



January 25, 2019

Submitted electronically to: <http://www.regulations.gov>

The Honorable 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 Drug Prices and Reduce Out of Pocket Expenses; CMS-4180-P*

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses Proposed Rule (CMS-4180-P)* (the "Proposed Rule").

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA will be providing specific comments and recommendations on the following topic areas in the Proposed Rule:

- **Protected Classes:** Proposed changes to the protected classes that would allow for tighter utilization management or exclusion of drugs from coverage.
- **"Fail-First" Step Therapy:** Proposed changes that would allow for Medicare Advantage ("MA") plans to apply fail-first step therapy to Part B drugs.
- **Price Concessions:** Potential future changes to the definition of "negotiated price" to better reflect pharmacy price concessions.

Comments on Proposed Changes to Protected Class Drugs

While COA is very supportive of the focus of the Centers for Medicare & Medicaid Services (“CMS”) on lowering drug prices and costs for Medicare and its beneficiaries, we believe that ***weakening or dismantling protected classes would harm patients and risk increasing costs due to suboptimal outcomes.*** Protected classes were established to safeguard the most vulnerable Medicare patients, including those with cancer and other serious diseases. Any proposal to add barriers to access to the full spectrum of oncology treatments from protected classes would have a significant negative impact on patients with cancer, who often have few available treatment options. As oral anti-cancer medications comprise 25% to 35% of the oncology pipeline¹, the ability for patients to reliably get innovative treatment may be at risk with the added flexibility for plans to limit coverage or utilization.

COA Opposes Allowing Formulary Exclusion of Protected Class Drugs

For years, Medicare’s protected classes have offered a guarantee to patients that access to the medication prescribed by their treating physicians would never be at risk. Allowing Part D plans to exclude new formulations of drugs from formularies would undermine physician decision-making and patient-centeredness. As our health care system shifts from volume to value, patient preferences are important facets in evaluating the clinical and economic value of new therapies. A new formulation of an existing product could, therefore, have an important role in facilitating symptom relief, improving quality of life, and/or increasing adherence. CMS should thus preserve uninhibited access to protected class drugs, including new formulations, in order to protect Part D patients and should not apply exclusionary criteria to these treatments.

CMS has also proposed to allow plans to exclude drugs from protected classes if the price increases by more than inflation (CPI-U) in a given year. While COA strongly supports value-based pricing and care, we do not agree that tying drug coverage to inflation dynamics will necessarily reflect value. ***We are concerned that adding arbitrary pricing thresholds in Part D is a policy that lacks safeguards to prevent patient harm.*** Indiscriminate inflationary targets fail to account for the potential changes in the evidence base, new populations or indications, or any other innovations that may offer new promise for patients with cancer.

COA Opposes Allowing Greater Utilization Management for Protected Class Drugs

CMS should not allow for utilization management strategies such as “fail-first” step therapy to be applied to protected class drugs. This proposal serves largely to empower financially motivated health plans and pharmacy benefit manager (“PBM”) middlemen rather than put patients first.

PBM-dictated restrictions on drug access already cause patients extreme difficulty, even with the status quo in which oncology is a protected class, which can result in lengthy delays, restricted pharmacy networks, and questionable denials for access to life-saving treatment. Countless times, bureaucratic PBM delays have meant that patients with cancer must postpone treatment that would give them their best chance at battling this devastating disease. COA has highlighted numerous PBM horror stories in a series of papers, with more to come pulled from our extensive and ever-growing database of real stories submitted

¹ Mosely WG, Nystrom JS. Dispensing oral medications: why now and how, Community Oncology. 2009

by practices across the country.² Giving plans more authority to place hurdles between patients and their prescribed therapies shifts decision making away from the clinical expertise of providers and instead places it with financially motivated issuers and drug benefit managers. Furthermore, it is our firm belief that this will result in unnecessary patient harm, suffering, and potentially even deaths if allowed to proceed.

Even though CMS proposes patient safeguards, such as an appeals process, it is incomprehensible to require patients in cancer treatment, or their already overwhelmed and distressed caregivers, to navigate a bureaucratic appeals process. Moreover, allowing broader use of prior authorization and fail-first step therapy for protected classes would put an additional administrative burden on providers to sort through utilization management processes in order to ensure access to cancer treatment in a timely manner. In fact, as we were drafting this comment letter, one provider at a community oncology practice relayed a horror story of having to spend a total of seven hours to overcome a PBM's denial of medicine that was critically important to their own cancer care!

CMS has a stated goal of paving the way for “patients over paperwork” policies, but instead by continuing to increase the flexibility of plans and PBMs to increase barriers to care and treatment, the agency ensures that community oncology practices would take time and resources away from patient care and invest them in sorting through even more red tape. Research has shown that physicians and nurses already spend countless hours handling formulary restrictions.

