improve workforce efficiency.

Reasons for the rescission or revision.

PAs are educated, certified, and licensed to provide care in all medical settings and among all patient populations, including older and/or disabled patients and those in long-term care facilities. When doing so, PAs, according to the Medicare Payment Advisory Commission, provide care with "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf). Further, 42 CFR § 483.30(c)(3) and 42 CFR. § 483.30(c)(4) were waived during the COVID-19 pandemic to temporarily allow physicians to delegate any required physician visit to a PA or other non-physician practitioner. According to a CMS report to Congress, these actions assisted in preventing and addressing potential staffing shortages, maximized the use of medical personnel, and protected the health and safety of residents. As such, the report noted that practices that authorized physician delegation of tasks to PAs and other clinicians "saw higher quality of care for older populations and better interdisciplinary team management" (https://www.cms.gov/files/document/covid-19-phe-report-congress.pdf).

Background for the regulation being rescinded or revised.

The physician requirements in long-term care facilities are not based on statute and are inconsistent with medical practice in other facilities. For example, there is no requirement for a physician to perform any specific service in an acute care hospital or critical access hospital. During the COVID-19 public health emergency, CMS waived 42 CFR § 483.30(c)(3) and 42 CFR. § 483.30(c)(4) and authorized the delegation of "physician-only" visits in SNFs to PAs. This waiver was terminated on May 7, 2022 per QSO-22-15-NH & NLTC & LSC. There was no clinical justification to reinstitute these outdated practice restrictions when years of experience have demonstrated the high-quality care PAs provide in skilled nursing facilities and other settings.

Agency Contact(s) - Patricia Taft for Skilled Nursing Facility Prospective Payment System

Regulations 42 CFR § 416.42, 42 CFR § 416.48, and 42 CFR § 416.52

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule or 42 CFR § 416.42; 42 CFR § 416.48; and 42 CFR § 416.52: *Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Part 416, Ambulatory Surgical Services, Subpart C Specific Conditions for Coverage*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416/subpart-C/section-416.42

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416/subpart-C/section-416.48

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416/subpart-C/section-416.52

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The following should be revised through an Interim Final Rule:

42 CFR § 416.42 should be revised to authorize physician assistants (PAs) to perform surgical procedures in ambulatory surgical centers (ASCs).

42 CFR § 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.

42 CFR § 416.48(a)(1), should be revised to authorize PAs to receive reporting of adverse reactions 42 CFR § 416.48(a)(2) should be revised to authorize PAs to administer blood and blood products; and 42 CFR § 416.48(a)(3) should be revised to authorize PAs to order drugs and biologicals in ASCs.

42 CFR § 416.52(c)(1) should be revised to authorize PAs to provide follow up appointments, 42 CFR § 416.52(c)(2) should be revised to authorize PAs to discharge patients (and issue and sign discharge orders), and 42 CFR § 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 in ASCs.

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

42 CFR § 416.42 is amended to read as follows:

42 CFR § 416.42 Condition for coverage—Surgical services. Surgical procedures must be performed in a safe manner by qualified physicians and physician assistants who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

42 CFR § 416.42 is amended by revising paragraphs (a)(1)(i) and (ii) to read as follows:

42 CFR § 416.42 Condition for coverage—Surgical services.

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(a) ***

(1) ***

(i) A physician or physician assistant must examine the patient to evaluate the risk of the procedure to be performed; and

(ii) (ii) A physician, physician assistant, or anesthetist as defined at § 410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia."

42 CFR § 416.48 is amended by revising paragraphs (a)(1), (a)(2), and (a)(3) to read as follows:

42 CFR § 416.48 Condition for coverage—Pharmaceutical services.

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(a) ***

(1) Adverse reactions must be reported to the physician or physician assistant responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians, physician assistants, or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or physician assistant.

42 CFR § 416.52 is amended by revising paragraphs (c)(1), (c)(2) and (c)(3) to read as follows:

42 CFR § 416.52 Conditions for coverage—Patient admission, assessment and discharge.

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(c) ***

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with a physician or physician assistant, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions, and practitioner contact information for follow-up care.

(2) Ensure each patient has a discharge order, signed by a physician or physician assistant in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by a physician or physician assistant.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery, risk assessment, and other medical services. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

Reasons for the rescission or revision.

