

September 24, 2019

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1716-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

RE: 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 [CMS-1715-P | RIN 0938-AT72]

Dear Administrator Verma:

The American Nurses Association (ANA) submits the following comments in response to the above-captioned Notice of Proposed Rulemaking (NPRM).

ANA whole-heartedly supports the practice reforms proposed in the NPRM and urges additional steps in the final rule and future rulemakings.

Overall, ANA is encouraged by CMS' progress, in this NPRM, to reduce barriers to practice for non-physician practitioners (NPPs) in the Medicare program. The NPRM focuses specifically on physician assistants (PAs), which singles out only one type of NPP. We urge CMS in the final rule to recognize the importance of full practice authority for advanced practice registered nurses (APRNs). APRNs in Medicare are subject to various restrictions such as physician supervision requirements even when state laws do not impose such rules. The "incident-to" billing rules further constrain APRN participation in the program.

It is imperative that CMS ensure that payment rules applied to APRNs do not have the effect of restricting patient access and choice. The Medicare Payment Advisory Commission (MedPAC) recently reported that Medicare beneficiaries are increasingly relying on APRNs as well as PAs for primary care.² The MedPAC analysis and recommendations are discussed more below. In addition, federal restrictions on APRN practice can have systemic consequences, especially in rural, underserved, and appointment shortage areas, where innovative models are sorely needed to ensure access and improve care experience, as well as increase quality and manage costs.

ANA proposes the following in our comments on the proposed rule.

- ***CMS finalize acceptance of the CPT codes, CPT guidelines and RUC recommendations exactly as implemented by the CPT Editorial Panel and submitted by the RUC.***

- ***CMS should support the health care community in recommending Congress implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.***
- ***Encourage Congress to support MedPAC recommendations related to Incident To billing.***
- ***Through regulatory language or clarifying guidelines, CMS should address how APRNs will be protected from risk of error associated with incident to billing rules and practices in relation to Open Payments.***
- ***CMS engage stakeholders throughout the MVP development process and ensure representation of the full range of front-line providers including APRNs.***
- ***CMS finalize the provisions of payment for Medicare telehealth services.***
- ***CMS allow for add-on codes for additional counseling or therapy services to ensure individualized quality patient care for opioid addiction.***
- ***CMS expand the role of APRNs in hospice care, including Nurse Practitioners (NPs) and Certified Nurse Specialists (CNSs), by allowing them to admit patients to hospice, as well as certify and recertify patients for hospice care.***

Payment for Evaluation and Management (E/M) Visits

ANA agrees with the CMS proposal to align the previously finalized E/M office visit coding changes with the framework adopted by the CPT Editorial Panel. The policy changes for the E/M office visits would be effective for services starting January 1, 2021. The CPT coding changes will retain 5 levels of coding for established patients; reduce the number of levels to 4 for new patients (by deleting 99201); and revise the code definitions and guidelines. A new CPT code for extended office visit time will also be implemented. The changes also revise the times and medical decision-making definitions for the office visit codes. History and physical exams should continue to be performed as medically appropriate; however, these elements will no longer be a consideration for code level selection. Health care professionals can choose the E/M visit level based on either medical decision making or time. ANA understands that this new coding framework will lead to administrative burden relief and better describe office visits as they are performed today.

ANA appreciates the confidence CMS displays in the RUC process in proposing to adopt the RUC recommended work values, health care professionals' times and practice costs for the stand-alone E/M office visits. CMS states, "The RUC recommendations reflect a rigorous robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians." In fact, one of the most consistent findings of the survey was that all specialty data indicated an increased complexity and time spent in providing office visits. ANA was one of the over 50 specialty societies that participated in this survey process, and our members contributed significantly to the recommendations that the RUC ultimately made to CMS. ANA believes that the new CPT framework, where code selection is dependent on time spent or the level of medical decision-making, inherently defines the work to be equivalent, regardless of the health care professional's specialty.

Based on the information provided in the *Proposed Rule*, the RUC recommendations for work, time and direct practice expenses contribute to a 5-6 percent redistribution between those health care professionals who routinely provide office visits and those health care professionals who do not report office visits. This is a significant reduction to absorb into practices that are already practicing at maximum efficiency.

Care Management Services

Beginning in late 2011, the CPT Editorial Panel and the RUC led the effort to describe and value care management services. Health care professionals and their staff had increasingly engaged in non-face-to-face services that, while uncompensated, were critically important to their patients. Care management services provide patients with higher quality care and save the Medicare program money by reducing readmissions and emergency room visits. Registered nurses play a crucial role in delivering these care management services.

