November 19, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attn: CMS-3346-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

RE: CMS-3346-P – Medicare and Medicaid Programs' Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (83 Fed. Reg. 47686, September 20, 2018).

Dear Administrator Verma,

The American Association of Nurse Practitioners (AANP), representing more than 248,000 nurse practitioners (NPs) in the United States, appreciates the opportunity to provide comment on CMS' proposed rule to promote program efficiency, transparency and burden reduction within the Medicare and Medicaid programs. In this proposed rule, CMS is soliciting feedback on specific burden reduction proposals as well as seeking feedback that expands upon previous requests for information. We thank CMS for working to reduce burden on health care providers and their patients and look forward to continuing to work together to achieve these goals.

NPs are advanced practice registered nurses (APRNs) who are prepared at the masters or doctoral level to provide primary, acute, chronic and specialty care to patients of all ages and walks of life. 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 practice in nearly every health care setting including clinics, hospitals, Veterans Affairs and Indian Health Care facilities, emergency rooms, urgent care sites, private physician or NP practices (both managed and owned by NPs), nursing homes, schools, colleges, retail clinics, public health departments, nurse managed clinics, homeless clinics, and home health. NPs hold prescriptive authority in all 50 states and the District of Columbia. It is important to note that 86.6% of NPs are certified in primary care, the majority of whom see Medicare and Medicaid patients. NPs complete more than one billion patient visits annually.

One of the primary issues impacting the Medicare and Medicaid programs is a clinician shortage, particularly in primary care, that is being exacerbated by an aging population.[1] Nurse practitioners are currently providing a substantial portion of the high-quality[2], cost-effective[3] care that our communities require, and will continue to do so to meet the needs of their communities. NPs are the fastest growing

[1] Impact of State Scope of Practice Laws and Other Factors on the Practice and Supply of Primary Care Nurse Practitioners, Final Report, page 4. https://aspe.CMS.gov/system/files/pdf/167396/NP_SOP.pdf.
[2] https://www.aanp.org/images/documents/publications/qualityofpractice.pdf.
[3] https://www.aanp.org/images/documents/publications/costeffectiveness.pdf.

provider specialty in the Medicare program and are on pace to be the largest provider specialty within a year.[4] "Eighty-four point nine percent" of NPs are accepting Medicare patients and 82.9% are accepting Medicaid patients.[5] This will have a particularly large impact on primary care as approximately 85% of all NP graduates go into primary care[6] and NPs comprise approximately one quarter of our primary care workforce, with that percentage growing annually.[7] Nurse practitioners are well-positioned to meet the increasing health care needs and enhance the well-being and economic prosperity of our communities.

Despite the need for nurse practitioners in our communities, and decades of evidence showing that NPs provide high-quality, cost-effective health care, NPs are constrained in their ability to practice by outdated statutes and regulations within the Medicare and Medicaid programs. Limiting the ability of qualified practitioners to practice to the full extent of their education and clinical training hampers the ability of our communities to utilize their entire health care workforce to meet their needs. These unnecessary barriers deprive patients of their provider of choice, reduce access to needed treatments and services and lead to delays in care. Below are our responses to the specific burden reduction proposals in this proposed rule, as well as further suggestions on burden reduction that can be taken by CMS. These proposals will improve care coordination and access to care, create cost savings, and improve upon quality of care and patient health and safety.

CMS has several tools at its disposal to enact these necessary changes:

- **many regulations are more restrictive than required under statute, such as skilled nursing facility (SNF) admissions that can be alleviated by CMS through rulemaking;**
- **CMS can issue enforcement moratoriums, such as that applied to supervision of outpatient therapy in critical access hospitals;**
- **it can use its regulatory authority to expand the definition of physician to include nurse practitioners, similar to the diabetes outpatient self-management training program, recognizing that much of the statutory language is outdated and not reflective of how care is currently delivered in the Medicare and Medicaid programs;**
- **it can ensure that any state waivers or future care models allow clinicians, including nurse practitioners, to practice to the full extent of their education and clinical training; and**
- **provide Medicare Advantage Plans and Medicaid Managed Care Organizations with additional flexibility within their Home Health Care benefits packages.**

The following changes are necessary to increase patient access to care and improve the efficiency of our health care system by removing duplicative treatment, maximizing the efficiency of the health care workforce and reducing health care costs. We encourage CMS to implement these proposals to decrease cost while increasing choice and competition in the health care marketplace and improve community health.

