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August 9, 2019

The Honorable Chuck Grassley
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden,

The American Academy of Neurology (AAN), the world's largest neurology specialty society representing over 36,000 neurologists and clinical neuroscience professionals, is strongly committed to improving the cost-effective care and outcomes of persons with neurologic illness.

One in six people live with a brain or nervous system condition, including Alzheimer's disease, Parkinson's disease, stroke, epilepsy, traumatic brain injury, ALS, multiple sclerosis, and headache. The annual cost of treating these disorders in the US is more than $600 billion, and prescription drugs for neurologic conditions are increasingly expensive. Neurologists seek to provide high-value care for their patients at the lowest cost possible.

The AAN applauds the Senate Committee on Finance for conducting several meaningful hearings this year and for advancing legislation aimed at lowering prescription drug costs for 46 million Medicare Part D beneficiaries. We write today to express our support for provisions in Title I of The Prescription Drug Pricing Reduction Act of 2019, discuss other provisions, and to highlight ideas not yet included in your legislation.

Rebates to Benefit Patients

The AAN supports efforts to require that patient cost-sharing be based on the negotiated price of the drug, rather than its list price and appreciates Chairman Grassley's comments during the July markup expressing his desire to include this policy in a final version of this legislation. This change would allow patients to fully benefit from discounts and rebates negotiated on behalf of their plan.

Prescription drugs for neurologic conditions are some of the most expensive on the market, with recent reports showing exponential growth compared to other fields of medicine. High drug prices create substantial challenges for neurologists to deliver accessible and affordable care for their patients. These challenges are compounded by the high out-of-pocket costs that patients pay to treat and manage neurologic conditions. One illustrative example of this burden is the out-of-pocket drug costs paid by patients with multiple sclerosis (MS). A recent study found that people taking these medications paid an average out-of-pocket cost of

$15 a month in 2004 compared to an average of $309 a month in 2016, meaning their out-of-pocket costs were 20 times higher in 2016 than in 2004.[1]

The rising cost of medicine coupled with increased cost sharing obligations threatens access to care for too many patients with neurologic illness. Financial toxicity, once limited to oncology, is now a real factor in treating many neurologic conditions. **The AAN strongly supports requiring negotiated discounts to be passed through to patients at the pharmacy counter.**

Inflationary Caps in Part D (Sections 128)

The AAN encourages the Committee to consider via a floor amendment permitting the Secretary of Health and Human Services to negotiate fair prescription drug prices under Medicare Part D, in addition to, or rather than, pursuing inflationary caps.

The AAN believes direct price negotiation is a vital tool to lower the cost of medications. Negotiation allows the government to leverage its purchasing power to obtain prescription drugs at a lower price. The purchasing power of the federal government cannot be matched, even by Part D plan sponsors who already negotiate on behalf of their plan beneficiaries. Additionally, the idea of direct negotiation is supported by the vast majority of Americans.[2] Leveraging the government's purchasing power is especially critical for high cost drugs and those with limited competition, for which Part D plans currently have little negotiation leverage.

The proposed inflation cap for Part D would only provide a back stop to prevent unlimited future price increases but would not proactively lower costs for consumers to reverse the dramatic price hikes that have occurred in recent years. For example, a well-established drug to treat symptoms of multiple sclerosis initially priced at $8,000 annually has increased tenfold in price over 20 years, despite generic competition. We also believe that establishing an inflationary cap in Part D creates a strong incentive for manufacturers to launch new drugs at higher prices because subsequent price increases would be limited by this policy. This is especially true because the current policy relies on CPI-U, rather than traditional medical inflation.

We recognize that authorizing direct negotiation may have only a modest effect without additional changes that provide the Secretary with more bargaining leverage. We believe additional leverage could be provided in your legislation, or through subsequent actions, in ways that would accomplish this goal while preserving access for patients. Potential ideas include creating backstops for negotiation failures such as a price floor based on the amount paid by the Department of Veterans Affairs (VA), or a well-structured international price index. Our members serving patients in VA facilities are able to provide significant prescription drug savings to their patients, and at a minimum, this value should be extended to the entire health care system.

Part B Reforms (Sections 102, 107, 110)

The AAN is concerned that the policy proposed in Section 102 to exclude the value of coupons provided to privately insured individuals from each drug's Average Sales Price (ASP) calculation would reduce add-on payments, having a disproportionate and unreasonable impact on neurology practices with infusion centers. Additionally, the Part B inflationary cap proposed in Section 107 would reduce the purchasing power of add-on payments over time because growth is limited to CPI-U inflation instead of medical inflation. The costs of storage, handling, and monitoring costs will

[1] https://doi.org/10.1212/WNL.0000000000007564

[2] https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/

likely rise more in line with medical inflation. The pressure to provide affordable access to biologics and other specialty medications has increased alongside the rising cost of care and declining reimbursement. If Part B reimbursement for these medications is further reduced, in combination with the existing reductions caused by sequestration, it will be more difficult for providers to sustain their infusion centers for Medicare patients. Some will be forced to refer them to the nearest hospital providing this service, greatly increasing costs and further burdening hospital facilities.

