October 5, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-1816

Submitted electronically to www.regulations.gov

RE: Medicare Program: CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment For Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

The American Nurses Association (ANA) is pleased to provide comments on the Centers for Medicare and Medicaid Services (CMS) CY 2021 Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies proposed rule, file code CMS-1734-P. ANA supports CMS' continued efforts to reduce unnecessary and burdensome regulatory barriers to access high-quality and affordable care. Through this comment letter, we urge CMS to:

- Make permanent reimbursement for audio-only technologies following the public health emergency to enable the 32 percent of the adults aged 65 and older who lack access to a computer, smart phone, or tablet with internet access at home, the ability to receive quality care.
- Expand the definition of treatment services for opioid use disorder (OUD) to include opioid antagonist medications, such as naloxone.
- Permanently remove federal barriers to Advanced Practice Registered Nurse (APRN) practice that go beyond state regulation, specifically supervision requirements in diagnostic testing.
- Use provider-neutral language in all future rulemaking.

Telehealth and other services involving Communications Technology
During the COVID-19 Public Health Emergency (PHE), APRNs, registered nurses (RNs) and patients have benefited from the expansion of services provided by telehealth technologies. We are encouraged by CMS's interest in learning from providers, patients, and the data to expand the Medicare Telehealth Services List, including remote patient monitoring which we know is important for patients to observe safe distancing when access to facilities is restricted and healthcare resources are strained. Additionally, coverage of telephone/audio-only visits has been vitally important to nurses and their patients who report difficulty accessing and utilizing other technologies such as computers, smartphones, or tablets.

8515 Georgia Ave., Suite 400
Silver Spring, MD 20910
www.nursingworld.org

An April 2020 poll by Kaiser Family Foundation found that 32 percent of the adults aged 65 and older did not have access to a computer, smart phone, or tablet with internet access at home.[1]

In the proposed rule, CMS proposes to alter the definition of an "interactive telecommunication system" in the Code of Federal Regulation 410.78 so that second sentence of the current definition, which completely excludes telephone from the definition is deleted, however that does not address the first sentence that would continue to limit the use of the telephone. ANA does not believe the definition needs to be limited, and we recommend that CMS consider the broader definition of a telecommunication system that allows for both telephone and store-and forward modalities.

ANA also supports the continuation of the waiver of 42 CFR § 483.30 for physicians and non-physician practitioners to personally perform required visits for nursing home residents via telehealth. This waiver allows the flexibility for a provider to determine the best tool to use to evaluate the beneficiary based on a clinician's education and training and the needs of the patient. This would also allow care to continue during future emergencies or disasters.

The proposed CY 2021 PFS also proposes continuation of a change made during the PHE to permit direct supervision to be provided using real-time, interactive audio and visual technology through the end of the calendar year in which the PHE ends or December 31, 2021. Instead of continuing a burdensome and unnecessary rule through a different modality, ANA requests CMS to review and remove costly and unnecessary physician supervision requirements of APRNs. There is no evidence that the physician supervision requirements contribute to higher quality, lower cost, greater value, or access to healthcare. ANA's position on federal practice restrictions is explored more fully below.

Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

ANA supports CMS's proposal to expand the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by the U.S. Food and Drug Administration under section 5050 of the FFDCA for emergency treatment of opioid overdose. ANA also agrees with the proposal based on the public health advisory that education related to overdose prevention should be included in the expanded definition of OUD treatment services. Proven harm reduction techniques to prevent unnecessary death, should be covered when provided to the patient, as part of the weekly payment bundle. ANA cautions CMS in creating an add-on code for education as this could limit the education a patient or their support system may get, depending how CMS defines the ability to utilize the code. We know that it is important to meet the patient where they are, and limits on codes should not be a barrier to education when the time is right and as often as necessary to prevent death.

