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January 18, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P]

Dear Administrator Verma,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 34,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

Lowering drug prices is a top priority for the AAN. We applaud the Centers for Medicare and Medicaid Service's (CMS) commitment to taking concrete steps to lower drug prices and increase access to care. The annual cost of treating neurologic disease in the United States exceeds $500 billion, and prescription drugs for neurologic conditions are some of the most expensive on the market. Medications prescribed by neurologists accounted for $5 billion in Medicare Part D payments in 2013, which trailed only internal medicine and family practice amongst specialties.[1] High drug prices create unnecessary challenges for neurologists to deliver accessible and affordable care for their patients.

While the AAN is committed to lowering drug costs for neurology patients, the AAN is deeply concerned with the proposed expansive implementation of utilization management protocols like prior authorization and step therapy across Medicare. Prior authorization and step therapy are two of the most time consuming and expensive administrative requirements preventing physicians from spending more time with patients and providing the highest standard of care. While the AAN recognizes Medicare Part D and Medicare

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[1] De Lott LB, Burke JF, Kerber KA, Skolarus LE, Callaghan BC. Medicare Part D payments for neurologist prescribed drugs. Neurology 2016;86:1491-1498

Advantage plans need to control costs and curtail medically unnecessary services, these concerns must be balanced against the issues caused by increasingly pervasive and burdensome utilization management requirements that are facing patients and providers. These requirements introduce additional costs to the health care system through the need for additional staff-time dedicated to handling utilization management requirements and through the need for additional care to treat patients dealing with adverse outcomes stemming from treatment delays. The AAN wants to collaborate productively with CMS to reduce the burdens associated with prior authorization and step therapy and cautions the administration against further expansion of utilization management tools.

Changes to the six protected classes

The AAN opposes the expansion of prior authorization and step therapy protocols within the six protected classes for non-protected indications. These policies have the potential to limit patient access to necessary drugs and create administrative burdens that delay care and often prevent providers from providing the most appropriate treatment. Defining a pharmacy benefit based on diagnosis may harm patients for whom a medication is known to have benefits, but the effects are understudied. Anticonvulsants and antidepressants are both commonly used for non-protected indications by neurologists for the treatment of a variety of neurological conditions, including headache and neuropathic pain. Limiting access to these medications would represent a significant reversal of progress in the ability of providers to treat pain with opioid alternatives.

The AAN believes the proposed changes to the protected classes are particularly misguided because most of the medications used within the six protected classes are generics. A recent study indicated that 90% of anticonvulsant and 97% of antidepressant utilization was for generic drugs.[2] Given the high degree of generic utilization, the AAN is skeptical that the proposed implementation of prior authorization and step therapy will result in significant savings, as physicians are already prescribing lower cost options. The AAN understands that utilization management protocols, like step therapy and prior authorization, can control costs when implemented in accordance with evidence-based clinical and safety data. The AAN is particularly concerned that the proposed change would apply to patients who are stable on existing therapies, as this change lacks a clinical basis. Disruptions in treatment are well known to diminish patient adherence to treatment plans and can result in costly and otherwise avoidable adverse outcomes. Additionally, the AAN believes that the current appeals and grievances procedures are insufficient to ensure that clinically necessary care is not disrupted due to the proposed expansion of utilization management tools. In March 2018, MedPAC stated that "CMS continues to find that a significant share of audited plans has difficulties in the areas of Part D transition fills, coverage determinations, appeals, and grievances."[3] As long as these difficulties continue, expansion of utilization management protocols will pose a substantial threat to care quality and patient wellbeing. The AAN asks that CMS reinforce the paramount importance of the physician's clinical decision making

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[2] Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs. Partnership for Part D Access, 29 Nov. 2018, www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

[3] The Medicare Prescription Drug Program (Part D): Status Report. MedPAC, Mar. 2018, www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

and rescind the expansion of prior authorization and step therapy within the six protected classes, or at a minimum not allow these protocols to be applied to generic medications.

Additionally, the AAN understands the need for CMS to give Part D plans flexibility to exclude new single-source drugs with identical active ingredients that do not provide a "unique route of administration" from plan formularies to combat evergreening practices. The AAN is committed to ensuring that ultra-high drug costs are reduced. The AAN believes this policy will give Part D plans needed leverage to prevent single-source drug manufacturers from delaying generic competition through market manipulation. Although the AAN is supportive of this provision, the AAN recommends that CMS ensure that sufficient guardrails are in place to ensure that patient access is not threatened to needed drugs due to the flexibility plans are given to exclude drugs within the protected classes. The AAN is particularly concerned with cases in which formulary restrictions may prevent patient access to new formulations of existing drugs that are modified to improve patient adherence and outcomes.

