

January 16, 2018

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attn: CMS-4182-P  
Mail Stop C4-26-05  
7500 Security Blvd  
Baltimore, MD 21244-1850

**RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (82 FR 56336, November 28, 2017).**

Dear Administrator Verma:

The American Association of Nurse Practitioners (AANP), representing more than 234,000 nurse practitioners (NPs) in the United States, appreciates the opportunity to provide comment in response to the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program proposed rule (82 FR 56336).

NPs are advanced practice registered nurses 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 89.2% 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.

### **Provider Neutral Language**

Throughout this proposed rule, CMS uses the term “physician” in situations where other qualified health professionals, including nurse practitioners, are authorized to provide care under the Medicare program. For example, CMS used this language in sections of the proposed rule related to the quality rating system, e-prescribing, the provisional drug supply and in the sections evaluating the anticipated effects of the proposed rule. The use of the term “physician” in these instances confuses patients and providers as to which clinicians are authorized to provide care under the Medicare program and undermines the scope of

practice and quality of care provided by nurse practitioners. This could lead to unfair restraints on practice and decreased access to care for patients. It is important that during rulemaking and in all other correspondence, CMS does not continue to utilize the word “physician” when other qualified health professionals are authorized to provide a service.

### **Implementation of CARA Provisions Related to Preventing Drug Abuse**

CMS made several proposals in this proposed rule related to the adoption of the CARA provisions and requested further feedback on ways to combat opioid abuse. We agree with the general framework presented by CMS and we have made some suggestions for this framework below.

*Provider “lock-in”:* We agree with CMS that prior to locking a patient into an individual provider or pharmacy it is important to go through the case management process to ensure that the patient is an “at-risk” or “potential at-risk” beneficiary. Provider feedback is the most significant component of this process and we support the proposal that the patient’s prescriber must agree with an “at-risk” or “potential at-risk” determination before it is implemented.

One area where we disagree with CMS is limiting the beneficiary’s “locked-in” provider to in-network providers and pharmacies. Even though MA plans are statutorily precluded from discriminating against providers based on licensure or certification, we repeatedly hear from our members that they have difficulty getting paneled with MA plans. Many MA beneficiaries continue to receive out-of-network treatment from these NPs due to their relationships with the NP and the high quality of care that they provide. These beneficiaries should be able to select these NPs as their locked-in providers. Continuity of care is an important component of treating drug abuse and patients should not be separated from their providers of choice at this critical juncture. We request that CMS amend their proposal to allow beneficiaries to select out-of-network providers as their locked-in providers of choice.

*Exempted Beneficiaries:* CARA requires the exemption of hospice patients, residents of long-term care facilities or similar facilities where drugs at risk of abuse are dispensed through a single pharmacy contract and patients with cancer diagnoses from the Part D Drug Management Program requirements. This exemption should be expanded to include other beneficiaries suffering from chronic pain. We ask CMS to create a provider panel, including NPs, to identify other conditions or circumstances that would warrant this exemption.

*Combating Opioid Abuse Request for Feedback:* In this proposed rule, CMS requested additional feedback on steps that MA and Part D plans could take to combat opioid abuse. Below are a few suggestions that CMS should incorporate to help combat opioid abuse.

Many providers have difficulty prescribing non-pharmacologic pain treatments due to a lack of available options. Since many insurers base their coverage criteria on CMS policies, incorporating alternatives to opioids such as physical therapy and massage therapy in prescription recommendations will help increase their availability. These recommendations should be consistent among all applicable entities (e.g. health plans, CMS, FDA) to increase the availability of non-pharmacologic pain treatments. CMS should also work with plans to produce incentives to cover more non-pharmacologic pain treatments. Creating pain treatment models through the Innovation Center would be one avenue to form these programs. Additionally, it is extremely important that any programs or incentives created are available to all providers, including nurse practitioners.

AANP is a strong supporter of provider education, and CMS should work with health plans (and other stakeholders such as SAMHSA and the FDA) to create consistent provider education materials for the

prescription of opioids and how to manage opioid abuse. It is important to ensure that providers have the most up to date information regarding opioid abuse, while also mitigating the burden on providers that can result from inconsistent educational materials.

### **Flexibility of Medicare Advantage (MA) Uniformity Requirements**

CMS proposes to reinterpret the MA uniformity requirements to allow plans to offer reduced cost sharing, specifically tailored supplemental benefits and lower deductibles for enrollees that meet specific criteria (e.g. patients with diabetes) as long as similarly situated enrollees are all treated the same.<sup>1</sup> We believe this benefit design offers potential for better tailored care of enrollees, but are concerned that there may be negative side effects, such as cost-shifting to other enrollees, that occur as a result of this reinterpretation. CMS must ensure that there are appropriate protections against any type of discrimination against enrollees before reinterpreting these requirements.

Additionally, the Value-Based Insurance Design (VBID) demonstration incorporates many of the elements in this proposal. It has only been running since January 1, 2017, and CMS has not yet assessed this model and its impact on enrollees. Given CMS' previous position that models should be tested in limited markets prior to making a nationwide change, amending the uniformity requirements seems premature in this instance. We would recommend that CMS continue to expand the VBID model and take the time to assess the impacts prior to changing the uniformity requirements. This would allow CMS to conduct more informed rulemaking so that flaws in the model could be addressed prior to enacting this change.