ASC Conditions for Coverage have limitations and restrictions that do not exist in hospitals, medical offices, and many other settings, and which conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs have the training, experience, and competency to evaluate patients before surgery and prior to discharge, perform procedures, determine if a patient may be discharged, whether they may be discharged without the company of a responsible adult, provide necessary follow-up care, and administer blood and blood products. PAs often perform surgical procedures that are performed in ASCs, including endoscopies, orthopaedic procedures, epidural injections, excisional biopsies, and other procedures safely and effectively in other outpatient settings. These services are consistent with PA education, training, and scope of practice and are performed with high-quality and safety in non-ASC settings.

The regulations do not represent the current practice of medicine, in which PAs are recognized as providing high-quality, cost-effective healthcare with, according to the Medicare Payment Advisory Commission, "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf).

Removing limitations to the services PAs are otherwise state-licensed to provide is consistent with the Administration's directive to improve workforce competition and is consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Allowing PAs to provide these services will expand patient access to needed care, as patients will not have to wait to see a physician when a clinically capable PA is available. In addition, there will be increased efficiency if an ASC can determine which health professional is most appropriate to see a patient based on factors such as qualification and availability, instead of making staffing decisions based on restrictive regulations.

Background for the regulation.

The CFRs specify the conditions for coverage in ASCs. The conditions historically have had restrictions that are not justified by statute and are more restrictive than other medical settings. CMS proposed in the CY 2020 PFS proposed rule proposed to allow certified registered nurse anesthetists to meet the regulation that required an examination of a patient immediately before surgery to evaluate the risk of anesthesia and the

risk of the procedure to be performed. CMS also requested comments and suggestions for how ASC requirements could be revised to allow PAs and other non-physician practitioners to allow for greater flexibility and reduce burdens. Despite the request for information, the regulations have not been modified to authorize the optimal and statutorily justified utilization of PAs in ASCs.

Agency Contact – Jacqueline Leach, as of 2020.

Regulation 42 CFR § 485.639

Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation or 42 CFR § 485.639: *Critical Access Hospitals: Conditions of Participation: Surgical Services.*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-F/section-485.639

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

42 CFR § 485.639(a) should be revised through an Indirect Final Rule to authorize physician assistants (PAs) to perform surgical procedures in critical access hospitals (CAHs).

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

For first:

42 CFR § 485.639 is amended by revising paragraph (a) to read as follows:

42 CFR § 485.639 Condition of participation: Surgical services.

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(a) ***

(4) a physician assistant as defined section 1861(aa)(5) of the Act

Short summary of the justifications for the rescission or revision.

42 CFR § 485.639(a) and 42 CFR § 485.631(b)(1)(iv) and (v) conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery. Amending these regulations will increase workforce adequacy and improve efficiency.

Reasons for the rescission or revision.

PAs are state-licensed to provide medical and surgical services and have the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including surgical procedures. PAs are also authorized by Medicare policy to perform minor surgery in medical offices, inpatient and outpatient hospital facilities, and other places of service. PAs often perform endoscopies, orthopaedic procedures, epidural injections, excisional biopsies, and other procedures safely and effectively in different settings. An arbitrary restriction on surgical services in a CAH is

unjustified and creates a further disparity between access to care, patient choice, and other factors affecting people living in rural areas compared to urban and suburban settings. Further, because section 1820(c)(2)(B)(iv)(III) of the Social Security Act allows PAs to staff CAHs without the presence of a physician, PAs may be the only practitioners onsite and available to perform surgical procedures. Unnecessary delays in access to surgical care by waiting for a physician to be onsite could worsen outcomes and increase healthcare costs.

Removing limitations to the services PAs are otherwise state-licensed to provide is consistent with the Administration's directive to improve workforce competition and is consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Further, the regulations do not represent the current practice of medicine, in which PAs are recognized as providing high-quality, cost-effective healthcare with, according to the Medicare Payment Advisory Commission, "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf).

Background for the regulation.

Congress created the CAH designation through the Balanced Budget Act of 1997 to improve access to healthcare by keeping essential services in rural communities. Despite this, staffing shortages and hospital closures in rural areas have continued to threaten access to care, necessitating that all available practitioners practice to the fullest extent possible. There has been no recent proposed rulemaking related to these regulations.

