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February 17, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs [CMS-4192-P]

Dear Administrator Brooks-LaSure,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 38,000 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, Alzheimer's disease, Parkinson's disease, headache, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

A. Improving Experiences for Dually Eligible Individuals

Attainment of the Maximum Out-of-Pocket (MOOP) Limit

The Centers for Medicare and Medicaid Services (CMS) proposes to revise the regulations governing the MOOP limit for Medicare Advantage (MA) plans to "require that all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit."[1] The effect of this proposal is such that once a dually eligible individual, with cost-sharing protections, has incurred cost-sharing that reaches the MOOP limit established by the plan "the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services."[2]

[1] 87 Fed. Reg. at 1884
[2] Id.

The AAN concurs with CMS that this proposal is necessary to promote equitable access to treatment for beneficiaries and to ensure that providers are not faced with disincentives when treating dual-eligible patients. Under current policy, "the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking to the enrollee's progress toward the plan MOOP limit."[3] In cases in which Medicaid rates are lower than negotiated MA plan rates, states are permitted to limit payments to cover Medicare cost-sharing obligations for dual-eligible beneficiaries. This ensures that the total payment to the provider is equivalent to the rate covered under the Medicaid state plan. Cases in which there are large gaps between Medicaid rates and negotiated MA plan rates can result in significant, unrecoverable financial liabilities for providers, as "Medicare cost-sharing protections for certain dually eligible individuals prohibit providers from billing any of that unpaid Medicare cost-sharing to the beneficiary."[4] As noted in the rule, the combined effect of the methodology for calculating the MOOP limit and the existing cost-sharing protections is that the MOOP limit "does not cap the amount of Medicare cost-sharing that remains unpaid for providers serving dually eligible enrollees."[5] The AAN concurs with CMS that the potential for uncapped, unrecoverable liabilities is a substantial disincentive against providing care to dual-eligible beneficiaries and may limit access to neurologic care. Promoting adequate reimbursement and payment parity across federal health care programs is critical to ensuring that providers equitably provide care to all Medicare beneficiaries. The AAN urges CMS to move forward with this proposal.

H. Pharmacy Price Concessions in the Negotiated Price

Addressing the high burden of out-of-pocket (OOP) drug costs is a key priority for the AAN. High drug costs pose numerous challenges for neurology patients, primarily by potentially limiting access to treatment. We applaud CMS' commitment to taking concrete steps to address the burdens of high OOP costs in the Medicare Part D program. 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.[6] The data indicates that the costs within the Part D program associated with the treatment of neurologic disease have grown by more than 50% in recent years.[7] Recent data also indicates that out-of-pocket costs for neurologic drugs have increased considerably in recent years.[8]

CMS proposes to redefine the term "negotiated price" to be "the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account all pharmacy price concessions."[9] The AAN notes that this point-of-sale price is

[3] 87 Fed. Reg. at 1883
[4] 87 Fed. Reg. at 1884
[5] Id.
[6] Callaghan, Brian, et al. Position Statement: Prescription Drug Prices. American Academy of Neurology, https://www.aan.com/siteassets/home-page/policy-and-guidelines/policy/position-statements/18_prescriptionpricesps_v304.pdf.
[7] Havenon, Adam de, et al. "Five-Year Trends in Payments for Neurologist-Prescribed Drugs in Medicare Part D." Neurology, Wolters Kluwer Health, Inc. on Behalf of the American Academy of Neurology, 20 Apr. 2021, https://n.neurology.org/content/96/16/e2132.
[8] Callaghan, Brian C, et al. "Out-of-Pocket Costs Are on the Rise for Commonly Prescribed Neurologic Medications." Neurology, Lippincott Williams & Wilkins, 28 May 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6556089/.
[9] 87 Fed. Reg. at 1912

used to calculate beneficiary cost-sharing. As stated in the proposed rule, "when price concessions are applied to reduce the negotiated price at the point-of-sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing. In contrast, when price concessions are applied after the point-of-sale, as DIR [direct and indirect remuneration], the majority of the concession amount accrues to the plan, and the remainder accrues to the government."[10] The primary benefit to beneficiaries from DIR being applied after the point of sale is the potential for lowered plan premiums. In certain cases, DIR received by a plan sponsor can contribute to sponsor profits without necessarily being reflected in lower plan premiums.

The AAN is concerned with the ongoing trend within the Part D program towards higher DIR[11] that may not be accruing sufficient benefits to Part D beneficiaries either in the form of lower premiums or lower OOP costs. The AAN concurs with CMS that cost-shifting to plan beneficiaries becomes increasingly pronounced as the proportion of price concessions not reflected at the point of sale continue to grow. The AAN is also concerned that ongoing cost-shifting reduces transparency and hinders patients' abilities to understand and anticipate the costs of their Part D medications.

The AAN concurs with CMS that changes to existing policies related to pharmacy price concessions are needed to promote transparency and to ensure that neurologic patients with high Part D drug costs are not paying higher costs at the pharmacy counter to effectively subsidize premiums paid by the broader population of Part D beneficiaries. As such, the AAN supports the agency's proposal to require that the negotiated price "reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug."[12] The AAN also supports that this calculation must "exclude any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest possible reimbursement level"[13] including incentive fees paid under a performance-based payment arrangement. The AAN appreciates that the agency included an example in the rule demonstrating the standard for the "lowest possible reimbursement" and encourages the agency to utilize similar illustrative examples in future rulemakings to provide clarity.

Thank you for the opportunity to provide comments on the proposed changes to Medicare Part D and Medicare Advantage policies. Please contact Matt Kerschner, Director, Regulatory Affairs at mkerschner@aan.com or Max Linder, Government Relations Manager at mlinder@aan.com with any questions or requests for additional information.

Sincerely,

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology

[10] Id.
[11] Table 3: Pharmacy Price Concessions by Year (2010-2020), 87 Fed. Reg. at 1910
[12] 87 Fed. Reg. at 1915
[13] Id.