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 and increasing market transparency is a top priority for the AAN. We applaud CMS’s commitment to taking concrete steps to increase the availability of drug pricing information to patients and providers. 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. High drug prices create unnecessary challenges for neurologists to deliver accessible and affordable care for their patients.

The lack of information and transparency in the current system makes patient drug costs unknowable for physicians. For some neurologic conditions, a physician may have several drugs that are relatively equal in efficacy for a patient, but each of which have drastically different prices. It can be difficult for neurologists to determine the medication that is best for a patient’s physical health and best for the patient’s financial wellbeing. We appreciate the opportunity to comment on policies that are aimed at lowering drug prices and improving availability of drug pricing information for patients and providers.
The AAN opposes direct to consumer advertising but welcomes increased transparency

In 2017, the United States pharmaceutical industry spent more than $6 billion in direct-to-consumer (DTC) advertisements, with more than half of that spending going to television advertisements. The United States remains one of just two countries that permit direct-to-consumer pharmaceutical advertising. These advertisements bypass the physician, and complicate patient relationships with their prescribers as they demand newer, more expensive, and often unnecessary or inappropriate treatments. Advertisements lack the comprehensive information required to present the full scope of potential risks to patients, and patients benefit from the support of trained medical professionals when making decisions about medication. The AAN opposes direct-to-consumer pharmaceutical advertising and encourages manufacturers to divert these funds to medical research and development.

While the AAN welcomes efforts to increase transparency and increase the availability of drug pricing information for patients and providers, the AAN is skeptical of the impact that will be made by CMS’s proposal to mandate inclusion of the list price in DTC television advertisements. The AAN believes the current proposal will not provide patients and providers with sufficient and actionable information. The AAN understands that CMS’s proposal to mandate inclusion of the wholesale acquisition cost (WAC) is based on the notion that this is the price controlled by pharmaceutical manufacturers and is the price that can most easily be included in the DTC advertisements generated by those companies. While this reasoning is sound, the actual price paid by consumers can vary widely from the WAC, based on insurance status. Therefore, the inclusion of the WAC price will not actually communicate the information that many patients will need.

In fact, inclusion of the WAC could be misleading to insured patients who would not be responsible for paying the full WAC price. The AAN is concerned that patients may forgo care out of fear of being responsible for paying inflated WAC prices. To offset the potential negative behavioral effects that can stem from mandated disclosure of extremely high WAC prices, the AAN recommends that CMS mandate inclusion of easily understood language indicating the likely range of out of pocket costs to be paid by patients with varying insurance statuses and cost sharing arrangements. Such a disclosure ought to include information relevant to those in high deductible plans who would be responsible for paying the WAC until they reach their deductible, as well as to those whose cost sharing is proportionally based on WAC.

The AAN is skeptical of the mechanics and impact of the disclosure requirement

The proposed rule requires DTC pharmaceutical advertisements to include a price disclosure in a “legible textual statement at the end of the advertisement, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.” Although the AAN supports the requirement, the AAN is concerned that the requirement could be too vague and open to manipulation. The AAN recommends that CMS release guidance relating to the specific duration, font and contrast requirements that would constitutes a legible textual statement.
The AAN is also concerned with the proposal to limit the disclosure requirement solely to television DTC advertisements. Although the majority of pharmaceutical advertisements are delivered via television, the AAN believes that the disclosure requirement should not be limited solely to television. As pharmaceutical investment in online DTC advertising continues to grow, it is important that disclosure requirements are consistent across platforms. In the absence of consistent disclosure requirements, it could be possible for the exact same ad to be delivered via television and the Internet, and for the disclosure to be included in one but not the other. The AAN recommends that CMS implement a consistent price disclosure requirement across advertising mediums.

