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Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4180-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The American Geriatrics Society ("AGS") 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).

The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners ("NPPs") who are devoted to improving the health, independence, and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policymakers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy.

We appreciate the Administration's focus on reducing the cost of prescription drugs, but urge the Centers for Medicare and Medicaid Services ("CMS") to be cautious about the impact of any new policy on ready access to needed medications for Medicare beneficiaries. Lack of access to the most appropriate treatments, even for as little as a week, could have significant consequences for this patient population, and existing protections are inadequate to ensure that access.

We urge CMS to consider the following concerns and/or adopt the following recommendations in the final rule:

- **The AGS is concerned that CMS's proposal to allow prior authorization requirements for any protected class product with more than one medically-accepted indication will limit access to these drugs for important uses that may not be considered a protected class indication.**

- **CMS identifies the protected class indication for antidepressants and antipsychotics to be “mental disorders.” We ask CMS to confirm our understanding that behavioral disorders associated with dementia is included within its definition of “mental disorders.”**
- **AGS strongly believes that if CMS finalizes an exception to permit Part D sponsors to use prior authorization and utilization management for protected class drugs, it should be limited to new starts only. Additionally, the AGS recommends that beneficiaries switching from one drug plan to another be allowed to stay on their existing therapy rather than being forced to re-initiate a new sequence of step therapy.**
- **The AGS recommends that CMS outline a model appeals process that all Part D plans must use in cases where step therapy would be medically inappropriate for the patient and a system whereby CMS signs off on step therapy programs for protected classes based on certain defined criteria, including that the program is evidence-based, or for areas where adequate evidence is lacking, is based on accepted standards or best clinical practice.**
- **The AGS supports CMS’s proposal to allow Part D plans to exclude new formulations of a single source drug or biological product, but suggests that CMS develop guidelines that dictate what type of exclusions would be reasonable.**
- **The AGS recommends that CMS’s proposal to permit Part D plans to exclude from their formulary any protected-class drug whose price exceeds a certain threshold be accompanied by an appeals process by which reasonable exceptions to this rule could be adjudicated promptly. The AGS does not support CMS’s alternative proposals as we believe they would be extremely punitive and deny patients access to important protected class drugs.**
- **The AGS supports CMS’s proposal to amend current contracting requirements between Part D sponsors and pharmacies to prohibit gag clauses. We also urge CMS to explore initiatives to make pricing more transparent for pharmacists.**
- **The AGS urges CMS to require that real-time benefit tools (RTBT) functionality be required to extend to a specified proportion of the provider and/or patient population covered by a plan.**
- **The AGS recommends that CMS consider making EHR / eRx tools that communicate when a drug for a particular patient has been discontinued by the prescriber mandatory (or at least strongly incentivized).**
- **The AGS disagrees with CMS’s proposal to allow plans to include drug price trend information for medications in their Explanation of Benefits (EOBs), which may be distracting and confusing for the patient and is not relevant unlike information about copayments.**
- **The AGS supports CMS’s proposal to require Part D plans to provide patients with information about lower-cost drugs that are therapeutically equivalent but expresses concern about the potential harms that might arise if patients are encouraged to switch to non-therapeutically equivalent drugs used to treat the same condition simply because they are lower cost.**

- **The AGS believes the 108-day look-back period for determining eligibility for proposed Part B step therapy programs is too short and may result in a disruption in therapy and lead to bad outcomes.**
- **The AGS supports the expansion of the P&T committee requirements to all MA plans in order to allow for more general oversight.**
- **The AGS feels strongly that safeguards are needed to prevent restrictions on MA patients' ability to access needed medications under CMS's proposal to apply step therapy to Part B and Part D drugs.**
- **The AGS advocates and supports price transparency and lower and more predictable prices for consumers. We would be supportive of CMS's "negotiated price" proposal for plan sponsors if it results in lower out-of-pocket costs for consumers.**

Our specific comments are set forth in more detail below.