APRN Scope of Practice

HHS proposes to amend 42 CFR § 410.32(b) to allow Nurse Practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and physician assistants (PAs) to supervise diagnostic tests, to the extent allowed by state practice regulations. ANA supports this step to remove a set of federal practice restrictions that reach further than some state rules governing practice of advanced practice registered nurses (APRNs). We also recommend including certified registered nurse anesthetists (CRNAs) in the group of clinicians authorized to supervise diagnostic tests. As noted in the NPRM, diagnostic

[1] Accessible at https://www.kff.org/policy-watch/possibilities-and-limits-of-telehealth-for-older-adults-during-the-covid-19-emergency/

testing takes a range of forms and complexity, from a simple throat swab to more invasive procedures. States traditionally determine the education and training needed to administer various tests within their borders and may further specify the professionals who are qualified to supervise this care. States recognize APRNs in supervisory roles for diagnostic testing. APRNs are bound by the rules in their state, and additional federal regulatory barriers serve only to restrict access for Medicare beneficiaries.

The proposed change to § 410.32(b) is supported by the National Academy of Medicine's (NAM) report titled The Future of Nursing: Leading Change, Advancing Health, which outlines how expanded APRN practice can improve access and quality, while controlling costs.[2] The NAM report specifically recommends that APRNs should be able to practice to the full extent of their education and training."[3] Removing these federal supervisory rules, as proposed, is also consistent with the President's October 3, 2019, Executive Order on Protecting and Improving Medicare for Our Nation's Seniors. We would also urge CMS to work with Congress to remove barriers that cannot be addressed through the rulemaking process.

Amending the basic supervision rule in § 410.32(b) would make permanent one of the dozens of regulatory flexibilities CMS promulgated during the PHE. ANA urges HHS to go further in the Final Rule and make permanent additional flexibilities that improve access through expanded APRN care. Examples of specific additional reforms include: Enhancing and clarifying Medicare payment for APRNs engaged in infectious disease prevention, as seen with COVID-19 testing and contact tracing operations; extending the provision that Medicare patients in hospitals do not have to be under the care of a physician, which improves access to acute care in areas of physician shortages, and potentially expands roles for APRNs in acute care.

The use of provider neutral language in all regulatory rulemaking

ANA continues to request that CMS use provider-neutral language in all rulemaking and administrative guidance. In the proposed rule, provider-neutral language is notably absent from section III.H. *Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services.* APRNs continue to grow the primary care workforce in both urban and rural communities. The March 2019 Medicare Payment Advisory Commission (MedPAC) report notes that APRNs and Physician Assistants billing Medicare grew by 10 percent, based on Medicare claims from 2015 to 2017.[4] ANA recommends CMS update all regulatory language to use provider neutral language to ensure that all health care practitioners are clearly recognized as being able to provide these and other services as allowed under their state scope of practice.

ANA is the premier organization representing the interests of the nation's 4.2 million registered nurses (RNs) through its state and constituent member associations, organizational affiliates, and the individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on healthcare issues that affect nurses and the public. RNs serve in multiple direct care, care coordination, and administration leadership roles, across the full spectrum of health care settings. RNs

[2] Institute of Medicine. The Future of Nursing: Leading change, advancing health. Washington, DC: The National Academies Press. 2011.

[3] Ibid., page 9.

[4] Medicare Payment Advisory Commission. Report to Congress: Medicare Payment Policy. March 2019. Accessible at http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf?sfvrsn=0

provide and coordinate patient care, educate patients and the public about various health conditions including essential self-care, and provide advice and emotional support to patients and their family members. ANA members also include the four APRN roles: NPs, CNSs, CNMs and CRNAs. ANA is dedicated to partnering with health care consumers to improve practice, policies, delivery models, outcomes, and access across the health care continuum.[5]

We look forward to engaging with CMS staff on the issues outlined in this comment letter. If you have any questions, please contact Ingrida Lusis, Vice-President, Policy and Government Affairs, at Ingrid.Lusis@ana.org or (301) 628-5081.

Sincerely,

Debbie Hatmaker, PhD, RN, FAAN
Acting Chief Executive Officer

cc: Ernest Grant, PhD, RN, FAAN, ANA President

[5] 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.