ANA's official position statement on *Care Coordination and Registered Nurses' Essential Role* states that, "Patient-centered care coordination is a core professional standard and competency for all registered nursing practice. Based on a partnership guided by the healthcare consumer's and family's needs and preferences, the registered nurse is integral to patient care quality, satisfaction, and the effective and efficient use of health care resources. Registered nurses are qualified and educated for the role of care coordination, especially with high risk and vulnerable populations."¹ ANA's official position statement further states that, "In partnership with other healthcare professionals, registered nurses have demonstrated leadership and innovation in the design, implementation, and evaluation of successful team-based care coordination processes and models."

ANA is supportive of efforts to increase the utilization of these services and expand care management to additional patients and urges CMS to recognize that the role of the RN in care management services should be accurately conveyed through the practice expense portion of the relative-value units for these care management codes. It is also unfair to ask health care professionals to pay for these newly described services by redistributing money away from other important services. CMS must account for the savings for these services in decreased hospital visits and emergency visits to offset the cost of new coverage of the Principal Care Management (PCM) codes.

Billing Incident To Physician Services

ANA strongly supports MedPAC's June 2019 recommendation that Congress eliminate *incident to* billing for APRNs and PAs. In the absence of an administrative pathway, it is incumbent upon CMS to work with Congress to implement this recommendation. Under *incident to* billing, Medicare allows APRNs to bill under the national provider identifier (NPI) of a supervising physician if certain conditions are met. Medicare pays for services at 100 percent of the fee schedule rate when a service provided by an NP, CNS, or PA is billed *incident to* and 85 percent of the fee schedule rate when the same service is billed under the NPI of the NP, CNS or PA who provided the service.²

¹ American Nurses Association. *ANA Official Position Statement: Care Coordination and Registered Nurses' Essential Role*. June 2012. Web: <https://www.nursingworld.org/practice-policy/nursing-excellence/official-position-statements/id/care-coordination-and-registered-nurses-essential-role/>

² Medicare Payment Advisory Commission. (2019). Report to the Congress: Medicare and the Health Care Delivery System. 128. http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0.

MedPAC's June 2019 report notes that, "the Commission has concerns about the supply of primary care physicians, but that the number of APRNs and PAs has increased rapidly and is projected to continue to do so in the future. Medicare beneficiaries rely on APRNs and PAs to provide an increasingly substantial share of their medical services."³ According to CMS' Medicare Part B billing data, NPs were the largest specialty group billing services to Medicare with 130,406 unique providers; this number does not account for the NPs who billed all Medicare services *incident to*.⁴ MedPAC's June 2019 report also notes that states have steadily increased NPs' and PAs' scopes of practice, and the vast majority of research indicates that NPs and PAs provide care that is substantially similar to physicians in terms of clinical quality outcomes and patient satisfaction within the confines of their respective scopes of practice.⁵

Eliminating *incident to* billing would give APRNs more autonomy in practice, particularly in providing primary care services to beneficiaries in areas with a shortage of primary care providers. In addition, the use of *incident to* billing means that Medicare lacks information about who is treating beneficiaries and providing which services. This lack of transparency in turn may undermine the appropriate valuation of fee schedule services and create a potential program integrity vulnerability because Medicare pays higher rates for services when they are billed *incident to* and masks the positive impact of APRNs and PAs on the health care system. The absence of data attributed to APRNs for the services they provide also affects their ability to appropriately participate in performance measurement programs and threatens their ability to be listed along with other health professionals on performance measure websites, such as Physician Compare.

Eliminating *incident to* billing would accrue positive benefits to providers, beneficiaries, and the Medicare program. It would create transparency with respect to reimbursement and quality outcomes and allow Medicare beneficiaries to have a clearer picture as to who is providing their care even as a greater share of beneficiaries receive primary care services from APRNs. It would also allow the Medicare program to more accurately value reimbursement for services – particularly evaluation and management services in the primary care setting – and allow more providers to participate in performance measurement programs.

Open Payments

CMS proposes through this rulemaking to implement statutory changes to the Open Payments program. The Open Payments program was created as a result of section 6002 of the ACA, requiring reporting and public disclosure of certain payments or transfers of value provided to physicians and teaching hospitals. The provision was intended to promote program integrity and address potential conflicts of interest in transactions between manufacturers and providers that could affect treatment decisions.⁶

³ MedPAC 2019. 127.

⁴ Centers for Medicare & Medicaid Services, Office of Enterprise and Data Analytics, CMS Chronic Conditions Warehouse. Medicare Providers: Number of Medicare Non-Institutional Providers by Specialty, Calendar Years 2013-2017. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2017/Downloads/PROVIDERS/2017_CPS_MDCR_PROVIDERS_6.PDF

⁵ MedPAC 2019. 127.