- **<u>Ambulatory Surgical Centers (ASCs)</u>**

CMS Proposal on Admission and Pre-Surgical Assessment requirements: CMS is proposing to remove the current ASC admission and pre-surgical assessment regulations at 42 CFR § 416.52(a)(1)-(4). These proposed changes would provide the ASC with greater flexibility in determining which patients require a pre-operative history and physical, and which examinations and tests are necessary. Currently qualified practitioners, such as NPs, can perform the comprehensive medical histories, physical assessments, and pre-surgical assessments in an ASC. We want to ensure that NPs continue to perform these functions if

[4] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/PROVIDERS/2016_CPS_MDCR_PROVIDERS_6.pdf
[5] 2016 AANP National Nurse Practitioner Sample Survey.
[6] https://www.aanp.org/images/documents/about-nps/npfacts.pdf.
[7] Rural And Nonrural Primary Care Physician Practices Increasingly Rely On Nurse Practitioners, Hilary Barnes, Michael R. Richards, Matthew D. McHugh, and Grant Martsolf, Health Affairs 2018 37:6, 908-914.

the proposed rule goes into effect. While the draft regulatory language does maintain the "other qualified practitioner" term, the description of the proposed changes refers to physician-centered decision making. We ask that CMS adopt the proposed regulatory language which uses the term "other qualified practitioner" and clarify that NPs and other qualified practitioners will be able to continue to perform the admission and pre-surgical assessments.

- **Hospice:**

Request for Information: NPs are attending physicians under the hospice care statute, but despite this designation they are not authorized to provide the initial certification that a patient is terminally ill and in need of hospice care. The very nature of hospice care and the terminally ill state of hospice patients demands that this process take place as expeditiously as possible. This hospice certification requirement is an unnecessary restriction on NPs that does not benefit the patient and serves only to complicate the hospice selection process. CMS can exercise its authority by issuing an enforcement moratorium in order to authorize NPs to certify that a patient is terminally ill and in need of hospice care.

- **Hospitals:**

Special Requirements for Psychiatric Hospitals (42 CFR § 482.61(d)): We support the proposal to amend the conditions of participation for inpatient psychiatric facilities to authorize NPs, PAs, psychologists and clinical nurse specialists to record the progress notes of patients receiving services in psychiatric hospitals. NPs are authorized to record progress notes in all other settings. Bringing the psychiatric hospital conditions of participation in line with other settings will lead to better documentation because the provider caring for the patient will be documenting the progress notes. This will allow psychiatric hospitals to have greater flexibility in caring for patients.

Request for Information: In some hospitals and other facilities NPs are still not allowed to practice to the full extent of their education and clinical training. CMS should ensure that all of the federal conditions of participation for hospitals and other facilities clearly allow nurse practitioners to practice to the full extent of their license. This includes serving as facility medical directors by amending 42 CFR § 482.22(b)(3) to add nurse practitioners. CMS is the leader in the health care industry and such guarantees will have a significant impact on access and the provision of high quality cost effective care.

- **Home Health Agencies**

Request for Information: In multiple requests for information on burden reduction, including last year's proposed rule for home health care, CMS has requested feedback on regulatory burdens that negatively impact care for home health care patients. We appreciate that CMS is responding to stakeholder feedback on regulatory burdens. We continue to request that CMS also update and remove the outdated and unnecessary requirements that only physicians be authorized to certify and recertify home health plans of care and document face-to-face patient assessments.

Under the current structure, NPs must find a physician to document that a face-to-face assessment has taken place, and have the physician certify the plan of care. NPs that are the primary care providers for patients in the Home Health Care Program are not able to initiate or make necessary adjustments to medication or treatment without obtaining a physician signature. This delays access to treatment and puts patients at risk for avoidable complications. Delays in care are especially problematic for home health care patients who suffer from more chronic conditions and report more limitations on activities of daily living than the non-home health care Medicare beneficiary population.[8] NPs are qualified to provide this

[8] http://ahhqi.org/images/uploads/AHHQI_2018_Chartbook_09.21.2018.pdf.

care without physician certification and are already doing so for millions of Medicare and Medicaid beneficiaries outside of the Home Health Care Program.

With the proven track record of NPs providing high-quality, cost-effective health care, we urge CMS to be more inclusive of NPs. As CMS seeks to make changes in the Home Health Care Program, we suggest making cost-effective changes to the program by removing administrative burdens from agencies, NPs and physicians. In that vein, we highly encourage CMS to use its regulatory authority to waive the requirements that physicians must document the face-to-face assessments performed by NPs and certify their plans of care. Removing these barriers would create cost savings for the program, increase efficiency and allow a patient's provider of choice to document their patients' face-to-face encounter and develop and update the plan of care.