A. Providing Plan Flexibility to Manage Protected Classes

CMS is proposing to establish additional exceptions to CMS's "protected classes" policy in the Part D program. As its rationale for these proposed changes, CMS states that it is "concerned that requiring essentially open coverage of certain drug categories and classes presents both enrollee cost and welfare concerns, as well as increased costs for the Part D program as a result of overutilization." It is unclear what data CMS is using to determine that the current policy results in overutilization. AGS members have found that the protected classes policy provides the needed flexibility to ensure that their patients, who typically have multiple comorbidities that increase the complexity of the treatment for the protected class indication, receive the right treatment.

1. Broader Use of Prior Authorization and Step Therapy for Protected Class Drugs

CMS proposes to permit Part D sponsors to impose prior authorization or step therapy on protected class drugs in broader circumstances than it permits today. Among its proposals, CMS is proposing that prior authorization requirements would be allowed for any protected class product with more than one medically-accepted indication to help the Part D sponsor determine that the product is being used for the protected class indication. **Many drugs in these classes have more than one FDA indication, including for protected and non-protected purposes.** For example, gabapentin which is indicated for seizures and neuropathic pain, and tricyclic antidepressants (TCAs) which is used off-label for pain. **The AGS is concerned that these changes will limit access to these drugs for important uses that may not be considered a protected class indication.** Further, CMS identifies the protected class indication for antidepressants and antipsychotics to be "mental disorders." We ask CMS to confirm our understanding that behavioral disorders associated with dementia is included within its definition of "mental disorders." Behavioral symptoms of dementia are fundamentally a consequence of brain dysfunction and are treated in similar ways as many other mental health conditions, with antidepressants and antipsychotics being important parts of the therapeutic armamentarium (alongside non-pharmacologic approaches).

We are concerned that CMS underestimates the burden and potential barriers to access prior authorizations can impose on vulnerable older adults. Due to limited cognition, healthy literacy and physical abilities, it can be especially hard for vulnerable older adults to successfully do their part navigating the prior authorization process, which when applied to critically important drugs such as anti-cancer medications may hinder access and lead to worse patient outcomes.

As proposed, the exception to permit Part D sponsors to use prior authorization and utilization management for protected class drugs would be applicable to both new starts and existing therapy. **The AGS strongly believes that if CMS finalized this exception, it should be limited to new starts only.** We are concerned that if step therapy is allowed for patients currently on one of these medications (i.e., “existing users”) that it will impose delays and burdens to patients and their providers, substantially upset ongoing regimens, and ultimately lead to worsened health outcomes. This is true for all medications, but it may be even more burdensome for drugs with more than one indication. There is potential that patients using these drugs would need to frequently recertify that their use is for a specific indication, which imposes substantial administrative burdens on both patients and providers and increases the risk of administrative snafus that would result in interruptions in the requisite approvals and thereby impact ongoing access to these medications.

In addition, we ask CMS to clarify how it intends to interpret the issue of step therapy for people who transition from one Part D plan to another, and who are currently stable on a medication for a given condition. Would that patient be subject to step therapy requirements in his or her new plan for that condition, and required to stop the existing medication and instead be trialed on the “first-step” medication favored by the new plan? This scenario would be highly burdensome to patients and would likely result in worse health outcomes. **We strongly recommend that beneficiaries switching from one drug plan to another be allowed to stay on their existing therapy rather than being forced to re-initiate a new sequence of step therapy.**

There is little stated in the proposed rule showing how well the Part D appeals process for step therapy has worked to promote access to medically necessary drugs. The appeals process is far from easy to navigate or a reliable tool to ensure that patients receive the medications they need. According to plan-reported data for Calendar Year (CY 2013), for example, CMS found that only 17 percent of all Part D denied coverage determinations were appealed, even though 80 percent of those appeals were ultimately successful.¹ Further, the Medicare Payment Advisory Commission’s (MedPAC’s) June 2016 Report to Congress noted that CMS continues to find that a significant share of audited plans have difficulties in the areas of Part D transition fills, coverage determinations, appeals, and grievances. For example, a common shortfall is that many plans provide enrollees with too little information about the rationale for a coverage denial or do not demonstrate that they have reached out to prescribers for additional information to make a coverage decision.²

We are concerned that the restrictions will be onerous and will result in bad outcomes for older adults — particularly those with limited health and health insurance literacy and the ability to advocate

¹ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2015. Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. <https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/downloads/advance2016.pdf>.

