January 25, 2019

BY ELECTRONIC DELIVERY

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses
CMS-4180-P

Dear Administrator Verma:

Patients Rising and Patients Rising NOW (Patients Rising) were organized to amplify the voice of patients in our nation's health policy and reimbursement discussions. Our mission is one of education and advocacy, and is grounded in the belief that empowered patients, armed with the right information, at the right time can break down access barriers to vital therapies and services. We believe that a functioning, competitive environment is one that focuses on patient needs, and facilitates access to treatments, affordable health care, and innovation toward new therapies. Patients Rising supports the Centers for Medicare & Medicaid Services (CMS) in its policy changes that arm patients with information on treatment options, their cost, and appropriate alternatives, so that they can make the best decisions in light of all factors. We offer our comments and responses to the above-referenced Proposed Rule to further that goal.

First and foremost, we are concerned that some policies in the Proposed Rule will leave CMS open to challenge and will ultimately inject uncertainty and increase costs.

Patients Rising supports CMS in its goal to reduce the out of pocket costs associated with necessary medications. High out-of-pocket cost may be the biggest barrier patients face in ensuring that they take are able to comply with treatment prescribed and avoid potentially serious health consequences. We believe that CMS has the tools and authority to target manufacturer behaviors that are unfair to patients and payers without impeding access to treatment. When, however, the Agency's legitimate interest in curbing health care costs becomes the primary goal, resulting policies can stray from the language and intent of the Medicare statute. We have over time seen a number of policy initiatives targeting health care costs successfully challenged, and patients end up bearing the costs of both sides of those challenges – as patients and as taxpayers. We hope that CMS will avoid this type of result with its Final Rule.

First, we are concerned about the 3 additional exceptions CMS proposes to add to increase Part D plan (PDP) flexibility and permit plans to:

- impose utilization management (UM) tools on drugs included in the protected classes, including increased use of prior authorization (PA) and step therapy;
- exclude drugs from formularies for new formulations of existing drugs; and
- exclude products with price increases exceeding CMS' defined threshold.

Patients Rising is concerned that CMS' decision to implement these exceptions has been explained as, and focused on, the goal of reducing prescription drug costs. Once again, Patients Rising supports CMS in its goal of reducing the cost of medications. While we have objections to the breadth of the proposed exceptions and believe that any unintended consequences will fall largely on patients, we believe that exceptions that are not "based upon scientific evidence and medical standards of practice" invite the costs and uncertainties of legal challenges and would have firmer `grounding if pursued through legislative mechanisms.

Similarly, while we discuss the substance of CMS' codification of its recently-implemented policy on use of step therapy and other utilization management tools within Medicare Advantage (MA) and its PDPs below, we note that the policy is in strong conflict with the Agency's admission that its long-held interpretation of the Medicare statute prohibits these restrictions on access to Part B drugs. CMS' Proposed Rule appears to state that projected cost savings justify actions that would otherwise violate the statute. We hope that CMS will take a more cautious, patient-focused approach so that its cost-saving goals are articulated and achieved without burdening access to Part B drugs within the MA program.

Patients Rising supports CMS in its proposals to increase the information patients and providers have about their medications and treatment options.

CMS has proposed 3 changes that will increase transparency on drug pricing and enhance the information available to both patients and their providers. Patients Rising supports CMS in its proposals to (1) require that prescription drug plans include drug pricing information in the explanation of benefits (EOB); (2) require plans to update their e-prescribing tools to include a real-time benefit tool; and (3) prohibit "gag clauses" that keep pharmacies from telling patients that their prescriptions can be filled at a lower out-of-pocket cost outside their PDP.

Patients Rising's foundational belief is that patients can make better choices about their health care when they have more information. We agree with CMS that enhancing the EOB to include information on drug prices and changes in prices could increase the dialogue between patients and their clinicians so that lower-cost alternatives are considered. Requiring that plans include information about drug price increases and lower-cost alternatives in the Part D EOB could play an important role in empowering patients to make the best decisions about their healthcare. This information would also be extremely helpful if included in the Medicare Plan Finder that patients rely upon in choosing a PDP.

We hope that CMS will reach out to stakeholders, including patients, to make sure that the information and language on drug price increases and/or lower-cost alternatives is clear and understandable. Patients also need to have the information that is most important to them – impact on out-of-pocket costs -- and any information on alternative treatments should be based upon the patient's condition(s), including any comorbidities and other important factors, rather than a broad therapeutic-category list of low-cost treatment options. We similarly ask that CMS ensure that incentives to plans and PBMs do not influence information passed on to patients about their treatment alternatives.

CMS has also announced its intention to update the standards for e-prescribing. Patients Rising strongly supports inclusion of a real-time benefit tool requirement for PDPs so that providers have complete, accurate, timely and clinically appropriate patient-specific information on drug cost, formulary alternatives and any utilization management requirements associated with particular drugs. We believe that the most cost-effective systems would permit providers to clear any prior authorization requirements, formulary exception requests, and step therapy hurdles in real time as well.

