Alliance of Specialty Medicine

Sound Policy. Quality Care.

January 25, 2019

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

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

Dear Ms. Verma,

On behalf of more than 100,000 specialty physicians from 15 specialty and subspecialty societies, and dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care, the undersigned members of the Alliance of Specialty Medicine (the "Alliance") write in response to proposals aimed at modernizing Part D and Medicare Advantage.

Providing Plan Flexibility to Manage Protected Classes

In the proposed regulation, CMS states it will empower MA plans to institute more utilization management for drugs in the protected classes. Additionally, MA plans will be empowered to exclude a drug from formulary if the product is a new formulation or if a drug's price rises more than inflation.

The protected classes were created to protect patients. The existing policy ensures that patients suffering from debilitating and deadly diseases will not have to battle formulary exclusions and aggressive utilization management by insurers. We are concerned that the proposed policy amendments effectively eliminate this patient protection as a "punishment" for certain behavior by manufacturers. Our members are practicing providers and, as such, we fully appreciate the challenge of high drug prices. However, dismantling patient protections in a quest to affect manufacturers is unlikely to accomplish our shared goal of a reduction in drug prices – and may seriously harm patients in the process. We urge the Administration not to move forward with its proposed changes to the protected classes.

Proposed Adoption of a Real-Time Benefit Tool

While there is no requirement that prescribers implement electronic prescribing (eRx), CMS proposes that each Part D sponsor be required to implement a real time benefit tool (RTBT) by January 1, 2020, capable of integrating with prescribers' eRx and EMR systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber and used with the patient's consent. CMS believes that making this information more readily available will lead to higher prescriber use during the eRx process, although the agency understands from

electronic medical record (EMR) vendors that half of their clients (prescribers) currently chose not to access F&B data at all.

CMS explains that the system would be required to present real-time values for the patient's cost-sharing information and additional formulary alternatives (i.e., the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits and prior authorization, and indications-based restrictions, for each specific alternative presented). While not a proposed requirement, CMS encourages plans to use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price, in addition to the beneficiary's out-of-pocket cost information.

We strongly encourage CMS to require plans to provide full drug cost transparency by showing each drug's full negotiated price, including manufacturer rebates or other discounts that factored into the price, in addition to the beneficiary's out-of-pocket cost information. We also urge CMS to require plans to include information on the plans process for obtaining an exemption from step-therapy and/or other requirements, where appropriate. Further, we recommend that CMS establish a connection through the RTBT to the plans prior authorization process. For straightforward prior authorizations where limited information is needed to render a determination, CMS should require plans to automate approvals so they occur within minutes. For more complex prior authorizations where more detailed information may be necessary, CMS should require plans to automate the process as much as possible and render determinations within 24 hours.

Medicare Advantage and Step Therapy for Part B Drugs

In August 2018, the Centers for Medicare and Medicaid Services (CMS) issued a memo ("2018 memo") to Medicare Advantage (MA) Organizations entitled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage." The 2018 memo rescinded a memo dated September 17, 2012 ("2012 memo") that prohibited MA plans from using step therapy for Part B drugs. In a letter dated September 4, 2018, the Alliance stated its opposition to this proposal and asked the Administration to leave in place the prohibition on step therapy for Part B drugs in MA. Unfortunately, in the proposed rule, the Administration proposes adding a new regulation, at § 422.136, entitled "Medicare Advantage and Step Therapy for Part B Drugs." We continue to oppose allowing MA plans to use step therapy protocols for Part B medications, for the reasons explained below.

As CMS notes in the proposed regulation, CMS previously prohibited 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[.]" CMS then states that utilization management tools can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. Because of this consideration, CMS is proposing to allow the use of step therapy for Part B drugs in MA. However, the concern about step therapy being an "unreasonable barrier" to coverage and access still exists, and our members' experience with this utilization management strategy in Part D and commercial plans confirms that it is a reality. With this proposed regulation, CMS effectively prioritizes cost negotiation over beneficiary access.

While the proposed rule attempts to impose a number of safeguards to alleviate these access concerns, they will likely be insufficient to prevent these concerns from becoming a reality. For example, in several aspects, CMS proposes to provide an appeals process similar to that currently in place for Part D. However, as we noted in our September letter, healthcare providers cite significant challenges with the Part D exceptions process. Additionally, in October 2017, the Medicare Payment Advisory Commission

staff presented on the Part D exceptions and appeals process and noted that "CMS has found that several plan sponsors fail to comply with regulations."[1] While the regulations may be protective of beneficiaries on paper, if plans are not complying with them, these protections fail to be of any use. We urge the Administration to ensure full compliance with the Part D exceptions and appeals process in determining where changes must occur, before replicating this system in Part B.