² Medicare Payment Advisory Commission. 2016. Report to the Congress: Medicare and the Health Care Delivery System. <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

for themselves. We urge CMS to proceed slowly. Step therapy plans must be evidence-based (i.e., evidence that supports the plan and that the agents that remain in the preferred tier are therapeutically equivalent).

As such, **the AGS recommends that CMS outline a model appeals process that all plans must use and a system whereby CMS signs off on step therapy programs for protected classes based on certain defined criteria, including that the program is evidence-based, or for areas where adequate evidence is lacking, is based on accepted standards or best clinical practice.**

2. Excluding New Protected Class Drug Formulations from Part D Formularies

CMS proposes that a “new formulation” of a single source drug or biological product (where the new formulation has the same active ingredient or moiety as the initial formulation and does not provide a “unique” route of administration) may be excluded from a Part D sponsors’ formulary.

The AGS appreciates CMS’s effort to discourage manufacturers from introducing a more expensive formulation of a protected class drug while discontinuing the original version (e.g., memantine (Namenda)). In this exemplar case, the manufacturer of Namenda (memantine) introduced a long-acting formulation of the drug and attempted to discontinue the short-acting formulation prior to losing marketing exclusivity, thus forcing patients to switch to the new version with prolonged marketing exclusivity before the generic alternative to the original version became available. **We suggest that CMS develop guidelines that dictate what type of exclusions would be reasonable**, for example, if a new formulation offers substantial advantages in convenience, tolerability, and so forth. These guidelines should take into account patient preference; convenient and appropriate administration; and the therapeutic indication.

3. Pricing Threshold for Protected Class Drug Formulary Exclusions

CMS is proposing to allow Part D sponsors to exclude from their formularies a single source drug or biological within the protected classes that has wholesale acquisition cost (WAC) increases compared to a baseline price that are beyond the rate of inflation.

Under the current system, drug manufacturers have monopoly pricing power. The AGS applauds efforts to rein in inflation in drug prices. While the proposed rule may promote this goal, it has the potential for unintended consequences whereby it could allow Part D plans to overly restrict access to valuable medications. **We therefore recommend that this proposed rule be accompanied by an appeals process by which reasonable exceptions to this rule could be adjudicated promptly.**

CMS also seeks comment on whether, alternatively, a Part D sponsor should be able to either 1) exclude a protected class drug from its formulary for any future contract year once the product’s WAC increases more rapidly than inflation or 2) exclude all drugs in the protected class of a given manufacturer if any one of those drugs’ WAC increases more rapidly than inflation. **The AGS believes that these proposed exceptions would be extremely punitive and deny patients access to important protected class drugs.**

4. Price Negotiations and Cost Savings for Patients

CMS states that under the proposal, just because a Part D sponsor may exclude a protected class drug that meets the requirements of the exception does not mean that the Part D sponsor *must* exclude the drug. CMS indicates that it believes that, instead, product manufacturers and Part D sponsors would negotiate rebate arrangements for formulary placement of the protected class drugs that meet the requirements for potential formulary exclusion. Studies have shown that rebate programs increase cost to patients and to Medicare while actually improving profit margins for Part D sponsors and pharmaceutical companies.³ Thus, the proposed rule may in fact reduce costs for Part D sponsors much more than it reduces costs for patients and the Medicare program. **The AGS feels strongly that rebates be passed through to patients at the point of sale. Cost savings accrued through rebate programs should benefit patients in the form of lower copays/coinsurance payments and/or lower premiums, and should benefit the Medicare programs in the form of lower expenditures, and not just the insurance companies.**

In addition, we are concerned that by allowing price negotiation for formulary status, name-brand protected class drugs will be pushed off formularies, potentially in a see-saw fashion (rotating between being covered vs. uncovered). CMS's proposal could create an unnecessary dynamic to formularies and frequent changes to beneficiaries' drug regimens, including therapeutic equivalent interchanges as one drug moves off and another drug moves on to a formulary.

B. **Prohibition Against Gag Clauses in Pharmacy Contracts**

The AGS appreciates CMS's focus on increased price transparency and supports the proposal to amend current contracting requirements between Part D sponsors and pharmacies to prohibit so-called "gag clauses." **We also urge CMS to explore initiatives to make pricing more transparent for pharmacists (e.g., by ensuring that side-by-side patient out-of-pocket cost comparisons of medications are easily available).**

C. **E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards**

CMS proposes to add a requirement that, by January 1, 2020, all Part D plan sponsors implement one or more real-time benefit tools (RTBTs) that is capable of integrating with at least one prescriber's electronic medical record (EMR) and e-prescribing (eRx) systems. While the AGS supports the proposal, it is unclear how robust its impact would be in practice since these tools would only need to be integrated with one EMR and eRx system, which may be used by only a limited number of providers and patients. **We urge CMS to require that RTBT functionality be required to extend to a specified proportion of the provider and/or patient population covered by a plan.** If many providers and patients were using a single EMR and eRx system, implementing only in that system would suffice, but this criterion would prevent token adoption that only reached a small number of people affected by the plan.

³ Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending. *JAMA Intern Med.* 2017;177(8):1185-1188.

These types of services have traditionally been paid for by EMR users, e.g., clinician practices and health systems. EMR users should *not* have to pay for developing or turning on the RTBTs, and **we thus request that the rules be changed to require Part D sponsors or actors other than the health system and individual clinician users of EMRs and eRx systems to bear the cost of developing and implementing these products.**

We also recommend that CMS consider making EHR / eRx tools that communicate when a drug for a particular patient has been discontinued by the prescriber mandatory (or at least strongly incentivized), for example the type of system developed by Cancel RX. Such tools provide a vital service by communicating to pharmacies when a drug should no longer be used, and thus prevent inadvertent continuation of obtaining and using that medication by patients.

D. Part D Explanation of Benefits

CMS is proposing to require sponsors to include information about both (1) negotiated price changes and (2) lower-cost therapeutic alternatives in Part D explanation of benefits (EOBs) in order to inform beneficiaries of the prices of their prescription drugs and prices of potentially lower-cost alternatives, in the hope of empowering them to make more informed decisions and to spark discussions with their providers.

1. Information About Negotiated Drug Price Increases

The AGS recommends that CMS withdraw this component of the proposal. We believe that there is little benefit to showing patients the drug price trend information for their medications. This information is not relevant to their use (as opposed to their copay or coinsurance payments, which are relevant), and may be distracting and confusing.

2. Information About Lower-Cost Therapeutic Alternatives

In general, the **AGS supports CMS's proposal that would require Part D plans to provide patients with information about lower-cost drugs (i.e. drugs with lower copays for the patient) that are therapeutically equivalent. We are, however, concerned about the potential harms that might arise when patients are encouraged to switch to non-therapeutically equivalent drugs that are used to treat the same condition** – and which may have a substantially different profile of benefits and risks than the medication a given patient is already taking. Providing this information would benefit plans by lowering these costs but at the risk of moving patients to less effective and or less safe therapy and therefore, we urge CMS to proceed with caution. We are concerned that the proposal would allow Part D sponsors and PBMs to elevate equivalencies without evidence.

Specifically, CMS is proposing to allow, but not require, plans to provide a variety of additional information, including information about therapeutic alternatives with the same copayments if the negotiated price is lower. **We strongly recommend that this component of the proposal should not be implemented.** It is unclear how this information would benefit the patient and we are concerned that it could confuse and worsen care for them.

E. Medicare Advantage and Step Therapy for Part B Drugs

CMS is proposing to allow Medicare Advantage (MA) Plans to implement utilization management programs – particularly step therapy programs. CMS states that this flexibility also would provide plans with more leverage to negotiate lower drug prices that would presumably lower costs to the government and beneficiaries.

1. General Feedback

While the AGS supports efforts to lower drug prices, we question whether these utilization management policies will decrease access or delay care for MA recipients. We urge CMS to ensure that these utilization management policies are available and transparent before plan sign up or switch to allow Medicare consumers to compare plans. Our main concern is access to drugs, delays in care, and whether older patients will choose a plan where they are unable to receive their needed medications due to lack of transparent information about what is covered in that plan and how it is covered. **CMS should ensure easy access to better tools for consumers to evaluate medication coverage and patient cost-sharing, e.g. on Medicare.gov's new beneficiary portal.**

As shown by a recent study, shifting therapy from Part B to Part D medications may reduce total drug spending by Medicare but increase out-of-pocket costs for patients.⁴ While reducing total drug spending is a laudable goal, the AGS feels strongly that patients should benefit from any achieved costs savings through reduced out-of-pocket costs.

2. Administration and Implementation of Step Therapy

a. 108 Day Look-Back Period

The 108 day look-back period for determining what is an existing vs. new therapy – and thus eligible for proposed Part B step therapy programs – is too short in the Part B setting. The interval for infusions is quite different than the interval for traditional Part D medications used by the patient (e.g., orally administered medications, inhalers), which was the basis for this 108 day rule. Some infusions, for example ibandronate, zoledronic acid, leuprolide, and others, are given only quarterly or less. And, if a patient is a little late in getting an infusion, for example due to scheduling conflicts or intercurrent hospitalization, they could potentially be disenrolled from being considered an “existing user” (due to the 108-day window) and kicked off their therapy, with the requirement to re-enter the step therapy pathway as a “new user.” This would be highly problematic, for example for antirheumatic or anticancer biologics. Such a disruption in therapy could result in poorer disease control including relapse of symptoms and other bad outcomes including hospitalization and death, depending on the drug and condition.

⁴ Hwang TJ, Jain N, Lauffenburger JC, Vokinger KN, Kesselheim AS. Analysis of Proposed Medicare Part B to Part D Shift With Associated Changes in Total Spending and Patient Cost-Sharing for Prescription Drugs. JAMA Intern Med. Published online January 14, 2019. doi:10.1001/jamainternmed.2018.6417

b. Pharmacy and Therapeutics (P&T) Committees

The proposal would require that step therapy programs be approved by a P&T committee. This is a positive step, although the AGS does not believe that this alone will provide a fully effective failsafe to prevent patients from being harmed by proposed integrated Part B and D step therapy programs.

CMS asked in the proposed rule whether the P&T committee requirements should be expanded to all MA plans. **The AGS supports the expansion of the requirements to all MA plans in order to allow for more general oversight.**

c. MA-PD Plans Applying Step Therapy to Part B and Part D Drugs

CMS has also proposed changes to MA-PD plans that would, starting in 2020, allow a step therapy trial of Part B drugs before coverage of Part D protected class drugs. This has potential to impose substantial hardship on some patients, for example, those who live at a distance from medical centers where infusions are administered, or when those infusions need to be given frequently. In addition, this proposal could put MA patients at a disadvantage since Part D and Part B benefits are not very well coordinated, which may result in delays going back-and-forth between benefits. Thus, while in general the integration of coverage decisions for Part B and Part D covered drugs is reasonable, **the AGS feels strongly that safeguards are needed to prevent substantial practical restrictions on patients' ability to access needed medications, with such safeguards accounting for patients' clinical conditions and for the realities of their lives** (for example, the ability to regularly access infusion therapy).

As noted above, this type of information (i.e., if there is utilization management for a drug) must be available before a beneficiary signs up for a plan, including better tools for consumers in terms of medication transparency.

F. Pharmacy Price Concessions in the Negotiated Price

CMS proposes to adopt a new definition of “negotiated price” that would include potential price concessions the plan sponsors could receive from the network pharmacy for a covered Part D drug. This change would presumably affect how quickly beneficiaries move through Part D benefit phases including what they pay in the coverage gap.

If this will help patients by reducing their overall out-of-pocket costs and reducing the windfall that plans can receive by retaining price concessions for themselves, AGS believes these are important, positive outcomes and would be supportive. In general, **the AGS advocates and supports price transparency and lower and more predictable prices for consumers.**

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Thank you for your attention to these comments. Please contact Alanna Goldstein at 212-308-1414 or agoldstein@americangeriatrics.org if you have any questions.

Sincerely,

Handwritten signature of Laurie Jacobs in black ink.

Laurie Jacobs, MD, AGSF
President

Handwritten signature of Nancy E. Lundebjerg in black ink.

Nancy E. Lundebjerg, MPA
Chief Executive Officer