Agency Contact(s) – David Wright, Donald Thompson, and Michele Hudson

Regulation 42 CFR § 485.631

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19 or 42 CFR § 485.631: *Critical Access Hospitals: Conditions of Participation: Staffing and Staff Responsibilities*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-F/section-485.631

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The following should be rescinded or revised through an Interim Final Rule:

42 CFR § 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.

42 CFR § 485.631(b)(2) should be revised to remove the requirement that a physician be present at a CAH for "sufficient periods of time."

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

42 CFR § 485.631 is amended by deleting paragraphs (b)(1)(iv) and (v).

42 CFR § 485.631 is amended by revising paragraph (b)(2) to read as follows:

42 CFR § 485.631 Condition of participation: Staffing and staff responsibilities.

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(b) ***

(2) A doctor of medicine or osteopathy is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Short summary of the justifications for the rescission or revision.

42 CFR § 485.631(b)(1)(iv) and (v) and 42 CFR § 485.631(b)(2) conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State and section 1820(c)(2)(B)(iv)(III) of the Social Security Act, which authorizes PAs to provide inpatient care in a CAH without the need for a physician to be present in the facility and without the requirement for physician co-signatures of medical records. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

Reasons for the rescission or revision.

PAs are state-licensed to provide medical and surgical services and have the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. They are generally authorized to do so without a physician present and without a physician's co-signature. Co-signatures create an administrative burden in locations that seek to improve access, without providing a known benefit. No such review and co-signature is required in acute care hospitals, inpatient or outpatient facilities, or other places of service.

Imposing unnecessary supervision requirements (e.g., physician presence and co-signatures) does not represent the current practice of medicine. It also contradicts the Administration's directive to reduce regulatory burden and improve workforce competition. Removing physician supervisory requirements for PAs in CAHs is also consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set"

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

Background for the regulation.

Congress created the CAH designation through the Balanced Budget Act of 1997 to improve access to healthcare by keeping essential services in rural communities. Despite this, staffing shortages and hospital closures in rural areas have continued to threaten access to care, necessitating that all available practitioners practice to the fullest extent possible.

During the COVID-19 Public Health Emergency, the Centers for Medicare and Medicaid Services waived the requirement at 42 CFR § 485.631(b)(2) that a physician be physically present at a CAH (https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf) Medicare felt that waiving the first part of the requirement at § 485.631(b)(2) of a physician's physical presence but retaining the regulatory language in the second part that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral" assured an appropriate level of physician oversight (as required by statute). This temporary regulatory waiver should be made permanent to allow PAs to practice to the fullest extent possible.

Agency Contact(s) – David Wright, Donald Thompson, and Michele Hudson

Regulation 42 CFR § 485.524

42 CFR § 485.524: *Rural Emergency Hospital: Condition of Participation: Additional Outpatient Medical and Health Services*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-E/section-485.524

Title, parts, and/or sections of the C.F.R. should be rescinded or revised.

42 CFR § 485.524(d)(1) should be revised through an Interim Final Rule to authorize physician assistants (PAs) to perform surgical procedures in rural emergency hospitals (REHs).

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

42 CFR § 485.524 is amended by revising paragraph (d)(1) to read as follows:

42 CFR § 485.524 Condition of participation: Additional outpatient medical and health services.

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(d)***

(1)***

(iv) A physician assistant.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including minor surgery. Amending these regulations will increase workforce adequacy and improve efficiency.

Reasons for the rescission or revision.

PAs are state-licensed to provide medical and surgical services and have the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including surgical procedures. PAs are also authorized by Medicare policy to perform minor surgery in medical offices, inpatient and outpatient hospital facilities, and other places of service. PAs often perform endoscopies, orthopaedic procedures, epidural injections, excisional biopsies, and other procedures safely and effectively in different settings. An arbitrary restriction on surgical services in a REH is unjustified and creates a further disparity between access to care, patient choice, and other factors affecting people living in rural areas compared to urban and suburban settings. Unnecessary delays in access to surgical care by waiting for a physician to perform a surgical procedure a PA is licensed and qualified to provide could worsen outcomes and increase healthcare costs.

Background for the regulation.