Recommendation:

CMS should not finalize proposals that weaken protected class requirements. In fact, we believe that plans and PBMs have a fiduciary responsibility to grant their enrollees uninhibited access to the highest value care. Consequently, we would recommend that treatments prescribed in line with provider-developed clinical guidelines, pathways, or evidence-based protocols, should be available on the lowest or preferred tiers. This would better align stakeholders and incentivize high-value care, preempting the need for utilization management. At the very least, cancer should remain a protected class.

Comments on Introduction of “Fail-First” Step Therapy Requirements for Part B Drugs

COA is very concerned by the CMS decision to allow MA plans to apply fail-first step therapy for Part B drugs, as *the proposal would negatively impact patient outcomes, harm the patient-physician relationship, and increase costs due to ineffective treatment while increasing the administrative burden for providers.*

This proposal undermines clinical judgment and devalues the expertise of treating physicians, who thoughtfully consider the most appropriate treatment options for each patient's individualized, specific needs. Fail-first step therapy emphasizes the use of cheaper, older treatments over state-of-the-art therapies regardless of physician recommendations. As oncology treatment continues to advance and personalized

² Pharmacy Benefit Manager Horror Stories – Part I, II, III, and IV. Available online at: <https://www.communityoncology.org/category/horror-stories/>

treatment gains a larger role, we are concerned that fail-first step therapy may deprive patients of the newest, most effective and innovative treatment options prescribed by clinical experts.

We recognize that in specific situations, step therapy can be used to reduce costs, especially when it is a generic being used first for a brand, but motivations to reduce spending must be balanced against concerns for patient safety and well-being. By pushing patients toward cheaper treatment options, effectiveness could ultimately be sacrificed as well. Fail-first step therapy is a poor fit for oncology treatment where time is of the essence and the consequences can be especially harmful if not life-threatening.

When fail-first step therapy is applied in other specialties, such as primary care, there is less risk when an initial treatment is ineffective. However, in oncology, where treatment is extremely time-sensitive and highly personalized, the imposition of requirements to pursue potentially ineffective therapy that may fail for a patient could be life-threatening. In the Medicare population, this risk is increased as older patients are less likely to recover from ineffective, failed therapies.

Additionally, instead of reducing costs, COA believes that this policy will likely result in higher overall Medicare spending as patients may require multiple office visits and utilize multiple drugs prior to reaching the initially prescribed treatment. If patients are subjected to less effective treatments due to fail-first step therapy requirements, the risk is increased for costly hospitalizations and poorer outcomes that require more utilization of health services. These costs may be further compounded when considering the additional administrative burden placed on providers, as we outlined above.

It is very disconcerting that CMS is proposing to make such a radical change without studying the potential adverse impact on Medicare seniors with cancer. This is especially true given that CMS is effectively empowering corporate middlemen to make clinical decisions when their current track record in delaying and restricting cancer treatment is nothing short of an abomination.

Additionally, COA questions whether CMS has the legal authority to allow for the use of fail-first step therapy through sub-regulatory guidance. This is a topic that remains unsettled, and CMS communications on the topic have represented multiple conflicting viewpoints as to whether MA plans may impose fail-first step therapy. A 2012 memo from CMS noted that MA plans must provide all benefits covered under Original Medicare, concluding that MA policies “*may not be more restrictive than what Original Medicare allows and may not impose barriers to Parts A and B services, including...the imposition of step therapy requirements for Part B drugs and services.*”³ In August 2018, CMS released a conflicting memo, which notes that Section 1852 of the Social Security Act “*anticipates a plan’s application in of utilization management tools*” and recognizes step therapy as one such tool.⁴ We question whether this interpretation of the statute will stand up to legal scrutiny, and therefore also question whether this policy can be advanced by CMS.

Recommendation: CMS should not allow for greater utilization management of Part B drugs through fail-first step therapy requirements dictated by health plans and PBM middlemen. As

³ Dr. Danielle R. Moon to Medicare Advantage Organizations. “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services.” September 17, 2012.

⁴ Seema Verma to Medicare Advantage Organizations. “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage.” August 7, 2018.

outlined in COA’s letter to CMS on the International Pricing Index (IPI) model for Part B drugs,⁵ *we instead believe that CMS should consider employing Clinically Appropriate Utilization Management (CAUM) for Medicare physician-administered drugs.* The appropriate tools and incentives should be given to physicians themselves instead of PBMs or other middlemen to select high-value care, while anchoring to clinical considerations. A potential CAUM program that incentivizes the use of pathways and clinical protocols developed by physicians would protect evidence-based care much more effectively than other entities whose motivations are purely based on profit. The CAUM model would emphasize the development of clinical guidelines that account for cost as a concern and emphasize high-value treatment pathways. We believe that a CAUM provider-led model would be patient-centric, but, at the same time, it would provide CMS an opportunity for savings by ensuring that Part B drug utilization best reflects value and efficacy while encouraging more competition between manufacturers.

