September 13, 2021

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, Maryland 21244-8016

RE: CMS–1751–P; Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure,

The American Association of Nurse Practitioners (AANP), representing more than 325,000 nurse practitioners (NPs) in the United States, appreciates the opportunity to provide comment on the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule. AANP is committed to working with CMS on modernizing the health care delivery system to provide the highest quality care to patients across the country.

As you know, NPs are advanced practice registered nurses who are prepared at the masters or doctoral level to provide high-quality primary, acute, chronic and specialty care to patients of all ages and backgrounds. Daily practice includes assessment; ordering, performing, supervising and interpreting diagnostic and laboratory tests; making diagnoses; initiating and managing treatment including prescribing medication and non-pharmacologic treatments; coordinating care; counseling; and educating patients and their families and communities. NPs hold prescriptive authority in all 50 states and the District of Columbia (D.C.) and perform more than one billion patient visits annually. Currently, twenty-four states and D.C. are considered Full Practice Authority (FPA).2 No state has ever moved away from FPA once it has been enacted.

NPs practice in nearly every health care setting including hospitals, clinics, Veterans Health Administration and Indian Health services facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), skilled nursing facilities (SNFs) and nursing facilities (NFs), schools, colleges and universities, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health care settings.

As of 2019, there were more than 163,000 NPs billing for Medicare services, making NPs the largest and fastest growing Medicare designated provider specialty.3 Approximately 40% of Medicare patients receive billable services from a nurse practitioner4 and approximately 80% of NPs are seeing Medicare and Medicaid patients. NPs have a particularly large impact on primary care as approximately 70% of all

NP graduates deliver primary care. In fact, NPs comprise approximately one quarter of the primary care workforce, with that percentage growing annually.

We appreciate the actions taken by CMS to waive Medicare and Medicaid barriers to further enable nurse practitioners to meet the health care needs of their communities during the COVID-19 Public Health Emergency (PHE). NPs have been on the front lines caring for patients throughout the pandemic, and these important actions have improved their capacity to deliver necessary health care to their patients. Please find our comments on specific sections of this proposed rule below.

1. **Practice Expense RVUs (section II.B)**

   - **Clinical Labor Pricing Update**

   The agency proposes to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update. As noted by CMS, clinical labor rates were last updated for CY 2002. We agree with the agency that it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates, and support this proposal.

2. **Telehealth and Other Services Involving Communications Technology (section II.D.)**

   - **Revised Timeframe for Consideration of Services Added to the Telehealth Services List on a Temporary Basis**

   CMS is proposing to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023 to allow for additional time for stakeholders to collect, analyze and submit data on those services to support their consideration for permanent addition to the list on a Category 1 or Category 2 basis.

   **AANP supports this proposal.** The expansion of covered telehealth services under the Category 3 codes has been beneficial for nurse practitioners and their patients. In a 2020 AANP member survey, 76% of nurse practitioners identified federal telehealth waivers as one of the most beneficial flexibilities throughout COVID-19. These flexibilities, including expanded coverage of certain services under category 3, have enabled NPs and other clinicians to reach patients who otherwise may have been unable to receive medically necessary health care, particularly in rural and underserved communities.

   We agree with CMS that a defined timeframe for consideration of coverage under categories 1 and 2 is an important component of the decision-making process. Expanded coverage of certain telehealth policies will be an integral component of providing care moving forward, and these decisions will have a direct impact on clinicians and their patients. As noted in a Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) titled ‘Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic’, “Telehealth policy changes might continue to support increased care access during and after the pandemic.” Ensuring there is an adequate time frame for analysis of the impacts of telehealth is important as the agency considers permanent additions to the telehealth list. Providing stability and ensuring an adequate adjustment period for patients, clinicians and facilities utilizing these services will help prevent confusion and delays in care. We look forward to continuing to

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5 NP Fact Sheet (aanp.org)
6 Rural and Nonrural Primary Care Physician Practices Increasingly Rely On Nurse Practitioners, Hilary Barnes, Michael R. Richards, Matthew D. McHugh, and Grant Martzolf, Health Affairs 2018 37:6, 908-914.
7 Nurse Practitioner COVID-19 Survey (aanp.org)
8 Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020 | MMWR (cdc.gov)
work with the agency on the expansion of telehealth services covered under the PFS, including the permanent coverage of additional telehealth services.

- **Implementation of Provisions of the Consolidated Appropriations Act, of 2021 (CAA)**

The inclusion of coverage of telehealth services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder in the Consolidated Appropriations Act of 2021 is an important step towards expanding access to care for patients seeking mental health treatment. As the agency notes in this proposed rule, “preliminary analysis of Medicare claims data suggest that, for many mental health services that were permanently and temporarily added to the Medicare Telehealth list, there is a steady utilization trend from April 2020 and thereafter.” NPs have made a rapid transition to telehealth, with over half of AANP members reporting their practices have adopted, or increased the use of, telehealth and virtual platforms.\(^9\)

Section 1834(m)(7)(A) of the CAA requires a practitioner to have furnished an in-person, non-telehealth service to a beneficiary within the 6-month period before the date of the telehealth service. While we do not believe that this requirement is necessary to provide care via telehealth, we understand the agency is bound by statute to implement it. **Therefore, we strongly support a flexible implementation of this requirement which recognizes that equitable access to care must be the primary consideration, and that the agency not require additional in person visits beyond the statutory requirements.** Whether an in-person visit is required should be a clinical decision made between the patient and the clinician.

The stigma surrounding mental health, as well as the ongoing COVID-19 pandemic, have led to enhanced challenges for patients accessing mental health care.\(^10\),\(^11\) While the CAA does require an in-person visit, we appreciate the agency’s application of the policy in a manner which lessens the burden on patients. Patients in all geographic areas face challenges accessing care. These can include physical distance from a healthcare facility or limitations to accessible transportation. To comply with the statutory requirements of an in-person, non-telehealth service, patients will be required to overcome those challenges to receive telehealth care. As the agency approaches policy implementation with a focus on equity, it is important to consider the impact these policy changes will have on equitable access to mental health services.