Congress established the REH designation in December 2020 in Section 125 of the Consolidated Appropriations Act, 2021. In 2022, CMS issued proposed rules to establish Conditions of Participation for REHs. Many of the proposed regulations related to PA practice and physician supervision were similar to regulations in CAHs and problematic to the AAPA. Despite public comment of concern, the rules were finalized as proposed in RIN 0938–AU82.

Agency Contact(s) – David Wright or Karen Tritz

Regulations 42 CFR § 485.528

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19 or 42 CFR § 485.528: Rural Emergency Hospital: Condition of Participation: Staffing and Staff Responsibilities.

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-E/section-485.528

Title, parts, and/or sections of the C.F.R. should be rescinded or revised.

The following should be rescinded or revised through an Interim Final Rule:

42 CFR § 485.528(c)(1)(iv) should be rescinded.

42 CFR § 485.528(c)(2) should be revised to remove the requirement that a physician be present at an REH for "sufficient periods of time".

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

42 CFR § 485.528 is amended by deleting paragraph (c)(1)(iv).

42 CFR § 485.528 is amended by revising paragraph (c)(2)

42 CFR § 485.528 Condition of participation: Staffing and staff responsibilities.

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(c) ***

(1) ***

(2) A doctor of medicine or osteopathy must be available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act 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.

Reasons for the rescission or revision.

The regulation requires a physician to periodically review and sign outpatient records of patients cared for by PAs 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. Stating a hypothetical requirement not required by most states could create confusion and is unwarranted. Additionally, imposing unnecessary supervision requirements (e.g., physician presence and co-signatures) does not represent the current practice of medicine. It also contradicts the Administration's directive to reduce regulatory burden and improve workforce competition. Removing physician supervisory requirements for PAs in CAHs is also consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Background for the regulation.

Congress established the REH designation in December 2020 in Section 125 of the Consolidated Appropriations Act, 2021. In 2022, CMS issued proposed rules to establish Conditions of Participation for REHs. Many of the proposed regulations related to PA practice and physician supervision were similar to

regulations in CAHs and problematic to the AAPA. Despite public comment of concern, the rules were finalized as proposed in RIN 0938–AU82.

Agency Contact(s) – David Wright or Karen Tritz

Regulation 42 CFR § 424.13

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: CMS-Identified Overpayments Associated with Submitted Payment Data or 42 CFR § 424.13: *Conditions for Payment: Certification and Plan Requirements: Requirements for inpatient services of hospitals other than inpatient psychiatric facilities*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-B/section-424.13

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

42 CFR § 424.13(a), 42 CFR § 424.13(c)(1) and (2), and 42 CFR § 424.13(d)(1) should be revised through an Interim Final Rule to authorize physician assistants (PAs) to provide required certifications.

Text of the relevant C.F.R. provisions as they will exist after the rescission.

42 CFR § 424.13 is amended by revising paragraphs (a), (c)(1) and (2), and (d)(1) to read as follows:

§ 424.13 Requirements for inpatient services of hospitals other than inpatient psychiatric facilities.

(a) *Content of certification and recertification.* Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more, or are outlier cases under subpart F of part 412 of this chapter, only if a physician or physician assistant certifies or recertifies the following:

(b) ***

(c) *Certification of need for hospitalization when a SNF bed is not available.*

> (1) The physician or physician assistant may certify or recertify need for continued hospitalization if he or she finds that the patient could receive proper treatment in a SNF but no bed is available in a participating SNF.
>
> (2) If this is the basis for the physician's or physician assistant's certification or recertification, the required statement must so indicate; and the certifying physician or physician assistant is expected to continue efforts to place the patient in a participating SNF as soon as a bed becomes available.

(d) *Signatures* —

> (1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician or

physician assistant who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for physician assistants (PAs) to provide "physicians' services" they are authorized to perform by the State. Further, a certification is unnecessary because medical necessity and the documentation of that necessity is a general requirement for coverage of services.

Reasons for the rescission or revision.

The regulation that requires a physician certification as a condition of payment conflicts with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs are state-licensed to determine medical necessity, order inpatient services, and complete certification statements. Revising this regulation will increase healthcare efficiency and reduce administrative burdens.

Background for the regulation.

The regulation specifies requirements for certification for coverage of inpatient hospital services (other than inpatient psychiatric facility services) for cases that are 20 inpatient days or more. There has been no recent proposed rulemaking related to this regulation.