Patients Rising similarly applauds CMS' proposal to prohibit PDPs from preventing pharmacists from informing patients of lower cost options available to them through so-called "gag clauses" in contracts. These clauses are extremely unfair to patients, and Patients Rising has viewed them as a gross interference that distorts what should be a relationship of trust between patients and their pharmacists. We urge CMS to ensure that patients choosing to pay for their prescriptions without utilizing their PDP benefits do not lose "credit" for the associated out-of-pocket costs in calculating total out-of-pocket costs (TrOOP). Money spent for a Part D covered drug dispensed by a network pharmacy should count toward a beneficiary's TrOOP whether it is filled within the PDP benefit or the patient chooses lower-cost options outside the plan. We ask that CMS educate beneficiaries, prescribers and pharmacists so that all parties are aware of the financial considerations associated with decisions on which treatments to choose and how to pay for them.

Patients Rising previously commented on CMS' drug pricing transparency proposal in which the Agency requested comment on approaches including:

- an enhanced CMS drug pricing dashboard;
- a new payment code for drug pricing counseling (clinician dialogue w/ patients) on benefits of drugs and their alternatives); and
- intelligent plan selection or use of intelligent assignment (auto-generated list of plans based on drug utilization) -- enrollment in any of the plans would be voluntary.

We continue to support CMS in exploring those alternatives. The "drug pricing dashboard," and "intelligent plan selection" tool would be logical extensions of the proposed EOB enhancements that would permit patients to access detailed information on their plan-specific out-of-pocket costs so that they can optimize their health care dollars with an informed choice on both plans and treatments. Patients Rising also urges CMS to move forward with its proposal to devise a new payment code for drug price counseling so that clinicians can be appropriately paid for the time spent discussing all treatment options in light of both their effectiveness and costs. This initiative would maximize the benefit of the real-time benefit tool outlined in the Proposed Rule.

Patients Rising is concerned that increased use of utilization management tools within the MA program will create access hurdles and discourage enrollment among patients with chronic conditions.

Patients Rising shares CMS' interest in containing the costs associated with Part B drugs. We are, however, concerned that broader implementation of utilization management tools within MA plans will make it more difficult for providers to treat Medicare's sickest patients and deter enrollment for the more complex patients who could be best served by the primary-care-driven MA model of care.

Medicare was designed to address the needs of the elderly and disabled population it serves. Utilization management tools were largely developed by commercial payers so that they can maintain a profitable business while covering the health care needs of the general population. Patients Rising believes that Medicare implements a sufficient set of program integrity tools to curb over-utilization of Part B drugs, including national and local coverage policies and post-payment medical review. MA plans can and do implement restrictions consistent with that set of checks and balances. We are concerned that use of step-therapy requirements designed to work well for commercial lines of business would fail to consider the more complex needs of Medicare patients. The bottom line would be an increased revenue stream for pharmacy benefit managers

(PBMs) processing a high volume of prior authorization and formulary exception requests, and any associated appeals. Patients Rising is concerned that any cost savings garnered through MA plan and PBM negotiations would be offset by administrative costs and downstream medical expenses for beneficiaries unable to navigate the hurdles to access necessary medications.

We ask that CMS ensure that MA beneficiaries have the same set of checks and balances as patients enrolled in fee-for-service Medicare. Medicare coverage restrictions in traditional Medicare require notice and comment at the national level, and consultation with a coverage advisory committee, notice, and opportunity for comment at the local contractor level. Permitting coverage restrictions through a "black box" internal MA plan committee would deny MA enrollees this important protection.

Patients Rising is concerned that the proposed exceptions to formulary requirements within the Protected Classes could invite discriminatory formulary structures and impede access for Medicare's most vulnerable patients.

Just as MA plans currently have a set of tools available to curb medically inappropriate use of prescription drugs, PDPs currently utilize a range of formulary tools to discourage broad utilization of products within the protected classes. Patients Rising has several questions about the implementation of the proposed exceptions and how they might impact patient access, including:

- Would prior authorization requirements that ensure use is consistent with "protected class" place these treatment out-of-reach for patients needing them for other labeled uses or for off-label, medically-accepted uses?
- What protections are available to ensure that clinicians treating patients with rare diseases are not overly burdened with exceptions and appeals processes?
- If a patient requires a drug that was removed from formulary due to one of these exceptions, would they be required to pay out-of-pocket? Would these costs be included within TrOOP or fully absorbed by the patient?
- Why is route of administration the determining factor for determining whether a new formulation offers a benefit to patients?
- Do plans include the cost of administering utilization management tools, including exceptions and appeals, in their reported costs to CMS? How will CMS ensure that access restrictions are accompanied by cost savings?
- How is CMS going to ensure that patients do not have to re-negotiate step therapy protocols every year to receive a treatment they have relied upon in managing their condition?
- What is the clinical rationale for permitting PDPs to impose mid-treatment restrictions on access for patients under Part D but not under Part B?
- How will CMS ensure that PDPs do not use CMS' proposed exceptions to devise formularies that discourage enrollment by Medicare's higher-cost patients?
- Will PDP-imposed treatment changes jeopardize outcomes for cancer patients in the middle of a course of chemotherapy? Are there potential individual or public health harms for HIV patients successfully reducing viral load counts?

Conclusion

Once again, Patients Rising appreciates that CMS has afforded the opportunity for stakeholder comment as it works toward its goal of reducing drug costs and increasing information available to patients. Although we have significant concerns about the real-world impact that many of the Proposed Rule's provisions would have on patient outcomes and their autonomy in making decisions about their health care, we remain enthusiastic about participating in a continuing dialogue as CMS moves toward our shared goal of ensuring that Americans have access to high quality, cost-effective care.

Sincerely,

Terry M. Wilcox
Co-Founder and Executive Director, Patients Rising Now