While the AAN supports the expansion of strategies that are meant to combat significant price increases, the AAN is concerned with the potential for patient access issues stemming from allowing plans to indefinitely exclude otherwise protected drugs, due to price increases that exceed the rate of inflation. The AAN believes that a drug should not be excluded in perpetuity for a single price increase. The AAN recommends that CMS mandate that Part D plans immediately include previously excluded protected class drugs on their formularies once that particular drug's price is below its inflation adjusted benchmark price. Without this path back to formulary inclusion, the AAN believes that pharmaceutical companies will have minimal incentive to reduce prices after a drug is excluded due to a price increase exceeding the rate of inflation. The AAN is opposed to the proposal to allow Part D plans to exclude all drugs within all protected class from a particular manufacturer due to the price increase of a single drug. This proposal would significantly compromise patient access to needed products and is overly punitive. Policies meant to control costs need to be targeted and precise, without compromising patient access to drugs that have not undergone substantial price increases. The AAN recommends that CMS narrowly implement the proposal to allow plans to exclude individual drugs due to price increases exceeding inflation that are specific to the excluded drug.

Finally, the AAN is concerned with CMS's rationale that threats to patient access are diminished by the beneficiary's ability to switch plans if a particular plan is overly restrictive when applying new limitations to protected class drug coverage. It is important to note that dual eligible beneficiaries and low-income subsidy beneficiaries must enroll in plans below the benchmark threshold to qualify for a $0 plan premium. It is likely that the most restrictive plans will be the plans with the lowest premiums, and therefore dual eligible and low-income beneficiaries will have no choice but to enroll in a plan that may place significant access barriers on needed protected class medications.

Expansion of step therapy in Medicare Advantage (MA)

The AAN is deeply concerned with CMS's proposal to allow MA plans to implement step therapy protocols. The AAN is troubled by the process by which this change has been

implemented. By instituting the change via guidance that will be implemented as of January 1st, 2019, rather than through the formal rulemaking process, CMS circumvented stakeholders' ability to give the agency feedback on how the changes would impact both patients and providers. Although CMS is now implementing additional regulations pertaining to step therapy in MA, which gives stakeholders the opportunity to comment, such a significant policy change should not have been made outside of the regular rulemaking and comment process.

As noted previously, the AAN believes that expanding the usage of step therapy protocols places a significant burden on physicians which can delay care and prevent providers from providing patients with the most clinically appropriate treatment. The AAN asks that CMS reverse their guidance and reinstitute the prohibition on step therapy in Medicare Advantage. If CMS will not reverse the guidance, the AAN believes that the patient-provider relationship must be protected, and appropriate guardrails must be put in place. When faced with step therapy, it is critical that patients can receive an exception to one of the required steps when the plan-directed medication is inappropriate. MA plans' step therapy policies should be explicit regarding the circumstances that warrant an exception as well as the processes for requesting an exception. We recognize that balance needs to be struck so the exceptions process is not overly prescriptive. However, we believe beneficiaries should have access to a clear patient and provider-friendly exception when:

- A patient is currently stable on a therapy, including patients who switch plans or become newly eligible for Medicare. CMS's proposal for 2020 would require MA plans to utilize a 108-day lookback period, the AAN believes a 365-day lookback period would be more appropriate given that there are some Part B drugs with annual or biannual dosage frequencies.

- The beneficiary's provider determines that a particular step would jeopardize the beneficiary's life or could irreparably harm the beneficiary's physical or sensory function.

- The beneficiary's provider determines that the treatment is contraindicated.

- The beneficiary's provider determines that the treatment is expected to be ineffective based on the physical or mental characteristics of the patient or the nature of the treatment.

- The beneficiary's provider determines that the treatment will cause or is likely to cause an adverse reaction to the patient.

- The beneficiary's provider determines that the treatment is not in the best medical interest of the patient because the provider is already following applicable clinical practice guidelines or because the treatment is expected to decrease the individual's ability either to perform daily activities, occupational responsibilities, or adhere to the treatment plan.

Although the AAN is opposed to the expansion of step therapy protocols in MA, the AAN is grateful that CMS is requiring plans to meet the Part D organization determination exception process response timeline of 72 hours for standard cases and 24 hours in expedited cases. Delays in treatment can have devastating health implications. When patients and providers receive timely responses to their exception requests these adverse outcomes can be avoided.

The AAN asks for additional clarity and rulemaking on who would specify if a patient "fails" a particular step. The AAN believes that the beneficiary's provider is in the best position to exercise clinical judgement related to what constitutes failure and recommends that CMS explicitly state that it is the beneficiary's provider that determines failure rather than a third-party entity, such as an insurance company. The AAN also requests clarification on what constitutes a "new" patient and believes the definition of a "new" patient should exclude patients who are switching plans or have become newly eligible for Medicare. Additionally, the AAN asks for clarity on the issue of "unwritten" or implicit step therapy that is implemented through an alternative utilization management tool, such as prior authorization. The AAN asks that CMS ensure that such practices are explicitly forbidden.