- **Comprehensive Outpatient Rehabilitation Facilities (CORFs):**

Request for Information: NPs are important providers in CORFs, yet they are still prevented from practicing to the fullest capacity of their license. In CORFs, there are unnecessary restrictions that inhibit access to care and create additional administrative burdens within the setting. These restrictions include physician supervision and establishing and certifying a patient's plan of care. We suggest that CMS recognize that many of these patients may be under the care of an NP, thus making them the most appropriate provider to document and direct that patient's care. Facilitating the full utilization of nurse practitioner skills in these facilities will contribute to the safety and well-being of their patients in an efficient and cost-effective manner.

- **Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)**

Request for Information: The statutory definition of RHCs and FQHCs includes non-physician directed clinics, and states that when an RHC or FQHC is not directed by a physician, it must have arrangements for physician involvement in accordance with State and local law.[9] However, 42 CFR § 491.7 and 491.8 state that RHCs and FQHCs have to be under the direction of a physician. This is inconsistent with the statutory language, limits the ability of NPs to establish their own clinics, imposes unnecessary staffing requirements on areas with provider shortages. As a component of CMS' burden reduction initiative and rural health strategy, we request that CMS amend these regulations to align with the statutory language and ensure that NPs are able to direct RHCs and FQHCs in accordance with State law.

Additional Regulatory Burdens:

While the below settings and services were not referenced in this proposed rule, removing these barriers is consistent with the purpose of the Patients Over Paperwork initiative and we request that CMS address these issues in future rulemaking.

- **Decrease Administrative Burdens for Medicare Patient Access to Diabetic Shoes:**

NPs treating a patient with diabetes must locate a physician to certify the patient's need for diabetic shoes. Currently, an NP's patient must undergo the following redundant multistep process to obtain their necessary treatment: the NP who is treating the patient with diabetes makes the initial determination that the patient needs diabetic shoes; then the NP must send the patient to a physician who then refers that patient to a podiatrist or other qualified individual to fit and furnish the shoes. NPs are authorized to be reimbursed for the treatment of patients with diabetes under the Part B program. They have demonstrated that they provide expert treatment and management of patients with diabetes without the need for physician supervision. Requiring a physician to certify that a patient requires diabetic shoes after the

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patient's NP has already made that determination leads to delays in treatment, inhibits the ability of NPs to compete in the marketplace, decreases patient choice, and increases costs to the Medicare program by requiring the participation of an additional provider.

We suggest that CMS broaden the definition of "physician" to include nurse practitioners or add "nurse practitioner" after "physician" in the regulatory language covering diabetic shoes for Medicare beneficiaries. The statute governing diabetic shoes for Medicare beneficiaries does not define the word "physician" as it relates to those services. Thus, the Secretary has the discretion to revise the existing regulations to include NPs in that definition.

- **Documentation Parity Between NP and PA Preceptors and NP and PA Students and Teaching Physicians and Medical Students/Residents**

Prior to March 5, 2018 for billable E/M services, all clinical preceptors (teachers) had to re-document the clinical notes of medical students (MS), nurse practitioner (NP) students and physician assistant (PA) students. The release of Centers for Medicare & Medicaid Services (CMS) Transmittal 3971 (subsequently Transmittal 4068), revised the Medicare Claims Processing Manual, effective March 5, 2018, to allow teaching physicians to verify in the medical record any student documentation of the components of E/M services, rather than re-document the work. CMS unfortunately did not apply this same burden reduction to NP and PA preceptors even though they fill the same role as teaching physicians.

The updated policy removed burdens for teaching physicians but had the unintended consequence of exacerbating the disparity among teaching physicians and precepting (teaching) NPs and precepting (teaching) PAs. This has already led to an unwillingness of facilities to precept NP and PA students, nor did it help alleviate the shortage of NP and PA preceptors. While we understand that the initial action had the intent of burden reduction, the unintended consequences put NP and PA preceptors/clinical teachers at a significant disadvantage in relation to teaching physicians. We know this was not a goal of CMS as it would be contrary to the CMS Patients Over Paperwork initiative.

CMS can take the step of recognizing the role of NP preceptors and PA preceptors and students by including them in the regulations and guidance that currently exists for teaching physicians and medical students. In order to do this, CMS would need to do two things concurrently in order to prevent any further disparities:

- *Define Teaching Physician to Include NP and PA Preceptors/Clinical Teachers*

CMS can include NP preceptors and PA preceptors in the definition of "teaching physician." The Secretary has the explicit statutory authority to define "teaching physician" and the Secretary can define "teaching physician" to include NP and PA preceptors. We would recommend using the phrase "teaching clinician" which is a more inclusive term that recognizes the role of other providers in training our health care workforce. If CMS feels that this change must be completed through rulemaking, it can utilize its waiver authority, or issue a nonenforcement instruction to its carriers to enact the teaching physician burden reductions for NP and PA preceptors as well, to ensure there are no further disparities in clinical training opportunities. We encourage that to be accomplished immediately.