Access to infusion services with oversight by a neurologist is essential for Medicare beneficiaries. Many of the complex drugs and biologics that are administered intravenously for treatment of neurological conditions have the potential for severe allergic reactions, including anaphylaxis. The administration of many these infusions is not permitted in the home setting because of the need for medical monitoring and treatment. Additionally, many of the patients receiving these life-saving treatments are medically compromised, immunosuppressed, and neurologically impaired, requiring monitoring and/or intervention by the neurologist during the infusion. The in-office administration of certain infusions delivers value to the health care system by lowering patient and overall health system costs, while increasing patient access to high quality care.

The proposed $1,000 maximum add-on amount per day in Section 110 is a reasonable way to constrain costs in many circumstances, but the AAN urges the Committee to build in some flexibility to ensure that this broad policy does not adversely affect therapies that warrant a higher add-on payment. This could come in the form of either an appeals process, or providing the Centers for Medicare and Medicaid Services (CMS) flexibility to increase payments for treatments that warrant it due to exceptional storage, handling, administration, or other costs. We also encourage the Committee to change the inflation adjustment to match medical inflation, rather than CPI-U, to ensure the long-term sustainability of this policy. Finally, many higher-priced therapies have 60 to 90-day payment terms, but some are as short as 20 days to maximize discounts. If the payment terms become shorter, this could be problematic if facilities are financing their inventory until claims are paid.

Drug Manufacturer Price Transparency (Sec. 141)

The AAN applauds the Committee for including transparency requirements for pharmaceutical manufacturers in The Prescription Drug Pricing Reduction Act. The AAN supports proposals that promote transparency in prescription drug pricing. Broad disclosure of pricing information, including how drugs are priced, the prices paid by insurers, and the prices paid by consumers, would provide information critical to lowering costs for patients and the entire health care system.

The costs of existing prescription drugs for many neurologic conditions continue to increase and these reporting requirements would provide valuable information to patients and physicians as well as important documentation of price changes over time. The AAN also supports the requirement for public justifications for price increases, but we believe this provision can be strengthened. The Committee could require (rather than permit) the disclosure of the relevant components that impact the cost of specific drugs, such as the total manufacturer research and development spending on the drug; total revenue and net profit from the drug each year since approval, total costs for marketing and advertising the drug, and the percentage of total research and development spending for the drug that came from federal funds. We believe requiring both a justification and specific standardized data will provide consumers and the public greater transparency.

The AAN encourages the Committee to consider lowering the price increase thresholds for drugs that represent the top 50 percent of net spending (per dose) in Medicare or Medicaid to ten percent

per year in any given year. For longer term periods, we recommend 25 percent over three years, 35 percent over four years, and 40 percent over five years. We believe a ten percent increase in any year is a fair threshold that would not overburden the goal of pharmaceutical innovation. Several companies have selected the 10 percent threshold voluntarily[3] and this figure is still significantly above typical inflation and medical inflation. Additionally, thresholds for 3 to 5 year periods should be smaller on an annualized average basis, as your legislation already reflects. The ten percent threshold also mirrors the FAIR Drug Pricing Act (S. 1391), which the AAN supports. The FAIR Drug Pricing Act has bipartisan support and has already been advanced out of the Senate Committee on Health, Education, Labor and Pension.

Finally, the AAN encourages the Committee to consider having the disclosure requirements trigger in advance of a price increase, rather than retroactively. The responsibility of filing should be on the manufacturers themselves and required in all such cases, rather than only after being notified by the Secretary. We believe these changes will significantly increase the effectiveness of this provision and its usefulness to consumers.

Support for Structural Reforms in Part D to Make Medications Affordable to Patients (Section 121)

The AAN supports the Committee's proposal to eliminate the coverage gap and significantly lower the out-of-pocket maximum for prescription drugs costs to $3,100. 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[4], which trailed only internal medicine and family practice amongst specialties. High drug prices create unnecessary challenges for neurologists to deliver accessible and affordable care for their patients.

These challenges are compounded by the high out of-pocket costs patients pay to treat and manage neurologic conditions. As noted above, patients with MS, in particular, shoulder an increasing share of the rising costs of their medicines. A recent study found that the average Medicare Part D annual out-of-pocket cost across disease-modifying therapies (DMTs) for MS is $6,894 per patient[5], an amount well within the current coverage gap and likely exceeding the existing catastrophic threshold of $8,139 for someone with above average medical expenses. Because MS is a chronic condition, most patients will be on these drugs for their entire lifetimes, and their costs continue to rise annually. Many MS DMTs are not new, yet the average annual out-of-pocket costs in 2019 for several specialty drugs in Medicare Part D, including three MS DMTs, are 12 percent higher than in 2016.[6] Dramatic price increases have also occurred for brand name drugs for other neurologic conditions including peripheral neuropathy, dementia, and Parkinson's disease.