Agency Contact(s) - Ngozi Uzokwe, Lang Le, Elizabeth Goldstein, Melissa Hager, and Julia Venanzi

Regulation 42 CFR § 424.14

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status or 42 CFR § 424.14: *Conditions for Medicare Payment: Certification and Plan Requirements: Requirements for inpatient services of inpatient psychiatric facilities.*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-B/section-424.14

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

42 CFR § 424.14(a) and (b) should be revised through an Interim Final Rule to authorize physician assistants (PAs) to certify and recertify the need for inpatient psychiatric care.

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

42 CFR § 424.14 is amended by revising paragraphs (a) and (b) to read as follows:

42 CFR § 424.14 Requirements for inpatient services of inpatient psychiatric facilities.

(a) Requirements for certification and recertification: General considerations. Certification begins with the order for inpatient admission. The content requirements differ from those for other hospitals because the

care furnished in inpatient psychiatric facilities is often purely custodial and thus not covered under Medicare. The purpose of the statements, therefore, is to help ensure that Medicare pays only for services of the type appropriate for Medicare coverage. Accordingly, Medicare Part A pays for inpatient services in an inpatient psychiatric facility only if a physician or physician assistant certifies and recertifies the need for services consistent with the requirements of this section, as appropriate.

(b) *Content of certification.* The physician or physician assistant must certify—

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for physician assistants (PAs) to provide "physicians' services" they are authorized to perform by the State. Further, a certification is unnecessary because medical necessity and the documentation of that necessity is a general requirement for coverage of services.

Reasons for the rescission or revision.

The regulation that requires a physician certification as a condition of payment conflicts with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs are state-licensed to determine medical necessity, order inpatient services, and complete certification statements. Revising this regulation will increase healthcare efficiency and reduce administrative burdens.

Background for the regulation.

The regulation specifies requirements for certification for coverage of inpatient psychiatric services. There has been no recent proposed rulemaking related to this regulation.

Agency Contact(s) – Nick Brock or Kaleigh Emerson

Regulations 42 CFR § 485.914 and 42 CFR § 485.916

Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction or 42 CFR § 485.914 and 42 CFR § 485.916**:** *Conditions of Participation: Specialized Providers: Conditions of Participation: Community Mental Health Centers (CMHCs)*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-J/section-485.914

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-J/section-485.916

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The following should be revised through at Direct Final Rule:

42 CFR § 485.914(e)(3)(iii) should be revised to be inclusive of physician assistants (PAs).

42 CFR § 485.916(a)(3) should be revised to be inclusive of PAs.

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

42 CFR § 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client

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(e) ***

(3) ***

(iii) The client's most recent physician or physician assistant orders

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

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(a)***

(3) ***

(viii) Physician assistant.

Short summary of the justifications for the rescission or revision.

The regulations conflict with section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State.

Reasons for the rescission or revision.

The regulation that requires the inclusion of only physician orders on a discharge summary and the lack of inclusion of PAs in the interdisciplinary treatment team (which they are authorized to lead according to 42 § 485.916(a)(1)) does not represent the current practice of medicine and conflicts with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs are state-licensed to provide and order medical services. Revising this regulation will increase healthcare efficiency and reduce administrative burdens.

Background for the regulation.

The regulation specifies requirements for coverage of services in Community Mental Health Centers. There was a Final Rule related to these centers published on November 22, 2023, but there were no changes to the

relevant subregulations. https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

Agency Contact(s) – CMS Mary Rossi-Coajou and Cara Meyer

Regulations 42 CFR § 412.29

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2021 or 42 CFR § 412.29: *Prospective Payment Systems for Inpatient Hospital Services: Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-B/section-412.29

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised.

The following should be revised through an Interim Final Rule:

42 CFR § 412.29(d) should be revised to authorize physician assistants (PAs) to review and approve a patient's preadmission screening.

42 CFR § 412.29(e) should be revised to authorize PAs to perform all required face-to-face visits in an inpatient rehabilitation facility (IRF).

42 CFR § 412.29(h) should be revised to authorize PAs to establish, review, and revise a plan of treatment in an IRF.

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

42 CFR § 412.29 is amended by revising paragraph (d) to read as follows:

42 CFR § 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

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(d) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A fee-for-Service patient is reviewed and approved by a rehabilitation physician or physician assistant prior to the patient's admission to the IRF

42 CFR § 412.29 is amended by revising paragraph (e) to read as follows:

42 CFR § 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

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(e) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician or physician assistant with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act).