We strongly support the agency’s decision that the in-person service requirement shall not apply to telehealth services furnished for treatment of a diagnosed substance use disorder or co-occurring mental health disorder, or to services furnished in an originating site described in paragraphs (b)(3)(i) through (viii) or (xiii) that meets the geographic requirements specified in paragraph (b)(4) other than (b)(4)(iv)(D).

CMS has also requested feedback on whether the in-person visit requirement could be furnished by a different health care professional than the one furnishing the telehealth services. As the agency states in this proposal, there are several circumstances under which it has historically treated the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual. **We believe that the in-person, non-telehealth service could be furnished by another practitioner with a professional relationship to the practitioner who furnishes the telehealth service.** This would ensure maximum flexibility for patients and providers as they will need to match schedules and availability to fulfill this requirement.

While we do support flexibilities which would allow another practitioner in certain situations to conduct the required in-person visit, we are concerned with the use of the terms “specialty” and “group”. Across

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\(^9\) Nurse Practitioner COVID-19 Survey (aanp.org)

\(^10\) Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020 | MMWR (cdc.gov)

\(^11\) Public Stigma of Mental Illness in the United States: A Systematic Literature Review (nih.gov)
healthcare professions, specialty certifications vary, and there is potential for that requirement to be misinterpreted to deny access to care. We respectfully request that the agency clarify the definitions of the term ‘specialty’ and ‘group’ as they would be applied to clinicians treating patients under these new telehealth coverages. These definitions should recognize the differences among professions, and ensure maximum flexibility for NPs and other professionals conducting these visits.

Nurse practitioners work in various practice environments, and 89% of nurse practitioners are prepared in primary care. Many NPs are also certified in multiple population foci, including Family (69.7%), Adult (10.8%) and Adult-Gerontology Primary Care (7.0%). An application of the specialty/sub-specialty designation which does not recognize or maintain flexibility for these clinicians will result in patients being denied access to care. Therefore, we urge the agency to exercise caution when requiring a practitioner to be of the same ‘specialty’ to provide the requisite in-person service.

With regard to the agency’s use of the term ‘group’ in this proposal, nurse practitioners practice in a wide variety of settings including hospital outpatient clinics, private group practices, hospital inpatient units, urgent care and private NP practices. The context of the term ‘group’ is unclear, and does not provide the necessary clarity on whether it is intended to reflect a particular health care setting, a health care system, a certain group practice, or other parameters. Therefore, we suggest that the agency define its intended use of the term ‘group’, and ensure that it does not restrict health care professionals practicing in similar settings from conducting the in-person visit.

- Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

A critical component of providing telehealth throughout the COVID-19 pandemic has been the CMS coverage of audio-only services. We strongly support the agency proposal to amend the regulation at § 410.78(a)(3) to define interactive telecommunication system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home.

Research shows that NPs are more likely to practice in rural areas and areas of lower socioeconomic and health status. In an AANP membership survey conducted in August, our members reported that the three most significant barriers to telehealth adoptions were patient connectivity issues, patient access to technology and the internet and patient comfort with technology.

For patients experiencing these issues, the coverage of audio-only visits will be an important component of telehealth moving forward. It is important to recognize that individuals may face barriers including access to broadband and technology which may prohibit them from utilizing synchronous two-way technology. Coverage of audio-only mental health telehealth is an essential lifeline for these patients. We

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12 Nurse Practitioners in Primary Care (aanp.org)
13 2020-NP-Sample-Survey-Report.pdf (aanp.org)
14 2020-NP-Sample-Survey-Report.pdf (aanp.org)
appreciate CMS recognizing the importance of audio-only services, and look forward to working with the agency on an implementation that ensures equitable access to patient-centered care.

The agency also proposes to adopt a similar ongoing requirement that an in-person item or service must be furnished within 6 months of the first mental health telehealth service. **We understand this is a requirement of the CAA, and encourage the agency to consider this burden and not adopt any further in-person service requirements than required under statute.** The COVID–19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America, and has highlighted long-standing vulnerabilities in the American health care system. For patients seeking mental health treatment, the issues which prevent them from accessing care existed prior to the pandemic, and will continue to exist beyond its duration. It is important to ensure the provisions intended to maintain program integrity do not also inhibit patient access to care.

As the agency notes within this rule, if a provider within their clinical judgement believes a patient requires an in-person visit, an NP or other provider may schedule that in-person service, regardless of the minimum requirements established by the rule. Nurse practitioners have the education and clinical training required to treat patients as they deem necessary, and we believe the regulatory requirements should allow providers to assess a patient’s needs, and use their clinical judgement to determine the appropriate treatment for a patient. This will ensure that patients have the access to care they need while balancing the requirements of the CAA and program integrity.

The agency also solicited comment on whether it would be appropriate to establish a different interval for telehealth services, for the diagnosis, evaluation, or treatment of mental health disorders, other than for treatment of diagnosed SUD or co-occurring mental health disorder, when furnished as permitted through audio-only communications technology. Coverage of audio-only telehealth has been critical for NPs and patients who do not have access to adequate broadband or technological devices capable of synchronous two-way audio video technology. As the agency notes in the proposed rule, “availability of telehealth services for mental health care via audio-only communications technology would increase access to care. This is especially true in areas with poor broadband infrastructure and among patient populations that do not wish to use, do not have access to, and/or are unable to utilize devices that permit a two-way, audio/video interaction.”

Requiring different intervals for in-person services for individuals seeking mental health treatment through audio-only telehealth would run counter to the objective of increasing care through telehealth, and create regulatory confusion for patients and providers. This modality removes hurdles for certain patient populations, including technological challenges, physical challenges, and the stigma associated with mental health care. Treating this population differently because of the modality of care is not congruent with the objectives of ensuring patient-centered equitable access to care.