⁶ 78 Federal Register 9458 (February 8, 2013). CMS. Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests. Final Rule. Accessible at <https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf>. See also Richardson, Elizabeth. The Physician Payments Sunshine Act. Issue Brief. Health Affairs. October 2014.

The SUPPORT Act of 2018 expanded the list of covered recipients to include APRNs, specifically naming NPs, CNSs, Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse Midwives (CNMs), as

well as PAs. To revise Open Payments regulations accordingly, CMS proposes to define these APRN types by reference to existing definitions found in section 1861 of the Medicare law. We generally concur that section 1861 is an appropriate reference to describe the characteristics of the practitioner types added by the SUPPORT Act. However, we are concerned that the proposal does not address the potentially confounding factor of Medicare's "incident to" billing policy.

As discussed in the preceding section of this letter, Medicare allows APRNs to bill under the NPI of a supervising physician if certain conditions are met. Medicare pays for services at 100 percent of the fee schedule rate when a service provided by a NP, CNS, or PA is billed *incident to* and 85 percent of the fee schedule rate when the same service is billed under the NPI of the NP, CNS or PA who provided the service.⁷ MedPAC estimates that fully half or more of NP services are billed in this manner.⁸

Incident-to billing creates a unique hazard for APRNs now subject to Open Payments regulations. Specifically, transfers of value could be misattributed to an APRN, when the actual or intended recipient is a physician who engages APRNs and requires them to bill *incident to* physician services. We are concerned that existing provisions in 42 CFR 403.908 do not offer an adequate process for addressing this specific type of error. These provisions allow covered recipients to dispute reported data that comes to their attention in a certain time period. However, an APRN may not even know about a transfer, does not benefit from it, and in fact has no agency in the practice. Even if they are aware of an error in Open Payments reporting, they may not have the means or authority, e.g., as an employee, to ensure that inaccurate information is corrected. Errors in identifying actual recipients in a practice could be misleading to public viewers of Open Payments data, while potentially prejudicing individual APRNs.

MIPS and MIPS Value Pathway

The NPRM presents an initial framework for a MIPS Value Pathway (MVP). The MVP addresses some of the challenges CMS and stakeholders have identified for small practices and individual clinicians to participate in MIPS in its current form. The proposed MVP framework would restructure MIPS to reduce burden on participants and develop quality information that is more meaningful for patients. At the same time, the MVP is intended to support clinicians to move into advanced alternative payment models (APM), as envisioned by the Medicare Access and CHIP Reauthorization Act.

ANA appreciates CMS' objective to simplify MIPS for clinicians, while also centering improvements on patients. We believe that this process must also center payment and delivery reforms on non-physician practitioners, including RNs and APRNs. Nurses are indispensable to delivery of high-quality care in all settings, providing hands-on, high-touch care, and care coordination. Yet ANA has heard from our members, especially APRNs, that they face significant challenges participating meaningfully in existing quality and value incentive programs. Some of the reasons include payment models that do not account for the value of nursing care, a lack of relevant measures and measurement strategies, and unnecessary

⁷ Medicare Payment Advisory Commission. (2019). Report to the Congress: Medicare and the Health Care Delivery System. http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0.

⁸ *Ibid*.

regulatory restrictions on APRN practice in Medicare. We believe that the MVP development process should seek to address these challenges and commit to an innovation agenda that rewards and incentivizes RN and APRN care.

Some of our specific suggestions include:

- For MVP measure sets, identifying and selecting clinical quality measures that are sensitive to nursing care in non-hospital settings.
- Reporting patient-facing quality metrics that recognize the role of non-physician practitioners in all health care settings.
- Developing patient experience measures of nursing care in non-hospital settings.
- Within HHS and with external stakeholders, developing a research agenda to document and understand the roles of NPPs in non-hospital care and the data needed to incorporate their care in payment and delivery models.
- Collaborating with the Health Resources and Services Administration (HRSA) to test models for APRN care in rural areas.

Payment for Medicare Telehealth Services

ANA supports CMS' proposed codes for telehealth services as it relates to the SUPPORT Act and Substance Use Disorders (SUDs). ANA supports the continued actions of CMS to take steps to combat the opioid epidemic by removing barriers for patients to access care. The act of removing the geographic restriction on telehealth services for patients diagnosed with SUDs, allows patients more options to access the care needed. We encourage the agency to continue to collect data on telehealth access and use for underserved and appointment shortage areas.