42 CFR § 412.29 is amended by revising paragraph (h) to read as follows:

42 CFR § 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

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(h) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician or physician assistant in consultation with other professional personnel who provide services to the patient.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including completing and reviewing screenings and treatment plans and perform face-to-face encounters. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

Reasons for the rescission or revision.

IRF Conditions for Coverage have limitations and restrictions that do not exist in hospitals, medical offices, and many other settings, and which conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs have the training, experience, and competency to complete and review screenings and treatment plans and perform face-to-face encounters. These services are consistent with PA education, training, and scope of practice and are performed with high-quality and safety in non-IRF settings.

The regulations do not represent the current practice of medicine, in which PAs are recognized as providing high-quality, cost-effective healthcare with, according to the Medicare Payment Advisory Commission, "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-

content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf).

Removing limitations to the services PAs are otherwise state-licensed to provide is consistent with the Administration's directive to improve workforce competition and is consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Allowing PAs to provide these services will expand patient access to needed care, as patients will not have to wait to see a physician when a clinically capable PA is available. In addition, there will be increased efficiency if an IRF can determine which health professional is most appropriate to see a patient based on factors such as qualification and availability, instead of making staffing decisions based on restrictive regulations.

Background for the regulation.

The regulation specifies requirements for coverage of services in IRFs. CMS proposed in the CY 2019 IRF PPS proposed rule (83 FR 20972) to expand the use of PAs and other non-physician practitioners (NPPs), in part, by removing all the face-to-face requirements for rehabilitation physician visits. However, in the CY 2019 IRF PPS final rule [CMS-1688-F] RIN 0938-AT25, the requirements in § 412.622(a)(3)(iv) and § 412.622(a)(4)(ii) were amended to only authorize PAs and other NPPs to provide some of the physician requirements. The regulations should be further amended as previously proposed to authorize PAs to practice to the full extent of their license in IRFs.

Agency Contact(s) – Kadie Derby, Catie Cooksey, and Gwendolyn Johnson

Regulation 42 CFR § 412.622(a)(3) and (a)(4)

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals or 42 CFR § 412.622: *Prospective Payment Systems for Inpatient Hospital Services: Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised:

42 CFR § 412.622(a)(3)(iv), 42 CFR § 412.622(a)(4)(i)(D), and 42 CFR § 412.622(a)(4)(ii)(A) should be rescinded through a Direct Final Rule because they are duplicative with 42 CFR § 412.299(e), 42 CFR § 412.299(d) and 42 CFR § 412.299(h), respectively, and are unnecessary.

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

42 CFR § 412.622 is amended by deleting paragraphs (a)(3)(iv), (a)(4)(i)(D), and (a)(4)(ii)(A).

Short summary of the justifications for the rescission or revision.

The regulations are duplicative with other regulations and are not necessary. Further, they conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including completing and reviewing screenings and treatment plans and perform face-to-face encounters. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden.

Reasons for the rescission or revision.

IRF Conditions for Coverage have limitations and restrictions that do not exist in hospitals, medical offices, and many other settings, and which conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs have the training, experience, and competency to complete and review screenings and treatment plans and perform face-to-face encounters. These services are consistent with PA education, training, and scope of practice and are performed with high-quality and safety in non-IRF settings.

The regulations do not represent the current practice of medicine, in which PAs are recognized as providing high-quality, cost-effective healthcare with, according to the Medicare Payment Advisory Commission, "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf). Further, PAs are authorized to lead interdisciplinary teams in other settings, including in Community Mental Health Centers (42 § 485.916(a)(1)).

Removing limitations to the services PAs are otherwise state-licensed to provide is consistent with the Administration's directive to improve workforce competition and is consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Allowing PAs to provide all medically necessary services and lead interdisciplinary teams will expand the workforce available to IRFs and increase efficiency by allowing staffing decisions to be made by the qualification and availability of practitioners, instead of making staffing decisions based on restrictive regulations.

Background for the regulation.

The regulation specifies requirements for coverage of services in IRFs. CMS proposed in the calendar year (CY) 2019 IRF PPS proposed rule (83 FR 20972) to expand the use of PAs and other non-physician

practitioners (NPPs), in part, by removing all the face-to-face requirements for rehabilitation physician visits. However, in the CY 2019 IRF PPS final rule [CMS-1688-F] RIN 0938-AT25, the requirements in § 412.622(a)(3)(iv) and § 412.622(a)(4)(ii) were amended to only authorize PAs and other NPPs to provide some of the physician requirements. The regulations should be further amended as previously proposed to authorize PAs to practice to the full extent of their license in IRFs.

Agency Contact(s) – Kadie Derby, Catie Cooksey, and Gwendolyn Johnson

Regulation 42 CFR § 412.622(a)(5)

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals or 42 CFR § 412.622: *Prospective Payment Systems for Inpatient Hospital Services: Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units*

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622

Title, parts, and/or sections of the C.F.R. that should be rescinded or revised:

42 CFR § 412.622(a)(5)(i) should be revised through a Direct Final Rule to authorize PAs to lead interdisciplinary team meetings.

Text of the relevant C.F.R. provisions as it will exist after the rescission or revision.

42 CFR § 412.622 is amended by revising paragraphs (a)(5)(i) and (iii) to read as follows:

42 CFR § 412.622 Basis of payment.

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(a)***

(5) ***

> i. The team meetings are led by a rehabilitation physician or physician assistant and further consist of a registered nurse with specialized training or experience in rehabilitation; a social worker or case manager (or both); and a licensed or certified therapist from each therapy discipline involved in treating the patient. All team members must have current knowledge of the patient's medical and functional status. The rehabilitation physician or physician assistant may lead the interdisciplinary team meeting remotely via a mode of communication such as video or telephone conferencing.
>
> ii. ***
>
> iii. The results and findings of the team meetings, and the concurrence by the rehabilitation physician or physician assistant with those results and findings, are retained in the patient's medical record.

Short summary of the justifications for the rescission or revision.

The regulations conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State, including completing and reviewing screenings and treatment plans and perform face-to-face encounters. Amending these regulations will increase workforce adequacy, improve efficiency, and decrease administrative burden

Reasons for the rescission or revision.

IRF Conditions for Coverage have limitations and restrictions that do not exist in hospitals, medical offices, and many other settings, and which conflict with the statutory authority of section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide "physicians' services" they are authorized to perform by the State. PAs have the training, experience, and competency to complete and review screenings and treatment plans and perform face-to-face encounters. These services are consistent with PA education, training, and scope of practice and are performed with high-quality and safety in non-IRF settings.

The regulations do not represent the current practice of medicine, in which PAs are recognized as providing high-quality, cost-effective healthcare with, according to the Medicare Payment Advisory Commission, "health outcomes that are equivalent to physician-provided care" (https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf). Further, PAs are authorized to lead interdisciplinary teams in other settings, including in Community Mental Health Centers (42 § 485.916(a)(1)).

Removing limitations to the services PAs are otherwise state-licensed to provide is consistent with the Administration's directive to improve workforce competition and is consistent with recommendations in the 2018 federal government report on healthcare competition entitled, *Reforming America's Healthcare System Through Choice and Competition*, in which the U.S. Departments of Health and Human Services, Treasury, and Labor recommended removing supervision requirements for PAs that are "not justified by legitimate health and safety concerns" and authorizing PAs to "practice to the top of their license" and utilize "their full skill set" (https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf).

Allowing PAs to provide all medically necessary services and lead interdisciplinary teams will expand the workforce available to IRFs and increase efficiency by allowing staffing decisions to be made by the qualification and availability of practitioners, instead of making staffing decisions based on restrictive regulations.

Background for the regulation.

The regulation specifies requirements for coverage of services in IRFs. CMS proposed in the calendar year (CY) 2019 IRF PPS proposed rule (83 FR 20972) to expand the use of PAs and other non-physician practitioners (NPPs), in part, by removing all the face-to-face requirements for rehabilitation physician visits. However, in the CY 2019 IRF PPS final rule [CMS-1688-F] RIN 0938-AT25, the requirements in § 412.622(a)(3)(iv) and § 412.622(a)(4)(ii) were amended to only authorize PAs and other NPPs to provide

some of the physician requirements. The regulations should be further amended as previously proposed to authorize PAs to practice to the full extent of their license in IRFs.