Comments on Future Rulemaking Related to “Negotiated Price” Definition

COA is encouraged by CMS’ intention to consider changes to the definition of “negotiated price” in order to increase transparency and provide clarity on expected reimbursement for dispensed medications. We agree that all pharmacy price concessions should be reported and reflected in the negotiated price at the point-of-sale, which would ultimately benefit patients. However, this proposal does not go far enough – the proposal focuses only on pharmacy price concessions, but *we believe that manufacturer rebates should also be included and reflected in the negotiated price.* Including all price concessions and rebates in the definition of “negotiated price” would reduce costs for beneficiaries and the Medicare program, while protecting access to treatments.

While including manufacturer rebates and pharmacy price concessions in negotiated price would be a positive step, *we also have serious concerns about how incentive-based Direct and Indirect Remuneration Fees (“DIR Fees”) impact pharmacies, and even more importantly, community oncology practice in-house pharmacies and physician dispensing facilities (collectively “Community Oncology Pharmacies”).* Community Oncology Pharmacies are exposed to significant financial risks and penalties because they are forced to contend with inappropriate quality performance measures that are better suited to retail pharmacies. Because DIR Fees charged against Community Oncology Pharmacies are often based on performance in primary care-focused quality metrics that are irrelevant to oncology, Community Oncology Pharmacies are at risk of financial penalty. While the proposed changes to pharmacy concessions as currently drafted do not take on the issue of how DIR Fees and quality arrangements are applied, we are encouraged that CMS is increasing its scrutiny over pharmacy concessions and looking for ways to improve transparency.

Finally, to the extent point-of-sale reimbursement moves to a paradigm where Community Oncology Pharmacies are provided an opportunity to earn additional bonuses through incentive arrangements, *it is critical that the upfront, point-of-sale reimbursement be reasonable and relevant, and not be structured in a way that fails to compensate Community Oncology Pharmacies for acquisition costs, actually*

⁵ COA Formal Comments on International Pricing Index Model for Medicare Part B Drugs. December 2018. https://www.communityoncology.org/wp-content/uploads/sites/20/2018/12/COA_CMS_IPI_5528-ANPRM_Comment_FINAL.pdf

available in the marketplace. Requiring Community Oncology Pharmacies to be reimbursed below available drug acquisition costs, with only the hope of achieving performance bonuses set by plan sponsors and PBMs, and, in turn, not being reimbursed enough to cover the costs of the medication, is not a viable framework and risks causing severe access issues. This is especially more pronounced in the specialty drug space, where a limited number of providers may even carry or have the ability to dispense a particular medication.⁶

Recommendation:

CMS should consider redefining “negotiated price” to include all pharmacy price concessions and manufacturer rebates. In light of incentive arrangements that emphasize inappropriate quality measures, CMS should promulgate rules requiring plan sponsors and PBMs to utilize quality measurement criteria that are consistent with the various specific provider types, such as specialty pharmacies, retail pharmacies, physician in-office dispensing, and other providers, to ensure that providers’ performance is measured against similarly situated providers and is relevant to the type of medical care provided. Finally, in redefining “negotiated price” in such a way that would reflect the lowest possible reimbursement, CMS should promulgate rules requiring plan sponsors and PBMs to ensure that even the lowest possible reimbursement is reasonable and relevant, and does not result in reimbursement below available acquisition costs, especially for specialty medications.

Conclusion

COA appreciates CMS’s efforts to reduce spending on drugs in Part B and Part D, but we have deep concerns that the utilization management approaches outlined in this proposed rule miss the mark by putting the health of Medicare seniors with cancer and other serious diseases in jeopardy. We highly recommend that CMS consider the CAUM model as a step forward in controlling costs while emphasizing high-value care determined by physicians’ clinical expertise rather than third-party corporate middlemen. We ask that CMS consider the potential impact of the proposals on patient outcomes, the physician-patient relationship, and administrative burden.

We appreciate the opportunity to provide insight and comments to CMS and, as always, welcome the opportunity to discuss any of our comments with you.

Sincerely,



Michael Diaz, MD
President

⁶ Medicare Prescription Drug Benefit Manual, Chapter 6, Section 50.3 (“Offering pharmacies unreasonably low reimbursement rates for certain “specialty” drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18).”)