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

RE: Modernizing Part D and Medicare Advantage to Lower Out-of-Pocket Expenses

Dear Administrator Verma:

The under signed organizations greatly appreciates the opportunity to comment on the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule (CMS-4180-P) (hereinafter the "Proposed Rule").

Together, we oppose CMS's proposal to permit Medicare Advantage plans to implement step therapy for Part B drugs. **Step therapy is a coverage tool that, if used by Medicare Advantage ("MA") Plans, will inappropriately deny Medicare beneficiaries access to Part B items and services that they would receive under Original Medicare, it will delay access to necessary care, and will interfere in physician decisionmaking**. Importantly, the Medicare statute precludes CMS from permitting Medicare Advantage ("MA") plans to impose step therapy on Part B drugs and CMS should therefore not finalize this rule. Should CMS decline to accept our recommendation and decide to finalize this rule and permit MA Plans to impose step therapy on Part B drugs, we strongly recommend changes to the proposed regulatory text in order to protect patients and ensure access to covered drugs.

- **CMS Lacks Statutory Authority to Permit MA Plans to Impose Step Therapy, Which Is a Coverage Tool**

As recognized by CMS in the Proposed Rule, prior to the release of the August 7, 2018 Health Plan Management System ("HPMS") memo titled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage" and subsequent FAQs, "CMS guidance interpreted existing law to prohibit MA plans from using step therapy for Part B drugs because such a utilization management tool would create an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law."[1] We believe this is the correct interpretation of Social Security Act ("SSA") §§ 1852(a)(1)(A) and (B), which mandate that MA Plans "provide to members enrolled under [Medicare Advantage] . . . benefits under the original Medicare fee-for-service program option, defining these benefits as "those items and services

[1] 83 Fed. Reg. 62152, 62169 (Nov. 30, 2018).

(other than hospice care) for which benefits are available under parts A and B." The Medicare statute unequivocally entitles both fee-for-service and Medicare Advantage enrollees to coverage of any drug within a Part B benefit category that is reasonable and necessary to diagnose or treat illness or injury or improve the functioning of a malformed body member.

Despite this clear mandate, which prohibits CMS from permitting MA Plans to impose step therapy (putting forward a coverage decision, not a utilization management tool, as discussed below) on Part B drugs, CMS reversed this longstanding interpretation with an inadequate explanation. In the Proposed Rule, CMS explains that it is reversing its prior interpretation because "CMS recognizes that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs."[2] In support of the reversal, the sole statutory authority that CMS relies on are the provisions at Social Security Act ("SSA") §§ 1852(c)(1)(G) and (c)(2)(B), which use the words "utilization management" and "prior authorization." From Congress's use of the words "utilization management" and "prior authorization", CMS contends in the Proposed Rule that "MA plans are not prohibited by the statute from implementing utilization management tools such as step therapy."[3] **This provides no explanation why CMS has reversed its position and now believes that step therapy imposed by MA Plans on Part B drugs does not create an unreasonable barrier to coverage of and access to Part B benefits, or why step therapy by MA Plans does not contravene SSA § 1852(a)(1)(A) which requires that MA Plans provide benefits under the original Medicare fee-for-service program**.

CMS's reasoning for its change in position does not provide opportunity for meaningful comment on the basis of the change in position. CMS's explains that the use of the words "utilization management" permits step therapy similar to how it permits prior authorization, however, it is important to point out that while Congress clearly states that MA Plans must cover Part A and B benefits, and contemplates that MA Plans may implement utilization management tools like prior authorization, there is no mention of step therapy in the Medicare statute. **In fact, our groups believe that the concept of step therapy is antithetical to the requirement that MA Plans provide equal access to and coverage of Part B drugs as Original Medicare.** This is primarily the case because step therapy is not a utilization management tool, it is a coverage tool. On the one hand, prior authorization is "[a] process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to an enrollee."[4] Thus, prior authorization does not narrow Original Medicare coverage in any way, nor deny coverage of one product until a different product is tried first; it simply requires providers to verify that an item or service is covered before furnishing the item or service to a plan enrollee. Conversely, as recognized by CMS in its proposed definition in the proposed regulatory text, step therapy is a "utilization management policy ***for coverage of drugs*** that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary."(emphasis added) **In other words, CMS acknowledges that step therapy is a coverage tool that restricts access of Medicare beneficiaries to Part B drugs including restricting access solely on the basis of cost.**

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[2] *Id.*
[3] *Id.*
[4] Medicare Management Care Manual, Ch. 4, § 110.1.1.

We are also concerned that CMS intends to "rely on the MA plan's responsibility to provide all medically necessary covered services and items under the original Medicare program as meaning that cases raising ineffectiveness or adverse effects of treatment as being sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol." By failing to impose standards and requirements on when MA Plans must grant an exemption or not implement a step therapy policy altogether, CMS is granting MA Plans broad discretion in contravention of the Medicare statute. CMS must make it clear that MA Plans are required to "comply with – (1) CMS's national coverage determinations; (2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations . . . or related instructions; and (3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area [served by the MA plan]"[5] when adopting a step therapy policy. This also means that when there is an applicable national coverage determination ("NCD") or local coverage decision ("LCD") relevant to the disease state and/or drugs that could be subject to the step therapy policy, that the MA Plan is required to comply with and defer to the NCD or LCD, which may result in the MA Plan not being permitted to adopt the step therapy policy at all. This is true even if the NCD or LCD is silent with regard to step therapy. Until recently, Medicare contractors were required to consider "prerequisite therapies" (*i.e.*, "the concept that use of an alternative item or service precedes the use of another item or service," in other words, step therapy) when issuing LCDs.[6] Thus, any LCDs issued prior to January 7, 2019 must be deemed to have considered prerequisites, even if no prerequisites are imposed in the LCD, and MA Plans must be prohibited from implementing a step therapy policy when that LCD would apply.

- **CMS's Proposals Are Inadequate to Ensure That Imposition of Step Therapy Will Not Interfere With Access to Part B Drugs**

After careful review, our group do not believe CMS has the authority to permit MA Plans to impose step therapy for Part B drugs and the rule should therefore not be finalized. If CMS finalizes the rule in spite of our recommendation, we have significant concerns about the proposed regulatory text. **Specifically, we are concerned that CMS's proposed regulatory language and preamble text does not do enough to ensure that step therapy will not impede MA Plan beneficiary access to Part B drugs**.

- Step Therapy Should Be Based on Clinical Outcomes and Not Cost Alone

As noted above, in the proposed regulation text, CMS defines step therapy to mean "a utilization management policy for coverage of drugs that begins medication for a medical condition with the **most preferred or cost effective drug therapy** and progresses to other drug therapies if medically necessary." CMS does not clarify what a "most preferred" medication would be. Furthermore, by using the word "or" CMS would allow MA Plans to require patients to use a less expensive drug, even if it is not "most preferred" clinically or not supported by clinical evidence as having the same or better clinical outcomes as an alternative drug.

[5] 42 C.F.R. § 422.101.
[6] Medicare Program Integrity Manual, Ch. 13, § 13.5.5 (valid through Jan. 7, 2019).

CMS's proposed requirements for step therapy decisions by pharmacy and therapeutic ("P&T") committees do not do enough to ensure that step therapy will be based on improved clinical outcomes and not solely on cost. CMS proposes to require that P&T committees include practicing physicians, base clinical decisions on scientific evidence, and consider the therapeutic advantages of step therapy. We point out that at the same time, these requirements are all qualified in a way that would permit MA Plans to make inappropriate decisions that harm patients and provide the physician community with little information to challenge a harmful step therapy policy or request an exemption for a particular patient. For example, in the proposed regulatory text, CMS proposes to require the P&T committee to "[b]ase clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate." This suggests that an MA Plan could choose to ignore information that it deems "inappropriate." Similarly, CMS proposes to require the P&T Committee to "[c]onsider whether the inclusion of a particular Part B drug in a utilization management program, such as step therapy, has any therapeutic advantages in terms of safety and efficacy." Simply requiring an MA Plan to "consider" whether inclusion of a Part B drug has any therapeutic advantages is insufficient and gives MA Plans unbridled discretion to ignore clinical outcomes when imposing step therapy. **If a drug does not have therapeutic advantages in terms of safety and/or efficacy, then we do not consider it appropriate to make that drug a preferred step therapy drug, particularly not based on cost alone.** If the purpose of step therapy is to reduce cost, then only drugs that have a therapeutic advantage in terms of safety and efficacy should be required as a part of a step therapy program.

Additionally, although CMS's proposed requirements for composition of the P&T committee mirror those currently in place for Part D Plans, it is necessary for the P&T Committee to also include one or more specialists who are not affiliated with the MA Plan to be part of step therapy decisions for given therapeutic areas in order to best serve patient care. For example, if an MA Plan intends to develop a step therapy requirement for an ophthalmic drug, it is imperative that an independent ophthalmologist be part of the P&T committee for purposes of that step therapy policy. More specifically, if an MA Plan intends to impose step therapy for drugs for the treatment of diseases or conditions treated primarily by particular specialists, then physicians from those specialties knowledgeable about those drugs and how patients respond to treatment on different potential treatments must be part of the P&T committee. For example, ophthalmologists treating age related macular degeneration or other specialties like rheumatology and oncology. Because step therapy policies are inherently focused on sub-specialties with high-risk patient populations, implementing step therapy policies without input from independent specialists would significantly harm patients. We propose that CMS add the following language to proposed section 422.136(b)(3): "[x] In addition to all other members of the P&T committee outlined in this section, include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan and is a specialist in the disease area that will be affected by the step therapy policy."

In conclusion, although we are very concerned that *any* policy that permits MA Plans to impose step therapy on Part B drugs will harm patients, if CMS decides to finalize the proposal, our recommendation is that CMS,

1) **Require that MA Plans imposing step therapy only do so when there is an alternative drug that has the same or better clinical outcomes, as supported by substantial medical literature, and to prohibit MA Plans from implementing step therapy based on cost alone.**
2) **Furthermore, the MA Plan should be required to publish the clinical data and supporting documents that it relies on when imposing step therapy as well as its reasoning in making the decision in order to enable providers to submit informed exceptions requests and appeals.**
3) **Additionally, the P&T committee making decisions about step therapy policies must include at least one independent specialist that treats patients in the disease state subject to the step therapy policy.**

- Patients Will Not Be Provided With Adequate Notice or Information About Step Therapy Policies

In the rule CMS states that patients must be provided with specific information about an MA Plan's step therapy policies prior to enrollment despite this, CMS's proposed notification requirements are insufficient for that purpose. CMS proposes that "[c]onsistent with our existing disclosure requirements at § 422.111, when applying step therapy to Part B drugs, MA plans must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) document. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under 'Medicare Part B prescription drugs.'" Although CMS tells MA Plans *where* they must disclose information about step therapy, CMS provides no guidance on the substance of the information that must be disclosed.

In addition to requiring MA Plans to disclose the existence of a step therapy policy in the ANOC and EOC, **CMS should also require MA Plans to make the step therapy policies publicly available on the MA Plan's website and in enrollment materials. For each step therapy protocol, the publicly available information must include all drugs subject to the policy and their indications, as well as the data and publications the P&T committee relied on when creating a step therapy policy for those drugs. This information is necessary to enable patients to make informed decisions about whether they will be potentially impacted by an MA Plan's step therapy policy and to permit physicians to submit exceptions and appeals requests.**

Additionally, MA Plans should be prohibited from adding drugs to existing step therapy policies or creating new step therapy policies mid-year. If an MA Plan wishes to add drugs to a step therapy protocol or create a new step therapy protocol, it should not be permitted to take effect until the following calendar year or else patients will have chosen an MA Plan based on misleading coverage information.

- The Standard Timeframe For Appeals Should Be 24 Hours

CMS proposes to follow the Medicare Part D timeframes for organization determinations related to step therapy, imposing a standard 72 hour timeframe and expedited 24 hour timeframe for MA

Plans to respond to requests for Part B drugs. **While we appreciate that CMS has determined that the Medicare Part D, and not the existing Medicare Part C organization determination timeframes are most appropriate, for the sake of our patients, 24 hours should be the standard timeframe for all Part B drug requests.** Unlike Part D drugs, Part B drugs are almost exclusively administered to the sickest patients. These drugs are required to be administered by a healthcare professional, and, therefore, require a patient to go to their doctor to receive treatment. Thus, there is the additional complicating factor for Part B drugs that physician offices need to schedule patients to receive the treatment. For this reason, MA plans should be required to make decisions about Part B drugs on a standard 24-hour timeframe.

- **The Part D Prior Authorization Proposals Are Problematic**

With regard to CMS's proposals for Part D, our groups also do not support CMS's proposal to permit Part D sponsors to impose prior authorization requirements on protected class drugs. Without such limits, our physicians have experienced prior authorization requirements that create substantial barriers to access for patients and impose significant administrative burden on providers without substantially reducing unnecessary utilization.

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Our groups greatly appreciates your attention to our concerns. For additional information or if you have questions, please contact Ms. Cherie L. McNett, Director of Health Policy at the American Academy of Ophthalmology at cmcnett@aao.org or via phone at 202-737-6662.

Sincerely,

The American Academy of Ophthalmology

American Society of Cataract and Refractive Surgeons

The American Glaucoma Society

The American Society of Retina Specialists

The Retina Society