Agency Contact(s) – Kadie Derby, Catie Cooksey, and Gwendolyn Johnson

Regulations Promulgated by the Food and Drug Administration that Should be Rescinded or Revised

U.S. Food and Drug Administration
Martin A. Makary, M.D., M.P.H, Commissioner
10903 New Hampshire Avenue, Silver Spring, MD 20993

Regulations 21 CFR § 606.110, 21 CFR § 606.151 and 21 CFR § 606.160

Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use or 21 CFR § 606.110, 21 CFR § 606.151 and 21 CFR § 606.160.

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606/subpart-F/section-606.110

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606/subpart-H/section-606.151

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-606/subpart-I/section-606.160

Title, parts, and/or sections of the C.F.R. should be rescinded or revised.

The following should be revised through a Direct Final Rule:

21 CFR § 606.110(a)(1) and (2) should be revised to authorize physician assistants (PAs) to determine when a recipient must be transfused with the leukocytes or platelets from a specific donor and supervise the procedure.

21 CFR § 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.

21 CFR § 606.160(b)(1)(iv) should be revised to allow records to include signed requests from PAs for therapeutic bleedings.

21 CFR § 606.160(b)(3)(v) should be revised to authorize PAs to order and sign for the emergency release of blood.

Text of the relevant C.F.R. provisions as they will exist after the rescission or revision.

21 CFR § 606.110 is amended by revising paragraphs (a)(1) and (2) to read as follows:

21 CFR § 606.110 Plateletpheresis, leukapheresis, and plasmapheresis.

(a) ***

(1) A physician or physician assistant has determined that the recipient must be transfused with the leukocytes or platelets from a specific donor, and

(2) the procedure is performed under the supervision of a responsible physician or physician assistant who is aware of the health status of the donor, and the physician or physician assistant has determined and documented that the donor's health permits plateletpheresis or leukapheresis.

21 CFR § 606.151 is amended by revising paragraph (e) to read as follows:

21 CFR § 606.151 Compatibility testing.

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(e) Procedures to expedite transfusion in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by a physician or physician assistant.

21 CFR § 606.160 is amended by revising paragraph (b)(1)(iv) to read as follows:

21 CFR § 606.160 Records.

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(b) ***

(1) ***

(iv) Therapeutic bleedings, including signed requests from a physician or physician assistant, the donor's disease and disposition of units.

21 CFR § 606.160 is amended by revising paragraph (b)(3)(v) to read as follows:

21 CFR § 606.160 Records.

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(b) ***

(3) ***

(v) Emergency release of blood, including signature of requesting physician or physician assistant obtained before or after release.

Short summary of the justifications for the rescission and revision.

The regulations conflict with the authority of Section 1861(s)(2)(K)(i)) of the Social Security Act for PAs to provide “physicians’ services” they are authorized to perform by the State

Reasons for the rescission or revision.

21 CFR § 606.110(a)(1) and (2), 21 CFR § 606.151(e), 21 CFR § 606.160(b)(1)(iv), and 21 CFR § 606.160(b)(3)(v) conflict with the statutory authority of Section 1861(s)(2)(K)(i)) of the Social Security Act

for physician assistants (PAs) to provide "physicians' services" they are authorized to perform by the State. Additionally, a physician determination and signature after administration is an administrative burden that does not benefit patient care. A physician's determination is also 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.

Background for the regulation.

The rules relate to the manufacturing and administration of blood and blood products. The last known revision to the regulations was through a Direct Final Rule published in the Federal Register on August 19, 1999 and revised in 2015 (https://www.federalregister.gov/documents/2001/01/10/01-533/revisions-to-the-requirements-applicable-to-blood-blood-components-and-source-plasma-confirmation-in).

Agency Contact - Anne Eder, CBER

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). 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 Assistant), 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 organizations, professional training programs, and state and territory laws and licensure. 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."

Conclusion

The identified regulations are not based on statute or the current practice of medicine. The 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 while providing comparable outcomes.

AAPA appreciates the opportunity to provide recommendations to the Office of Management and Budget and welcomes further discussion with the Centers for Medicare and Medicaid Services and U.S. Food and Drug Administration 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,

Sondra M. DePalma, DHSc, PA-C
Vice President, Reimbursement and Professional Practice
American Academy of Physician Associates