**We strongly support the proposal to revise the regulation at §410.78(b)(4)(iv)(D) to specify that the geographic restrictions in §410.78(b)(4) do not apply to telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder after the end of the PHE.** This is important for patients who face issues with transportation and access to health care providers, which impacts both rural and non-rural patient populations.

According to the United States Health Resources and Services Administration (HRSA), there are 5,812 mental health professional shortage areas (HPSA) which impacts 124 million patients across the United States. According to HRSA’s Fiscal Year 2021 third quarter report, there are 3,370 rural mental health

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19 [https://www.govinfo.gov/content/pkg/FR-2021-01-26/pdf/2021-01852.pdf](https://www.govinfo.gov/content/pkg/FR-2021-01-26/pdf/2021-01852.pdf)
HPSAs, and 1,986 non-rural HPSAs. These statistics underscore the importance of the agency’s revised regulations, which would help patients access care, regardless of their geographic location.

CMS is also proposing that for coverage of audio-only services the distant site practitioner has the technical capability at the time of the service to use an interactive telecommunications system that includes video; and the patient is not capable of, or does not consent to, the use video technology for the service. As previously stated, we appreciate the agency’s expanded coverage of audio-only services; however, we are concerned that this provision is unnecessarily limiting. Audio-only telehealth is important for patients and providers who may not have access to broadband capable of supporting two-way, audio/video telehealth services.

If a clinician treats a patient using audio-only technology, it is unclear why they would also need to certify access to technology that they are not using. Furthermore, the agency does not specify in this proposal how a clinician would certify and attest to their ability to meet the proposed criteria. As some providers also face challenges accessing broadband, it is possible that this requirement would restrict access to care, which is counter to the intention of the coverage of audio-only care. Additionally, imposing technological requirements has the potential to place an increased financial burden on practices which have been negatively impacted by the ongoing COVID-19 pandemic. Therefore, we do not support the agency’s proposal to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services.

While we appreciate the agency’s focus on patient safety and program integrity, we also have concerns regarding the proposal to restrict coverage of audio-only services to only level 2 or 3 visits. It is important to recognize clinicians’ ability to utilize their clinical training when determining an appropriate care modality. If a clinician does not believe audio-only treatment is the appropriate mechanism for care, that is a clinical decision which is between the clinician and their patient. The agency’s proposal to exclude certain higher-level services also presumes that a provider is knowledgeable of a patient’s acuity prior to the visit. There may be a situation where the visit begins as a level 2 or level 3 service, and escalates to a level 4 or 5. In this scenario, the provider should be able to bill for the service level they provided.

For mental health services, if a patient is in crisis and seeking mental health treatment, an exclusionary policy may deter them from seeking the treatment they need. We do not support the proposal to exclude level 4-5 codes from the audio-only mental telehealth coverage for this reason. Within the proposal, the agency notes that “maintaining the availability of these services through audio-only communication technology might give patients access to care needed to address their higher level or acute mental health needs in instances where they are unable to access two-way, audio/video communication technology.” We agree with the assessment of these detrimental and negative impacts, and believe is it why the agency should not exclude level 4-5 codes from audio-only mental telehealth coverage.

- **Rural Emergency Hospitals as Telehealth Originating Sites**

We support the proposal to amend the regulation at §410.78, telehealth services, to include rural emergency hospitals as telehealth originating sites beginning in CY 2023. Rural emergency hospitals will provide a critical bridge for communities which lack access to care, and for patients who may face challenges in accessing broadband. Ensuring that these rural emergency hospitals can serve as an originating site will expand equitable access to care for the communities they serve. As the agency establishes regulations for rural emergency hospitals, we emphasize the importance of ensuring nurse practitioners can practice to the top of their license and clinical training.

- **Expiration of PHE Flexibilities for Direct Supervision Requirements**
While this temporary policy during the PHE has helped minimize disease exposure, we continue to have concerns about the overutilization of “incident-to” billing which would be exacerbated by making this policy permanent. The concerns over ‘incident-to’ billing were also expressed by MedPAC in their June 2019 report\textsuperscript{20}. MedPAC recommended “eliminating incident to billing for APRNs”, which would “update Medicare’s payment policies to better reflect current clinical practice.”\textsuperscript{21} The extension of this policy would likely exacerbate the overutilization of incident-to billing and increase Medicare spending. If CMS extends this policy, \textbf{we recommend that it be limited to circumstances where the billing practitioner is supervising clinical staff who are not authorized to bill the Medicare program directly, consistent with MedPAC’s recommendations.}

- \textit{Interim Final Provisions in the CY 2021 PFS Final Rule}

CMS is proposing to permanently adopt coding and payment for CY 2022, HCPCS code G2252 for virtual check-in services, as described in the CY 2021 PFS final rule. \textbf{AANP supports this proposal.}

3. \textbf{Evaluation and Management Visits (section II.F.)}

- \textit{Split (or shared) Visits}

CMS is proposing to amend the “split (or shared)” visit requirements to align with recent changes to the E/M code set by using a time-based evaluation of which clinician should bill for the “split (or shared)” encounter. CMS is also proposing to extend the ability to bill “split (or shared) visits” to new patient visits, critical care services and skilled nursing facility and nursing facility visits.

We appreciate that CMS recognizes the important and growing role of nurse practitioners and other clinicians in health care delivery. As noted above, NPs are the fastest growing Medicare-designated provider specialty and over 40 percent of Medicare beneficiaries receive care from a nurse practitioner. We also appreciate that CMS is attempting to adapt payment policies to reflect a team-based approach to health care, and support team-based care that is focused on the needs of the patient and authorizes all members of the health care team to practice to the full extent of their education and clinical training.