### **Updating Part-D E-Prescribing Standards**

CMS proposes to adopt the National Council of Prescription Drug Programs (NCPDP) Script Standard Version 2017071 for e-prescribing for Medicare Part D Patients effective on January 2, 2019, and retire NCPDP version 10.6.<sup>2</sup> CMS described the increased efficiencies of the newer version, particularly that it allows for prescribing multi-ingredient compounds, as the impetus for the change. We also ask that CMS ensure that the newer standard supports prescribing by all providers, including nurse practitioners. While we support the adoption of the newer standard, we would ask that CMS include a hardship exception for NPs and other providers who have difficulty transitioning to this new system due to technical limitations or circumstances outside of their control. This hardship exception could be modeled after the advancing care information hardship exception in the Quality Payment Program.

### **Provider Preclusion List**

CMS proposes replacing the regulations that require MA and Part D providers to be enrolled in Medicare. Instead, CMS' proposal would incorporate a preclusion list that would bar providers from participating in the programs if they engage in detrimental conduct. We agree with this decision and believe that it will reduce the burden on providers who do not wish to enroll in the Medicare program, while also providing protection to enrollees from providers engaging in harmful conduct.

However, we ask CMS to clarify some components of this proposal prior to adopting this policy. First, while it is easy to identify clinicians who would be placed on the list due to Medicare disenrollment, it is more difficult to identify the non-Medicare providers who would be placed on the list. We ask that CMS clarify the conduct that would lead non-Medicare providers to be included on the preclusion list,

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<sup>1</sup> 82 FR 56336, 56360.

<sup>2</sup> 82 FR 56336, 56438.

including which data sources CMS would use to obtain this information. Second, we ask that CMS align the appeals process and the provisional supply runout so that an initial appeals determination would be rendered prior to the end of the runout period. This would help reduce patient care disruption when clinicians are incorrectly placed on the preclusion list. Third, the proposed rule did not clarify what happens to a clinician who wins their initial redetermination, but has this redetermination challenged by CMS. Is a provider taken off the preclusion list if they are initially successful in their appeal, but has their appeal challenged by CMS?

### **Changes to Medical-Loss Ratio (MLR) Calculations**

CMS proposes to include fraud reduction activities, such as fraud recovery efforts, in the list of quality improvement activities (QIA) that can be included in the numerator for the calculation of the MA plan's MLR. Combatting fraud is an important initiative, but we are concerned that this method will lead to increased claim audits. Audits are extremely burdensome to NPs and other providers, especially small practices, and they often do not detect any fraud. Many audits are performed by third parties who use blanket claim-line edits and give providers little guidance regarding which, if any, claims guidelines they violated. This is particularly problematic for NPs because these blanket audits do not consider the authorizations held by nurse practitioners in State and Federal statutes. Dealing with these audits is a cumbersome and lengthy process for all clinicians and providers. There are few safeguards to protect providers from frivolous audits, and this change will likely exacerbate the issue. This change is inconsistent with CMS initiatives to reduce provider burdens and it should not be adopted in the final rule.

### **MA Contract Provisions**

CMS proposes changes to the stop-loss requirements for MA plan "physician incentive programs." We would like to take this opportunity to note the importance of ensuring that MA plans have incentive programs that are open to all providers, including NPs, and not just physicians. Limiting incentive programs to only physicians is inconsistent with the provider anti-discrimination statute. CMS must enforce the provider non-discrimination statutes and regulations to ensure that these incentive programs are available to all providers, including nurse practitioners. This would ensure that NPs and other providers are rewarded for providing high-quality healthcare.

### **Request for Information on Reducing Provider Burden Due to Medical Record Requests**

CMS is soliciting information from providers on how to reduce the provider burden of medical record requests in the MA program. Many medical record requests that are made to evaluate the medical necessity of a service are too broad, often request information from NPs that is not relevant or required for reimbursement and do not give the provider a clear indication of why a record is being requested or what information is being sought. CMS regulations regarding a denial for medical necessity say that the plan must give the specific reason a service is being denied, but plans often use language such as "does not meet medical necessity criteria" in order to satisfy this requirement. This is still not specific enough to give the provider a clear indication of what they need to provide to the health plan to establish medical necessity.

CMS should indicate through guidance that plans must identify the specific guidelines that they are using, including the portions of the guidelines that are not met, and, if applicable, any specific dates or the timeframe for which they are seeking information. This would reduce the burden on the provider by limiting the scope of the record they need to provide, and the burden on the health plan by reducing the size of the records that providers send to the plan for review.

We thank you for the opportunity to comment on this proposed rule. We look forward to an ongoing dialogue to ensure NPs and their patients are equal participants in the MA and Part D programs. Should you have comments or questions, please direct them to MaryAnne Sapio, V.P. Federal Government Affairs, [msapio@aanp.org](mailto:msapio@aanp.org), 703-740-2529.

Sincerely,

A handwritten signature in black ink, reading "David E. Hebert", followed by a long horizontal flourish line extending to the right.

David Hebert  
Chief Executive Officer