Finally, the AAN asks that CMS increase transparency related to the implementation of step therapy protocols. CMS should require insurance companies to make a clear description of the step therapy exception process readily available on its website so that patients can understand their right to an exception. The AAN is concerned that the current exception and appeals process is overly opaque, leading to low utilization. Additionally, the AAN asks that CMS require plans to include clear language in their explanation of coverage documents during the open enrollment process so that patients can understand what step therapy requirements mean for their care and what their options are in the marketplace.

Implementation of real-time benefit tools (RTBTs)

The AAN supports CMS's proposal to require Part D plans to implement one or more RTBTs that can provide patient-specific real-time prescription benefit information including patient cost-sharing. The AAN believes this tool has the potential to convey actionable, patient specific information that can lower drug costs and reduce the administrative burden associated with utilization management tools.

Although the AAN is supportive of the RTBT proposal, the AAN cautions CMS to ensure that implementation of the proposal does not impose additional administrative burden and avoids the need for significant time or resource investments on the part of providers when implementing an RTBT. It is of the utmost importance that RTBTs are implemented without imposing costs on physicians. RTBTs need to be fully integrated in provider's workflow within their existing EHR systems. They also need to be truly up to date real-time tools, allowing for both single queries and batch queries. Additionally, cost sharing information should be communicated in an easily understood manner and cost sharing data should be communicated in the form of concrete dollar amounts, rather than opaque references to formulary tiers or coverage limits. Information communicated in the form of out-of-pocket cost in dollars per dose or treatment regimen would be the most helpful to patients and providers.

The AAN believes that development of this tool will require real-time integration with an EHR billing program to know patient specific out-of-pocket costs from specific formularies. This will therefore require a greater degree of payer connectivity with each individual EHR at the granular level. Mass adoption of this tool will require billing interoperability across both EHR and payer platforms. This will require a significant degree of standardization to ensure interoperability. The AAN recommends when developing RTBT guidelines, that CMS look to the most widely used formats. Many vendors have already created and implemented similar tools that can be integrated with existing EHR systems. The AAN believes that standards should be set according to the formats that are most widely in use to minimize the administrative burden that will be associated with updating and implementing new RTBT development guidelines.

Provisions aimed at promoting price transparency and lowering out-of-pocket costs

The AAN supports CMS's proposal to change the definition of the "negotiated price" for the purpose of point-of-sale rebates. The more inclusive definition will reduce patient out-of-pocket costs by mandating that patient cost sharing is calculated based on a percentage of what is actually paid at the pharmacy by health plans after rebates, rather than according to the "list price" which does not account for discounts and rebates. The AAN believes that this change will improve price transparency by ensuring that cost sharing is based on what is actually paid for pharmaceutical products. The AAN agrees with CMS that these changes will also incentivize plan sponsors and pharmacy benefit managers (PBMs) to negotiate lower prices at the point of sale, rather than negotiating to increase direct and indirect remuneration fees that only serve to insert additional costs into the health system and enrich PBMs. The AAN notes that throughout the proposed rule, CMS repeatedly indicates that they are "considering" making this change for 2020 or a future year and believes that this proposal warrants implementation due to the need to decrease out-of-pocket costs and improve drug price transparency.

The AAN appreciates that CMS is implementing regulations prohibiting Part D plan sponsors from restricting network pharmacies from informing beneficiaries of the availability of comparatively lower cash prices. The AAN supported the passage of legislation that prohibited pharmacy "gag clauses." The AAN believes that it is critical that patients are made aware of payment options at the pharmacy counter and understand whether utilizing insurance or paying out-of-pocket would provide the most savings to purchase needed medication. This change serves the important goals of promoting price transparency and lowering beneficiary out-of-pocket costs.

Conclusion

Reducing exorbitantly high drug prices is a top priority for the AAN. We appreciate CMS's commitment to reducing extremely high drug costs that negatively impact patients and providers across the country. The AAN believes that the proposed expansion of utilization management tools like step therapy and prior authorization will compromise patient access to life-saving Part D drugs and impose significant burdens on providers. The AAN asks that CMS reconsider this proposal and work with patient and provider groups to formulate a proposal that would address the true drivers of ultra-high drug costs, without compromising

quality of care or the doctor-patient relationship. The AAN is appreciative of CMS's other proposals that will promote price transparency and reduce beneficiary out-of-pocket costs and believes these are proposals that warrant continued collaboration between the provider community and CMS moving forward.

Thank you for the opportunity to provide comments on the proposed changes to Medicare Part D and Medicare Advantage drug policy. Please contact Daniel Spirn, Senior Regulatory Counsel at dspirn@aan.com or Matt Kerschner, Government Relations Manager, at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

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President, American Academy of Neurology