CMS has long recognized nurse practitioners as leaders of health care teams and they are recognized as such within the Medicare and Medicaid programs, and in models such as the Programs for All Inclusive Care for the Elderly (PACE), Direct Primary Care, Comprehensive Primary Care Plus and Independence at Home. NPs are also recognized as health care team leaders in state programs and in Patient-Centered Medical Homes, the Veterans Health Administration and the Indian Health Services, to name a few.

Our concern with this proposal, and the previous “split (or shared)” requirements, is that despite the best intention of CMS there is an inherent incentive within the Medicare program for groups and practices to bill for services under a physician’s NPI because that allows them to be reimbursed at a rate 15 percent higher than if billed by an NP. This increases health care costs and conflict with true team-based care which should be focused on the needs of the patient and empower all clinicians to practice to the full extent of their education and clinical training. Accordingly, we request that CMS meet with NPs and other stakeholders to discuss further.

4. \textbf{Changes to Beneficiary Coinsurance for Different Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests (II.I.)}

\textsuperscript{20} jun19_medpac_reporttocongress_sec.pdf
\textsuperscript{21} Ibid.
The agency proposes to implement Section 122 of the *Consolidated Appropriations Act (CAA)* of 2021, which waives Medicare coinsurance for certain colorectal cancer screening tests. This amends section 1833(a) of the Act to offer “a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test.” The reduced coinsurance will be phased-in beginning January 1, 2022. As noted in this proposed rule, under current regulations the addition of any procedure beyond a planned colorectal cancer screening test results in the beneficiary having to pay coinsurance.

CMS is proposing to modify the current regulations to codify the amendments made by section 122. We support the proposed changes that between CYs 2022 and 2030, the Medicare beneficiary coinsurance for planned colorectal cancer screening tests resulting in additional procedures furnished in the same clinical encounter will be reduced from 20 or 25 percent to zero percent in CY 2030 and remain at zero percent thereafter.

5. **Vaccine Administration Services (section II.J.)**

AANP agrees with CMS that the PHE for COVID-19 has reinforced the importance of preventive vaccines on the health of Medicare beneficiaries and the broader public. As trusted health care providers, NPs continue to play a critical role in COVID-19 vaccination efforts. AANP is a founding member of HHS COVID-19 Community Corps and nurse practitioners are recognized as trusted voices in communities across the country.\(^22\) Using their voice as trusted providers, NPs have been involved with efforts to encourage vaccinations and increase vaccine confidence, especially in hesitant communities.\(^23\)

Nurse practitioners will continue to be important for patients and their families in the vaccination process, both for COVID-19 and other vaccines. We specifically note the drastic decline in childhood vaccinations\(^24\), which will require a comprehensive effort to close this gap in care. Ensuring patients have the option to receive the vaccine from their health care provider of choice is an important component of the vaccination process. As noted by CMS, “the PHE for COVID-19 declaration is still in effect and the United States is in the middle of a national effort to vaccinate as many people against COVID-19 as quickly as possible. This national effort has at least temporarily altered the landscape for vaccines and vaccine administration.” We agree that the COVID-19 PHE has altered the landscape for vaccines and vaccine administration, and believe that some of these changes may be permanent in nature.

We are concerned with the reduction in Medicare payment rates for the administration of preventive vaccines covered by Medicare Part B under section 1861(s)(10) of the Act, including the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. As noted in the proposed rule, the national payment rate for administering these preventative vaccines has declined more than 30 percent since 2015. This is inconsistent with the 2019 World Health Organization (WHO) report which identified vaccine hesitancy as one of the top 10 threats to global health.\(^25\) In fact, our members have reported that as vaccine hesitancy increases, their workload related to routine immunizations does as well.

As trusted healthcare providers, NPs spend an increasing amount of time educating and counseling patients and families about the safety and efficacy of vaccines. As noted by the WHO, “the reasons why


\(^{23}\) [https://www.aanp.org/podcast](https://www.aanp.org/podcast)


\(^{25}\) [Ten threats to global health in 2019 (who.int)](https://www.who.int)
people choose not to vaccinate are complex” and “[h]ealth workers, especially those in communities, remain the most trusted advisor and influencer of vaccination decisions, and they must be supported to provide trusted, credible information on vaccines.”26 We appreciate the agency seeking feedback on this issue, and strongly support CMS using a different process to update the payment rates for administration of the preventive vaccines on an annual basis. It is clear the current process does not result in accurate and sufficient payments to nurse practitioners and other healthcare professionals. **We believe CMS should decouple vaccination codes from the current crosswalk, and instead review and treat them as a wholly separate service.** This will allow CMS to consider routine input from providers on increased workloads for vaccinations, and ensure adequate compensation.

- **At-Home Vaccinations**

In the section discussing COVID-19 at home vaccinations, CMS identifies a patient as ‘hard-to-reach’ because ‘they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID-19 vaccine in settings other than their home.’ It is also noted that ‘these patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.’ As NPs are now the largest group of primary care providers delivering home-visits27, they understand the unique challenges facing these patients.

We agree with CMS on the issues facing ‘hard-to-reach’ patient populations. The challenges for this population existed prior to the PHE, and will continue to exist beyond its duration. The same barriers that prevent beneficiaries from obtaining a COVID-19 vaccine are also likely preventing them from obtaining other vaccines. As noted in a 2020 study, “despite being a fragile population, many homebound patients have inconsistent access to office-based care, often only receiving care for medical emergencies.”28 Therefore, we encourage CMS to make a similar add-on vaccine administration payment in those circumstances, to fully cover the cost of furnishing preventive vaccines in a beneficiary's home.