Moreover, as previously requested, recognizing all APRN groups and the services they provide in their community can help address the epidemic. Provider neutral language in regulation for coverage and payment parity can help ensure that all APRNs are practicing to the full extent of their education and training, reaching underserved populations, especially in rural communities that have been hit the hardest with provider shortages. These providers can also help provide the technology and coordination to other specialty providers when needed. RNs also have a role in providing access to telehealth services. Through better research and data collection, CMS could direct services that can and should be furnished through RNs in order to provide quality and cost-effective care including but not limited to care coordination, remote patient monitoring, and substance use disorder treatment. Improved patient outcomes can be obtained when identification of changes occur therefore preventing unnecessary trips to the emergency department of readmission into a healthcare facility.

Bundled Payments Under the PFS for Substance Use Disorders

In the proposed rule, CMS suggests a new bundled HCPCS code for office-based treatment for opioid use disorder, including care coordination, individual therapy, and group therapy and counseling. ANA does have concern with limiting the bundle to one substance use counseling session, one individual therapy session, and one group therapy session per week. We recognize that the agency understands that a patient may have needs outside of this proposed bundle and would recommend allowing for add-on codes for additional counseling or therapy services. Because of the potential for multiple chronic and

acute conditions that can influence this patient population, there is an increased need to coordinated and individualized care plans that address all the social, emotional, and physical needs of the patient.

Moreover, for patients with multiple chronic conditions facing a lifetime of treatment and recovery services, we encourage CMS to recognize the role nurses play in care management and care coordination services as part of the bundled payment. Careful coordinated care that is thoughtful and effective rather than punitive is essential to individualized care for all patients. Moreover, individualized coordinated care can reduce cost to the Medicare program, reduce burden on providers and patients, and ultimately improve care.

Deferring to State Scope of Practice Rules – ASCs and Hospice

ANA appreciates and supports CMS' ongoing efforts to address practice barriers that unnecessarily impede patient access and delivery of timely, high-quality care. The NPRM addresses scope of practice in several areas, through specific proposals and requests for additional public comment for future consideration. ANA urges CMS to expand APRN scope in particular through the final rule. All four APRN groups (NPs, CNSs, CRNAs and CNMs) should be included.

Supported by a growing body of evidence of the safe and cost-effective provision of care by APRNs, there is a national call to remove all barriers to full practice authority from organizations such as the Institute of Medicine, the National Governors Association, the Federal Trade Commission, the Veteran's Health Administration, and the Bipartisan Policy Center, among others.¹¹ This year, in *Reforming America's Healthcare System Through Choice and Competition*, the Administration discussed in depth the anticompetitive effects of APRN practice restrictions.¹² ANA has been a leader in support of efforts to remove state-based restrictions. However, we strongly believe that federal policy solutions are also needed, including Medicare regulatory and administrative reforms.

In the NPRM, CMS takes a helpful step forward for APRNs in ambulatory settings. Specifically, CMS proposes to allow CRNAs, as well as physicians, to perform anesthetic risk and evaluation prior to surgery at Ambulatory Surgical Centers (ASCs). Currently, rules permit CRNAs to perform this work post-surgery in anticipation of discharge. We agree with CMS that aligning these standards will enhance continuity surgical care at ASCs, and more fully recognize the CRNA professional role.

ANA further urges CMS to take additional steps, in the final rule, to remove regulatory barriers to APRN practice in Medicare. One area for action in this rulemaking is hospice care. The NPRM includes a request for comment on a series of questions related to roles and practice scopes on hospice care teams. ANA appreciates the opportunity to comment on the current and future role of NPPs in Medicare hospice care. The role of the APRN is essential in the care of hospice patients, as part of the interdisciplinary team. Considering the increase in chronic illnesses and an aging population, the expansion of the APRN role and inclusion of other NPPs must be considered in the hospice model of care to continue to provide high-quality care to patients.

Currently, the APRN role in hospice is distinct from the physician role in that, at this time, APRNs are not able to certify hospice eligibility, nor can they be responsible for interdisciplinary team meetings. ANA believes that all NPPs should have the ability to be equally involved in core hospice services, within the scope of their state practice laws.

ANA is the premier organization representing the interests of the nation's 4.0 million RNs, through its state and constituent member associations, organizational affiliates, and individual members. ANA members also include the four advanced practice registered nurse roles (APRNs): Nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs).⁹ ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

If you have questions, please contact Brooke Trainum, JD, Assistant Director of Policy and Regulatory Advocacy, at (301) 628-5027 or brooke.trainum@ana.org.

Sincerely,



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Chief Nursing Officer/EVP

cc: Ernest Grant, PhD, RN, FAAN, ANA President
Loressa Cole, DNP, MBA, RN, NEA-BC, FACHE, ANA Chief Executive Officer

⁹ The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.