The current extremely high levels of cost-sharing for neurologic conditions are unaffordable for many patients with neurologic disorders and act as a barrier to care. As such, the AAN supports the structural reforms proposed by the committee, which will significantly lower barriers to patient access to vital treatments.

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[3] https://www.citizen.org/wp-content/uploads/prescription-drug-corporation-ceo-price-survey.pdf

[4] Lott, Lindsey B. De, et al. "Medicare Part D Payments for Neurologist-Prescribed Drugs." Neurology, vol. 86, no. 16, 2016, pp. 1491–1498., doi:10.1212/wnl.0000000000002589.

[5] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05357

[6] https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/

For many of these patients, however, there is often no "one size fits all" course of treatment. Prompt access to prescribed care is essential to minimize risks of disease exacerbation and progression making it important that any shift in risk to insurers be paired with provisions to counteract the likely harmful increase of inappropriate utilization management strategies.

As drug prices increase, access to needed therapies is restricted as payers adopt practices to limit choice and shift costs to the patient. Utilization management tools such as step therapy and prior authorization are time consuming and expensive administrative requirements that detract from direct patient care and reduce access to prescribed therapies. According to a recent survey from the American Medical Association (AMA), physicians in the United States average 31 prior authorizations a week, taking an average of 15 hours a week to process.[7] Addressing the burden of prior authorization requires the hiring of additional full-time employees for many practices and can be another source of waste within the health care system. The AAN is very concerned by the expansion of prior authorization and medically unwarranted step therapy throughout the health care system and opposes further interference by payers in the physician-patient decision-making process.

Under the proposed structural reform, insurers may expand burdensome step therapy and prior authorization requirements to keep patients from receiving critical therapies to avoid reaching the catastrophic threshold. This expansion would be in addition to the rapid expansion of utilization management that has already occurred in recent years.

Patients and providers do not set the prices of drugs. Ultimate accountability for these prices should fall on the manufacturers that set unreasonable list prices, as well as the other actors in the system. Formulary controls incentivize insurance companies to artificially prefer one drug over another without clinical reason, even when drugs have similar wholesale acquisition costs. These controls mask exorbitantly high list prices and substitute financial incentives for the medical decision-making of clinicians. The practice of insurers and pharmacy benefit managers (PBMs) that favor one drug over another through formulary changes and step therapy and that lack a clinical rationale remains a persistent obstacle to providing high-quality patient care.

The AAN urges the Committee to ensure that patients and providers are not inappropriately restricted from treatments and burdened utilization management due to the structural reforms that shift risk to insurers. The Committee should consider developing policies to mitigate this challenge including utilization management transparency measures, requiring streamlined processes for approvals/exceptions, and minimizing the use of unnecessary prior authorization for routinely approved prescriptions.

Other Comments

The AAN encourages the committee to broadly consider how the policies within your proposal would affect orphan drugs, which warrant special attention. Neurologists treat nearly 20 percent of all rare diseases, and thus are particulary affected by the uniqueness of orphan drug policy. For example, over the last two years two treatment options for spinal muscular atrophy (SMA) have

[7] https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf

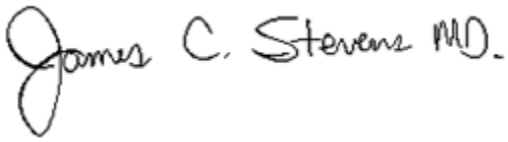
come to market—including the first neurology gene therapy—truly revolutionizing the treatment options for individuals suffering from this genetic condition. And yet both therapies are profoundly expensive, with one being priced over $2 million. These dramatic prices, combined with the potential for abuse of orphan drug incentives, warrant special attention to ensure that innovation for rare diseases is balanced with access.

The AAN is encouraged by the Committee's efforts to establish innovative payment agreements in Medicaid for potentially life-saving gene therapies like those for SMA. There will likely be more high-cost breakthrough therapies in the near future to treat neurologic conditions, and the United States must continue considering the best way to balance benefits vs. cost.

The AAN also encourages the Committee to continue its investigations into manufacturers who inappropriately put profits over patients by looking at instances of medications that were once affordable becoming profoundly expensive overnight. Many neurology patients have suffered as a result of this practice. In particular, a drug used to treat Lambert-Eaton Myasthenic Syndrome (LEMS) patients called 3,4-DAP[8] was previously available at no cost before becoming a $375,000 drug earlier this year.

Conclusion
We thank the Committee for the focus you have placed on addressing the high costs of prescription medications in America and we look forward to working with you to address this critical issue. If you have any questions or requests for additional information, please contact Derek Brandt, AAN's Director, Congressional Affairs, at *dbrandt@aan.com*.

Sincerely,



James C. Stevens, MD, FAAN
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CC: Members of the Senate Committee on Finance

[8] https://www.statnews.com/2018/11/30/fda-approval-lems-drug-costs/