6. **Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) (sections III.A.-III.C.)**

- **Section 132 of the Consolidated Appropriations Act (CAA)**

CMS is proposing to implement Section 132 of the CAA which authorizes RHCs and FQHCs to bill for hospice attending physician services provided by an NP, PA or physician who is designated by the patient as their attending physician at the time of hospice election, and who is employed by the RHC or FQHC at the time the services are furnished. As this policy will increase access to hospice services for patients in rural and underserved communities, **AANP supports this proposal.**

- **Concurrent Billing for Chronic Care Management Services and TCM Services for RHCs and FQHCs**

CMS is proposing to allow RHCs and FQHCs to bill for transitional care management (TCM) services and other care management services for the same beneficiary during the same service period. As noted in the rule, CMS previously finalized this policy for services billed under the PFS in the CY 2020 PFS final rule. **Care management is an integral component of NP practice and AANP supports this proposal.**

- **Revising the Definition of an RHC and FQHC Mental Health Visits**

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26 Ibid.
27 The outcomes of nurse practitioner (NP)-Provided home visits: A systematic review (nih.gov)
28 Ibid.
CMS is proposing to revise the current regulatory requirement that an RHC or FQHC mental health visit must be in-person to also include visits furnished through interactive, real-time telecommunications technology. This proposal only applies when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. CMS is also proposing to allow RHCS and FQHCs to furnish audio-only mental health visits when the beneficiary is not capable of, or does not consent to, a two-way, audio-video interaction. As discussed above, telehealth, including audio-only services, has been essential to NPs and their patients throughout the pandemic and will continue to be an essential health care modality after the PHE ends. **AANP supports these proposals.**

CMS also requested feedback on whether the agency should require an in-person service prior to the initiation of the telehealth services, and at regular intervals thereafter. **AANP opposes the implementation of an in-person visit requirement for these services.** Whether an in-person visit is required should be a clinical decision made between patients and their clinicians. In rural and underserved communities, where patients may have limited access to transportation and difficulty in attending in-person visits, this requirement would be unduly burdensome and discourage patients from obtaining medically necessary health care services.

7. **Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) (section III.H.)**

   - **Covered Conditions**

CMS is proposing to cover PR for Medicare beneficiaries “who have been diagnosed with severe manifestations of COVID–19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge.” We agree with the expansion of PR coverage for patients suffering from post-COVID conditions, including respiratory dysfunction, but recommend that CMS remove the requirement that the patient have a required “hospitalization in the ICU or otherwise.”

According to the CDC, patients who were mild to moderately ill with COVID-19 may develop new or worsening symptoms following an acute infection and non-hospitalized patients may have continued health care needs for a lengthy period after their initial diagnosis.\(^{29,30}\) While the data is still emerging, studies of non-hospitalized patients who were diagnosed with COVID-19 have found that symptoms, including shortness of breath, may persist for months following the diagnosis.\(^{31}\) Medicare beneficiaries who suffer from continued symptomatology, including respiratory dysfunction, should not be denied access to PR solely because they were not hospitalized at the time of their initial illness. Coverage criteria should focus on the patients’ symptoms at the time they are referred to PR. **We recommend that CMS remove the requirement for hospitalization in this criterion.**

   - **Authorizing Nurse Practitioners to Order, Establish Care Plans and Supervise CR, ICR and PR**

As noted by CMS, CR and PR are “severely underutilized” despite having been shown to decrease hospitalizations, increase adherence to preventive medication, improve overall health and reduce the need for costly care.\(^{32}\) This is particularly impactful for certain high-risk populations, such as patients with diabetes, due to their higher risk of heart disease. Research indicates that CR is associated with lower all-

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30 [https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e3.htm](https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e3.htm).
cause mortality rates in patients with diabetes, however patients with diabetes have lower participation rates than the non-diabetes population.\textsuperscript{33}

Congress passed the Bipartisan Budget Act of 2018 which authorizes NPs to supervise CR and PR starting in 2024. However, NPs are still not authorized to order and establish plans of care for CR and PR for their Medicare patients. NPs are fully qualified to order and supervise these services based on their education and clinical training. This barrier harms patients by causing unnecessary delay in treatment. CMS recognizes that cardiac rehabilitation improves long-term patient outcomes, but is underutilized.\textsuperscript{34} It is important that NPs be authorized to order and supervise these clinically effective and cost-saving treatments.

We encourage CMS to utilize its existing authority to expand patient access to CR, ICR and PR by authorizing nurse practitioners to order, establish plans of care and supervise these services. Examples of this authority include:

- Utilizing the authority under Social Security Act § 1115A to waive this barrier in CMS Innovation Center Models\textsuperscript{35} and utilizing the authority under § 1899 to waive this barrier in the Medicare Shared Savings Program. CMS previously approved a waiver for CR under the Cardiac Rehabilitation Incentive Payment Model\textsuperscript{36} and is currently considering a waiver in the Direct Contracting Models.\textsuperscript{37} Using these waiver authorities would increase access to CR, ICR and PR for millions of Medicare beneficiaries.
- Using the waiver authority granted under § 1135 to waive these barriers for the duration of the COVID-19 Public Health Emergency (PHE). As recognized by this rule, increasing access to these services is important to improving the condition of Medicare beneficiaries suffering from post-COVID cardiac and pulmonary symptoms.

8. Medical Nutrition Therapy (section III.I.)

We agree with CMS that MNT is a non-invasive, evidence-based assessment that helps patients suffering from conditions such as diabetes and renal disease improve their diets and better control their diseases. MNT has been shown to be an effective and affordable way to help control and prevent diabetes complications, leading to better care for patients and lower costs for health systems.\textsuperscript{38} This type of preventative, non-invasive care should be equally available to all Medicare patients, including those of nurse practitioners, and expanding access to these services will lead to lower costs and better care for Medicare beneficiaries. \textbf{We support regulatory and sub-regulatory actions by CMS that remove patient barriers and includes greater access for NPs’ patients to MNT.}

While we understand that the current interpretation of CMS is that the MNT benefit requires a physician referral, we continue to encourage the agency to use its authority to authorize NPs to refer for MNT. Nurse practitioners are qualified to refer patients to dietitians or nutrition professionals for MNT and they provide expert treatment and management of patients with diabetes. For example, a recent study supported by the Center of Innovation to Accelerate Discovery and Practice Transformation at the Durham VA Health Care System, found that patients with diabetes managed by NPs and PAs received the

\textsuperscript{33} https://www.ahajournals.org/doi/10.1161/JAHA.117.006404.
\textsuperscript{34} 82 FR 50784, 50800.
\textsuperscript{35} CMS has approved a similar waiver in the Primary Care First Model to authorize NPs to certify that patients require therapeutic shoes for the management of their diabetes.
same quality of care as patients managed by physicians, and had lower utilization and expenditure rates. The researchers found that “approximately $74 million could have been saved during the study year if utilization patterns of the entire cohort had more closely approximated those of NP and PA patients.”

Examples of ways that CMS could authorize NPs to refer for MNT include:

- Utilizing the waiver authority under Social Security Act § 1115A to waive this barrier in CMS Innovation Center Models and utilizing the authority under § 1899 to waive this barrier in the Medicare Shared Savings Program. This would increase access to MNT for millions of Medicare beneficiaries.
- Clarifying that NPs are authorized to refer for MNT as a component of the Medicare initial preventative physical examination (IPPE) or the annual wellness visit (AWV). Under the SSA, Medicare covers IPPEs and AWVs when performed by NPs, the same as it would if those services were furnished by physicians. The definition of IPPE includes “referrals with respect to screening and other preventative services”, and MNT is explicitly included in that definition. The AWV similarly includes referrals for preventative counseling services aimed at improving disease management. Thus, since the SSA states that Medicare covers IPPEs and AWVs when provided by NPs as it would when provided by physicians, and referrals for MNT are components of the IPPE and AWV, Medicare should cover MNT when a patient is referred by an NP as a component of an IPPE or AWV. This interpretation is consistent with the SSA and would increase access to MNT for Medicare beneficiaries.

9. **Medicare Shared Savings Program (MSSP) (section III.J.)**

- **Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity**

CMS has requested feedback on how ACOs can better address health equity, increase access and quality of care and encourage providers of vulnerable populations to participate in ACOs and other value-based care initiatives. We appreciate that CMS has focused on addressing issues of health equity through the MSSP and other payment models. NPs are committed to treating patients of all backgrounds, including in rural and underserved communities, and the NP approach to providing whole patient centered care directly aligns with the MSSP and other payment models. NPs are very involved in these models, and over 110,000 NPs are participating in MSSP ACOs.

As noted in the National Academies of Science, Engineering and Medicine (NASEM) report *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity* “nurses work in areas that are underserved by other health care providers and serve the uninsured and underinsured.” It is important that the efforts to address the challenges facing underserved communities recognize the important role of nurse practitioners in addressing the diverse needs of these patients. Ensuring that vulnerable patients have the necessary access to care is a critical missing link in the health care system, and NPs are well positioned to provide care for these populations.


40 CMS has approved a similar waiver in the Primary Care First Model to authorize NPs to certify that patients require therapeutic shoes for the management of their diabetes.

41 42 U.S.C. § 1395x(s)(K)(ii).
42 42 U.S.C. § 1395x(ww).
43 42 U.S.C. § 1395x(hhh)(2)(F). “The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.”
44 NASEM: The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity.
Nurse practitioner education and clinical training prepares them to address the complex needs of patients, including the social determinants of health. NASEM highlights that “the role of nurses in these efforts is key, given their interactions with individuals and families in providing and coordinating person-centered care for preventive, acute, and chronic health needs within health settings, collaborating with social services to meet the social needs of individuals, and engaging in broader population and community health through roles in public health and community-based settings.” Below are our recommendations on how CMS can continue to improve the MSSP and other models to increase access to care, improve clinician participation, and address health equity.

- **Patient Attribution**

Despite being recognized as ACO professionals, the claims-based assignment pathway requires an NP’s patient to receive at least one primary care service provided by a “physician” providing a primary care service (as defined by 42 CFR § 425.20 or with the specialty designation in 42 CFR § 425.402(c)) each year for the patient to be assigned to an ACO. Effective in 2019, CMS amended the voluntary alignment pathway to authorize a patient to select an NP as their primary care provider in an MSSP ACO and be assigned to the ACO without requiring that duplicative physician visit. This change provided greater opportunity for NPs and their patients to join and establish MSSP ACOs. However, the claims-based assignment barrier still exists. In its FY 2021 Budget in Brief, HHS estimated that basing ACO-assignment on a broader set of primary care providers, including NPs, better reflects our current primary care workforce and would lead to $80 million in savings for the Medicare program over ten years.  

The waiver authority granted to the Secretary of the U.S. Department of Health and Human Services (the Secretary) for the administration of the MSSP under 42 U.S.C. § 1395jjj(f) states that “[t]he Secretary may waive such requirements of sections 1320a–7a and 1320a–7b of this title and this subchapter as may be necessary to carry out the provisions of this section.” (emphasis added) This provision grants the Secretary broad authority to waive requirements under Subchapter XVIII, including § 1395jjj(c)(1)(A) which contains the aforementioned physician visit requirement. We request that CMS utilize this waiver to authorize a primary care service provided by an NP to meet this requirement. This will improve beneficiary assignment and encourage more NP-owned practices to join the MSSP.

- **Additional Waivers and Benefit Enhancements**

As CMS evaluates ways to address health equity and increase provider participation in the MSSP and other models, we encourage CMS to offer flexibilities that remove federal barriers on nurse practitioners, such as restrictive facility conditions of participation and unnecessary physician certification requirements, enabling them to provide health care to patients to the full extent of their education and clinical training.