The AAN is also skeptical of the impact that solely requiring a legible textual statement in a television advertisement will have on patients. Studies have shown that very few people read footnoted information in advertisements. Studies have also shown that dual-modality disclosures, requiring that information be conveyed simultaneously through text and spoken word, are more effective than text only disclosures. Text only television disclosures are also frequently not displayed for enough time for consumers to be able to read and synthesize the information contained therein. The AAN is concerned that those with cognitive and visual impairments, who are likely to disproportionately be in need of the pricing information contained in DTC price disclosures, will be especially impacted by the problems associated with text only disclosures in television advertisements.

**The AAN is concerned with a lack of a substantive enforcement mechanism**

The AAN is concerned by the lack of a substantive enforcement mechanism contained in the proposal. The rule states that no governmental enforcement mechanism is proposed aside from the Secretary maintaining and publishing “a public list including the drugs and biological products identified by the Secretary to be advertised in violation of this rule.” The AAN requests clarification on how the list will be generated and how violators will be determined. For example, will CMS or HHS be actively monitoring pharmaceutical advertisements airing on television to ensure compliance? In the absence of more clarity regarding enforcement, the AAN is concerned that there will be selective enforcement of the disclosure requirement, which will limit this proposal’s potential positive effects on price transparency.

Additionally, the AAN is concerned that the proposed list is merely a shaming tactic rather than a robust mechanism that would lower drug prices. This shaming tactic is unlikely to meaningfully reduce drug prices, as it does not directly address truly egregious prices. The AAN is concerned that pharmaceutical manufacturers may simply normalize ultra-high list prices by including them in advertisements. The AAN is unconvinced that this tactic will significantly impact the behavior of pharmaceutical companies who are ultimately responsible for setting extremely high list prices.

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3 Ibid
4 Ibid
The AAN supports the minimum price threshold to be subject to the disclosure requirement

The AAN believes it is reasonable to exclude drugs with prices that are below $35 for a 30-day supply or a typical course of treatment from the transparency requirements. Price transparency is most needed for drugs with exorbitantly high prices that far exceed the $35 threshold for exclusion. It is reasonable to base the threshold for inclusion on the average copayment for a preferred brand drug since CMS is correct that the public is already accustomed to paying roughly this price out of pocket for drugs.

The AAN supports creation of a drug price counseling reimbursement code and a robust drug pricing dashboard

The AAN supports the creation of a reimbursement code for physicians who choose to provide drug price counseling to their patients. Physicians who use their time to research and understand the impact that prescriptions will have on their patients’ financial well-being should be properly compensated for their time and effort. Although the AAN supports physicians receiving reimbursement that is resource based and reflective of the time and effort they have expended, the AAN is concerned with the potential for a shift in expectations when it comes to price counseling. It is unlikely that many practicing physicians will have the time or expertise necessary to provide accurate and up-to-date pricing information to their patients. Creation of this new price counseling code could create administrative burden if it becomes normalized for physicians to provide drug price counseling services. Normalization of this practice would create significant pressure on physicians, who would then need to ensure that they are knowledgeable enough to provide accurate and up-to-date drug pricing information. This knowledge can extend beyond a physician’s clinical expertise. The AAN recommends, prior to implementing a drug price counseling reimbursement code, that CMS ensure sufficient resources are in place so that physicians can provide accurate and up-to-date drug pricing information, including relevant cost sharing, without disrupting their clinical workflow.

The AAN supports a robust CMS drug pricing dashboard that can be accessed by patients and providers. The AAN agrees that relevant information including list price, typical out of pocket costs, therapeutic alternatives, and pharmacoeconomic research would promote transparency and be helpful to patients and providers.

Conclusion

Thank you for the opportunity to provide comments on this proposal to promote transparency in drug pricing through price disclosure in DTC advertising. While the AAN supports actions that would promote price transparency, the AAN believes that this policy will only minimally inform consumers and address rising drug prices. The AAN believes that the above recommendations can strengthen the impact of the disclosure and improve enforcement of the requirement. The AAN applauds the administration’s commitment to lowering drug prices and is committed to continuously engaging on this issue.
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,

Ralph L. Sacco, MD, MS, FAHA, FAAN
President, American Academy of Neurology