- *Define Student to Include NP and PA Students*

CMS can interpret the word "student" in Transmittal 4068 to include NP and PA students. "Student" is not defined in regulation, and the existing definition of "student" in the Medicare Claims Processing

Manual[10] includes NP and PA students. Interpreting "student" to include NP and PA students could be accomplished through issuing guidance, would not require rulemaking, and is consistent with the existing CMS definition of "student."

CMS is aware of the importance of NPs and PAs in meeting the nation's healthcare demands, most importantly the rural and underserved communities.[11] CMS has made a point to be inclusive of NPs and PAs in other programs, such as QPP, and should do the same in this instance because NP and PA preceptors perform the same roles as teaching physicians. We respectfully request that CMS create parity among NP preceptors, PA preceptors and teaching physicians by redefining "student" and "teaching physician" simultaneously to include NP and PA students and preceptors.

- **Skilled Nursing Facility (SNF) Admitting Examinations and Bi-Monthly Assessments:**

NPs are essential providers in SNFs. Studies have demonstrated that NP participation in SNFs has lowered overall costs and improved quality of care. Even though NPs provide high-quality care to SNF patients, they are still prevented from approving a SNF admission by not being authorized to perform the admitting examinations and every other required monthly patient assessment. These are unnecessary restrictions on practice that go further than statutory requirements and inhibit access to care in SNFs. This diminishes a facility's ability to utilize available clinicians to the full extent of their education and clinical training.

It is important for CMS to recognize that many of these patients may be under the care of an NP, thus making them the most appropriate provider to direct that patient's care. We encourage CMS to explore options that would modernize SNF regulations to authorize providers, such as NPs, to admit and perform the admitting assessment and all required bimonthly patient assessments.

- **Cardiac and Pulmonary Rehabilitation (CR and PR):**

In 2018, Congress passed legislation which would authorize NPs to supervise cardiac and pulmonary rehab starting in 2024. However, NPs are still not authorized to order cardiac and pulmonary rehab for their Medicare patients. NPs are fully qualified based on their education and clinical training to order and supervise these services and this obsolete barrier to care harms patients by causing unnecessary delays in treatment. We request that CMS update the regulations for cardiac and pulmonary rehabilitation to authorize NPs to order these treatments for their patients, and to expedite the implementation date of NPs being authorized to supervise these treatments through an enforcement moratorium.

- **Colonoscopy and Screening Barium Enema Coverage:**

Under Medicare regulations for colorectal cancer screening tests, NPs are currently reimbursed for performing sigmoidoscopies and fecal occult blood tests, but colonoscopies and screening barium enemas are only covered when performed by a physician. NPs have the clinical training and expertise to perform colonoscopies and screening barium enemas. These policies limit access to care in our communities for vital cancer screening services. We encourage CMS to amend the regulations to include NPs in the class of practitioners who are authorized under the Medicare program to perform these procedures.

[10] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.
[11] https://www.nejm.org/doi/full/10.1056/NEJMp1801869.

- **Outpatient Medicaid Psychiatric Services**

Medicaid coverage of organized outpatient programs for psychiatric treatment is primarily covered as an outpatient hospital service or a clinic service. 42 CFR § 440.20 states that hospital outpatient services must be provided "by or under the direction of a physician or dentist"; however, there is no statutory requirement that this be the case. Clinic services do have statutory language that states that the services are provided under the direction of a physician[12]; however, the Medicaid Provider Manual has overly stringent and unnecessary requirements that inhibit access to patient care. The Medicaid Provider Manual has interpreted this language to mean that a physician has to see the patient at least once, prescribe the type of care provided and periodically review for continued care.[13]

We request that CMS amend 42 CFR § 440.20 to authorize hospital outpatient services to be provided under the direction of a nurse practitioner. We also request that CMS amend the Medicaid Provider Manual to defer to States and the clinics in determining how the physician direction requirement is implemented. CMS has the regulatory authority to take both of these actions which will lead to greater access to psychiatric services for the Medicaid population.

We thank you for the opportunity to comment on the Medicare and Medicaid burden reduction proposed rule. As mentioned on page two, CMS has multiple tools at its disposal to enact these necessary changes and we encourage their utilization to remove these barriers. We look forward to continued work with CMS to reduce burdens on patients and providers and improve the health and economic prosperity of our communities. We would welcome an opportunity to engage in further discussions regarding the role of nurse practitioners in the Medicare and Medicaid Programs. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, msapio@aanp.org, 703-740-2529.

Sincerely,

David Hebert
Chief Executive Officer

[12] 42 U.S.C. 1396d(a)(9).

[13] Medicaid Provider Manual, Section 4320- Clinic Services.