As an example, we appreciate that CMS has included a waiver in the Direct Primary Care model that will authorize NPs to certify their patients need for therapeutic shoes for the treatment of diabetes. Similarly, we appreciate that CMMI is considering the implementation of an NP Services Bundle waiver in the Direct Contracting models which would enable participating NPs to practice to the full extent of their education and clinical training within the Medicare program. We strongly encourage a similar waiver to be adopted within the MSSP. Waiving unnecessary federal barriers to health care will provide our health care workforce with increased flexibility to meet their patient’s needs and improve access in underserved communities, consistent with the principles of the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

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• **Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment**

CMS is proposing to revise the definition of primary care services used in MSSP beneficiary assignment to include codes for principal care management services, prolonged office or outpatient E/M services, communication technology-based services and a newly created chronic care management services code. **AANP supports the addition of these codes to the permanent definition of primary care services.**

• **Extending the Applicability of the Expanded Definition of Primary Care Services in Response to the COVID–19 PHE**

CMS is proposing to extend the applicability of the expanded definition of primary care services for certain codes that are in effect during the PHE, but which are not permanent. **AANP supports this proposal.**

10. **Medicare Diabetes Prevention Program (MDPP) (section III.L.)**

CMS is proposing to permanently waive the enrollment fee for MDPP suppliers who enroll in the program after January 1, 2022. According to the agency, this waiver which was in place during the PHE led to an increase in enrollment of MDDP suppliers. **AANP supports the permanent waiver of this enrollment fee to increase access to these preventative services.** Additionally, encourage CMS to permanently waive other MDPP requirements (which have been waived during the PHE) including allowing patients to obtain MDPP services more than once in their lifetime, increasing the number of virtual make-up sessions and authorizing the delivery of virtual MDPP sessions.

11. **Medicare Provider and Supplier and Enrollment Changes (section III.N.1.)**

• **Creation of Specific Rebuttal Rights for Deactivations**

CMS is proposing to codify the provider deactivation rebuttal process into regulation and has requested feedback on the proposed regulations.

At newly created § 424.546(a)(1), CMS is proposing that providers or suppliers have 15 calendar days from the date of the written notice to submit a rebuttal to CMS. We recommend that CMS amend this language to state “15 calendar days from the date of receipt of the written notice to submit a rebuttal to CMS.” (added text in bold italic) Delays with mail delivery caused by the pandemic and other factors could substantially reduce the time a provider or supplier has to submit a rebuttal if the date the appeals process begins is the date that the notice is written. A potential rebuttal framework to use is that found under the Medicare redetermination process at §405.942(a). This uses *date of receipt* of initial determination to start the process, and assumes the date of receipt to be five calendar days after the date of the notice, unless there is evidence to the contrary.

12. **Modifications Related to Medicare Coverage Related to Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)**

NPs are educated in pharmacologic, pathophysiologic, psychologic and sociologic aspects of pain treatment that includes the diagnosis and treatment of patients with addictive diseases including those acquired from overdosing with opioids and other schedule drugs. The pharmacodynamics, therapeutics and management of controlled drugs including opioids is a part of both baccalaureate nursing education and graduate advanced practice nursing education. NPs hold prescriptive authority in all 50 states and the
District of Columbia and have been providing high quality health care to patients for over half a century. With the passage of the Comprehensive Addiction and Recovery Act (CARA) in 2016, NPs were initially authorized to prescribe medication-assisted therapies (MATs) after taking the necessary training and obtaining the required DEA waiver, for a period of five years. Recognizing the importance of NPs in delivering MAT, Congress made this five-year authorization permanent in the SUPPORT for Patient and Communities Act in 2018.

NPs are deeply committed to helping solve the opioid crisis. SAMHSA has reported that over 18,000 NPs have obtained a MAT waiver. This demonstrates that NPs are committed to using MAT to assist their patients suffering from opioid abuse and granting NPs the authority to obtain MAT waivers has been a success. Since the passage of CARA, studies have found that NPs have greatly increased patient access to MAT, particularly in rural and underserved communities. In rural communities, NPs or PAs were the first waivered clinicians in 285 rural counties covering 5.7 million residents. The Medicaid and CHIP Payment and Access Commission (MACPAC) found that the number of NPs prescribing buprenorphine for the treatment of opioid use disorder (OUD), and the number of patients with OUD treated with buprenorphine by NPs increased substantially in the first year they were authorized to obtain their MAT waiver, again with a greater impact in rural areas and for Medicaid beneficiaries. Since the end of these study periods, the number of DATA-waived NPs has grown significantly, increasing the number of NPs providing MAT to patients suffering from opioid use disorder.

- Counseling and Therapy Furnished via Audio-Only Telephone

CMS is proposing to permanently allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as additional therapy and counseling, using audio-only telephone calls after the PHE when audio-video communications technology is not available to the patient.

As previously mentioned, the coverage of audio-only visits has been important for patients who lack access to the necessary technology for audio-video visits, or for patients who have difficulty using audio-video technology, including patients with substance use disorder. AANP supports the proposal to permanently authorize the use of audio-only telephone calls in OTPs and we applaud CMS for listening to stakeholder feedback on this issue.

13. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan (Section 2003 of the SUPPORT Act (section III.Q.))

As noted by CMS, the SUPPORT Act requires that electronic prescribing for controlled substances under Medicare Part D be implemented by January 1, 2021. Despite this requirement, CMS recognizes that the COVID-19 pandemic has placed an unexpected burden on clinicians that could make compliance difficult. Accordingly, we support the proposal to extend the implementation date to January 1, 2023, and appreciate that CMS has recognized the potential burden on clinicians. We encourage CMS to provide technical assistance and resources for clinicians to streamline this transition.