Similarly, the existing Part D requirements for Pharmacy & Therapeutics (P&T) Committees, which CMS proposes to import into Part B, are often not sufficient to protect beneficiaries who suffer from conditions requiring specialty or subspecialty care. For example, it is our understanding that a six-person P&T Committee would satisfy CMS' requirements if it consists of 4 practicing pharmacists, 1 additional practicing pharmacist who is an expert "in the care of elderly and disabled persons," and 1 practicing family care physician. While these individuals undoubtedly bring critical expertise, they should not make coverage decisions for beneficiaries suffering from rheumatoid arthritis, Crohn's disease, or neurological conditions, to name a few. Given the severity of conditions that are treated by Part B products, we urge CMS to create more stringent requirements around P&T Committee membership that requires inclusion of specialists and subspecialists who treat conditions prevalent in the Medicare population.

With regard to off-label indications, CMS proposes to "permit MA plans to require an enrollee to try and fail an off-label medically-accepted indication (that is, an indication supported by one or more citations in the statutory compendia) before providing access to a drug for an FDA-approved indication (on-label indication)." It is well-established that pharmaceutical manufacturers are prohibited from proactively communicating about off-label indications of their products. We are concerned that allowing a party with a financial interest (the insurer) to require patients to try a therapy that has not been found safe and efficacious by the Food and Drug Administration for that indication runs afoul of the spirit underlying the restrictions on off-label communications. While the insurer must rely on statutory compendia and will likely have its own data supporting the off-label use, this falls short of the clinical data required for a finding of safety and efficacy by FDA. We urge CMS not to empower insurers to use financial incentives and disincentives to push patients into using a product for an indication that is not FDA-approved. These decisions should remain firmly with the physician and the patient.

CMS proposes to allow MA-PD plans to "cross-manage" the Part B and Part D benefits. That is, a patient may be subjected to step therapy requiring a Part D drug prior to a Part B drug, or vice versa. Often, Part D cost-sharing is financially prohibitive for patients, while Part B is more tenable due to wraparound coverage to help offset out-of-pocket costs. We are concerned that there will be increased financial burdens for the patient as a result of a plan cross-managing drug benefits via step therapy – and the increased cost will reduce access and create adherence issues. As such, we oppose empowering insurers to cross-manage the Parts B and D drug benefits in this way.

We appreciate the Administration's express statement that "step therapy would not be permitted to disrupt enrollees' ongoing Part B drug therapies." The proposed rule states that MA plans would be required to have a look-back period of 108 days to determine whether a patient is on an "ongoing" therapy. We appreciate this explicit parameter. We urge CMS to include in this look-back period patients who began a therapy in an acute care setting and were discharged for treatment in the community. These patients should be considered to be on an "ongoing" therapy.

[1] http://medpac.gov/docs/default-source/default-document-library/part-d-e-a-for-oct-2017.pdf?sfvrsn=0.

In the rule, CMS explains that an MA plan can determine through the organization determination process that a particular enrollee should be exempted from step therapy requirements for reasons of medical necessity. Although CMS is not proposing such requirements, CMS states that an MA organization may establish an evaluation process for the appropriateness of enforcing its step therapy protocols on an enrollee when the enrollee's healthcare provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug). CMS explains that MA organizations may work with their network providers to develop processes that eliminate the necessity for an enrollee to file a request for an organization determination in such cases. Rather than suggesting this activity, we urge CMS to make it a requirement that plans develop such processes. Specifically, plans should work in conjunction with network physicians to establish processes that would allow certain enrollees to be exempt, either automatically and/or on a case-by-case basis, from step therapy requirements.

Finally, as discussed during a recent meeting with Center for Medicare leadership, we would appreciate the opportunity to meet with agency officials from the Oversight and Enforcement Group, as well as those responsible for the Quality Ratings System (QRS). Alliance member organizations would like to establish a feedback loop whereby specialty physicians can share information when plans are not adhering to CMS' regulatory requirements related to the implementation of step therapy. In addition, we would like to discuss ways to leverage the QRS/Stars Rating program to hold plans accountable for ensuring enrollees are receiving medically necessary specialty care and any required medicines as part of a treatment protocol, in a medically appropriate timeframe. We appreciate your consideration of this request.

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We appreciate the opportunity to share our concerns. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons