

January 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (83 FR 62152, November 30, 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 in response to the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses proposed rule.

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 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.

In this proposed rule, CMS proposed changes to the Medicare Advantage and Medicare Part D programs with the goal of lowering drug prices and out of pocket costs to patients. We support those goals but do have concerns that the proposals related to prior authorization and step therapy could inhibit patients access to medically necessary care. Our responses to proposals related to prior authorization, step therapy, and real time benefit tools can be found below.

Providing Plan Flexibility to Manage Protected Classes

CMS proposes to establish additional exceptions to the requirement that all drugs in protected classes be included in a Part D plan formulary by permitting the use of additional prior authorization and utilization management tools. AANP shares the goal of lowering prescription drug prices and looks forward to

continued work with CMS on this goal. However, we are concerned that new exceptions, specifically prior authorization and step therapy, will place additional barriers on patients' ability to access medically necessary medications.

Our members have expressed concern about delays in care due to the onerous requirements and increased prevalence of prior authorization requirements. As CMS has highlighted in the Patients Over Paperwork initiative, clinicians experience significant documentation burdens that take time away from the delivery of health care. Obtaining prior authorizations is one of the primary causes of this burden. We encourage CMS to find ways to help plans negotiate with pharmaceutical companies that do not involve burdening clinicians, including nurse practitioners, and their patients.

CMS requested feedback on whether these policies should apply to both new start and existing medications. While we have concerns related to both categories, these concerns are greater when the patient is already on a course of effective treatment that is disrupted due to the new imposition of prior authorization or step therapy. As CMS noted in the proposed rule, Part D plan sponsors can already conduct retrospective utilization reviews. These should be sufficient to prevent the misuse of these medications. We request that CMS not implement the first proposed exception to allow Part D sponsors to use prior authorization and step therapy, particularly for patients who are already on satisfactory therapies. If CMS does move forward with these proposals related to new start medications, there must be a streamlined process in place to prevent delays to medically necessary treatment and ensure that patients are not forced to undertake therapies that their medical histories show would be ineffective.

Updating Part D E-Prescribing Standards

We support the principle of the proposal to require Plan D sponsors to require a real-time benefit tool (RTBT). We agree with CMS that while current formulary and benefits information is valuable, improved information is required to enable clinicians to provide their patients with useful information regarding real-time cost and coverage information for medications. Greater implementation of RTBTs will lead to better decision-making between providers and patients regarding therapies available through patients' Part D plans.

We request that as these new tools are developed, CMS and the health plans solicit feedback from clinicians, including nurse practitioners, on their effectiveness and utility. It is important that these tools be used to increase access to care and streamline prior authorization processes, and that no new barriers are imposed on a clinician's ability to access information and order medication for their patients.

Medicare Advantage and Step Therapy for Part B Drugs

Pharmacy and Therapeutics (P&T) Committees: While the proposed regulations regarding the membership requirements of P&T committees do not exclude nurse practitioners from membership, we are concerned that they are written in a manner that would lead health plans to exclude or marginalize nurse practitioners on P&T committees. We request that CMS amend the requirements in proposed 42 CFR § 422.136 to include "nurse practitioner(s)" after "practicing physician(s)" in subparagraphs (b)(1) through (b)(3).

Currently, there are 248,000 NPs in the workforce with 26,000 new NP graduates in 2016-2017.¹ NPs are the fastest growing provider specialty in the Medicare program and are on pace to be the largest provider

¹ <https://www.aanp.org/images/documents/about-nps/npfacts.pdf>.

specialty within a year.² NPs comprise approximately one quarter of our primary care workforce, and the gap in numbers between NPs and physicians providing primary care has narrowed significantly since 2010, particularly in rural and underserved communities.^{3,4} Nurse practitioners need to be included on P&T committees, and all other relevant committees and panels, to ensure that the interests of their patients are being represented. Nurse practitioners play a major role in health care delivery for Medicare patients. This needs to be reflected in the composition of these committees.

Step Therapy: We share the same concerns regarding increased step therapy for Medicare Advantage Part B drugs as we did for the implementation of step therapy for protected class medications. However, we do note that CMS is not proposing to authorize step therapy when a patient is on an effective existing medication, which we support. If step therapy is implemented, we believe that there needs to be a robust and timely exemption process to ensure that patients that may be negatively impacted by step therapy do not have their health put at risk.

We thank you for the opportunity to comment on this proposed rule. We look forward to an ongoing dialogue on ways to lower prescription drug prices without placing increased burden on clinicians and their patients. 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

² https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/PROVIDERS/2016_CPS_MDCR_PROVIDERS_6.pdf

³ [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.

⁴ Xue Y, Smith JA, Spetz J. Primary Care Nurse Practitioners and Physicians in Low-Income and Rural Areas, 2010-2016. *JAMA*. 2019; 321 (1): 102-105.