14. Updates to the Quality Payment Program (section IV)

- **MIPS Value Pathways (MVP) Implementation Timeline**

CMS is proposing to refine the MVPs and change the effective date for the initial set of MVPs to the CY 2023 MIPS performance period, and to make MVP reporting voluntary. Under this proposed timeframe, enrollment in MVPs would be gradual and CMS would consider sunsetting traditional MIPS in CY 2027 and making MVP reporting mandatory in CY 2028. CMS is also proposing further collaboration with clinicians to continue to develop and refine MVPs. **We support the delay of the implementation date and this gradual approach to MVP participation. We look forward to further work with CMS to ensure that the health care provided by NPs is accurately reflected in the MVPs.** We also support increased involvement with patients in MVP development. NPs deliver patient-centered health care and involving the patient voice will be important to the development of meaningful MVPs.

We support CMS in its goals to reduce clinician burden and revise the MIPS program to make it more meaningful for clinicians and patients. We agree that CMS should continue to unify the four MIPS performance categories so that they are not siloed, as there is significant overlap between all four.

- **Proposed Single Specialty and Multispecialty Groups Definition/Limiting Subgroup Composition to Single-Specialty**

CMS is proposing to add a definition of single specialty group that consists of one specialty type as identified by eligible clinicians in the Medicare Provider Enrollment, Chain and Ownership System (PECOS) and using the PECOS specialty-designation as a means of defining a subgroup. We have concerns regarding this approach and the potential exclusion of NPs. NPs do not have the same options for taxonomy codes as physicians within PECOS. We appreciate CMS recognizing this issue, and noting that NPs and other clinicians have designations in PECOS related to their clinical degree and not necessarily the specific clinical area in which they practice.

AANP and the nurse practitioner community look forward to working closely with CMS on how to best identify, develop and refine the appropriate MVPs for nurse practitioners. We are committed to working with CMS on positive revisions to the Quality Payment Program (QPP) and we are available for further discussions on the MVPs and any other refinements to the QPP. AANP has been supportive of CMS efforts to increase provider participation in value-based care programs. We will continue to work closely with the agency on this policy objective.

- **Promoting Interoperability Category**

In prior rulemaking, CMS has exempted NPs, PAs, CNSs and CRNAs from mandatory reporting on the Promoting Interoperability category because many of these clinicians were not eligible for the Medicaid and Medicare EHR Incentive programs. CMS stated that it did not have evidence regarding the presence of sufficient measures applicable to these clinicians. CMS planned to analyze the data from the 2019 submission period and re-evaluate this decision.

As noted in this proposed rule, CMS analyzed the data and found that most MIPS eligible clinicians reported the Promoting Interoperability category as a group. CMS data showed that approximately 30% of MIPS eligible NPs, PAs, CRNAs, and CNSs who reported data individually reported for the Promoting Interoperability Category. Accordingly, CMS is proposing to continue the existing policy of allowing NPs, PAs, CRNAs, and CNSs to reweight this category. **We support this proposal until CMS can obtain more robust data.** We continue to encourage the agency to provide technical assistance to
providers with the goal of increasing EHR adoption and familiarity with Promoting Interoperability reporting requirements for all clinicians.

15. **Additional Removal of Federal Barriers to Practice**

CMS has recognized that since the creation of the Medicare program, the health care field has diversified and other qualified health care providers, such as NPs, are providing a substantial amount of care as the primary care providers for Medicare and Medicaid beneficiaries. As noted by CMS, Medicare policies and regulations have been updated in recent years to authorize NPs and other providers to provide services within the extent of their scope of practice as defined by state law. AANP supports the position that providers should be authorized to practice to the top of their license and supports policy proposals that remove federal barriers to practice.

Removing federal restrictions on NP practice improves access to care for patients, particularly in rural areas, reduces unnecessary complications, lowers costs and improves quality of life. Currently, twenty-four states and D.C. are considered Full Practice Authority (FPA) states because their licensure laws allow full and direct access to NPs. No state has ever moved away from FPA once it has been enacted. In FPA states, NPs are authorized to practice to the full extent of their education and clinical training without a regulated relationship with a physician. In these states, the remaining statutory and regulatory barriers to care for NPs and their patients are federal restrictions in the Medicare and Medicaid programs. Even in states that still require an NP to have a formal relationship with a physician, the Medicare and Medicaid restrictions are often more stringent than those imposed at the state level.

Removing federal barriers to practice on NPs is consistent with the NASEM report *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity* which recommended that “all relevant state, federal and private organizations enable nurses to practice to the full extent of their education and training by removing practice barriers that prevent them from more fully addressing social needs and social determinants of health and improve health care access, quality, and value.”

The World Health Organization’s *State of the World’s Nursing 2020* report also recommended modernizing regulations to authorize APRNs to practice to the full extent of their education and clinical training, and noted the positive impact this would have on addressing health care disparities and improving health care access within vulnerable communities.

As CMS continues to pursue the policy of deferring to state regulation, we encourage the agency to address areas of the Medicare and Medicaid programs where barriers to care provided by NPs for their patients still exist. Deferring to state scope of practice requirements in these regulations would substantially benefit Medicare beneficiaries. These barriers inhibit access to care for patients seeking care in lower cost settings for services, such as home infusion, by requiring that physicians establish and oversee plans of care for patients. These regulations require physicians to order or supervise cost-effective treatments and services, such as diabetic shoes, cardiac and pulmonary rehabilitation and colonoscopies, that lower the rates of costly complications, hospital admissions and readmissions. They also prevent facilities from utilizing NPs to the full extent of their education and clinical training, such as in RHCs and skilled nursing facilities. CMS has waived many of these restrictions during the PHE and we look forward to continuing to work with CMS to permanently retire these barriers to care.

**Conclusion**

We thank you for the opportunity to comment on this proposed rule and the continued efforts by CMS to support clinicians and patients during the PHE. We look forward to discussing these issues with you.

49 https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf
Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

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American Association of Nurse Practitioners