CONSORTIUM FOR CITIZENS WITH DISABILITIES

January 25, 2019

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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

The CCD Health Task Force appreciates the opportunity to provide comments on the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses proposed rule issued by the Centers for Medicare and Medicaid Services (CMS). CCD is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities in all aspects of society. The Health Task Force is focused on health care policy and the impact on people with disabilities. The Health Task Force appreciates that this rule is part of the Administration's larger "Blueprint" to address prescription drug pricing and cost sharing for people with disabilities and serious health condition and their families.

Over the past 12 years, the Part D program has provided millions of beneficiaries with critical coverage for self-administered prescription drugs. However, OOP costs have continued to increase even as the doughnut hole has gradually closed, particularly for people with serious health conditions who need multiple medications, people who need medications to maintain their health, and people who rely on drugs that are placed on specialty tiers. The increased use of specialty tiers and coinsurance has made medication unaffordable for far too many people.

Do Not Provide Part D Plan Sponsors Greater Flexibility in the 6 Protected Classes

The Health Task Force has major concerns about the proposals in this rule to give health plans more formulary flexibility. The Health Task Force has consistently voiced strong support for the existing 6 protected classes policy and opposes changes that weaken those protections. People with disabilities and serious health conditions need access to a wide variety of medications to maintain their health and function, and often only a specific drug will work to meet their unique needs. This is particularly the case for people with disabilities with prescriptions for medications in the 6 protected classes. These six classes containing life-saving drugs, and requiring plans to cover "all or substantially all

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drugs" preserves access to such important options. For the disabilities and health conditions represented by the six protected classes, finding drugs, or combinations of drugs, that meet an individual's needs is often very difficult.

The legislative history of Part D demonstrates that Congress intended to ensure access to these medications. Floor debate from the original Medicare Prescription Drug, Improvement, and Modernization Act of 2003 shows substantial discussion of the protections that the new Part D program will provide. After the six classes were created by CMS guidance in implementing Part D, Congress codified the six protected classes – in Section 176 of the Medicare Improvement for Patients and Providers Act of 2008 – in order to recognize the need for these protections and ensure access to multiple treatment options. This policy is a bulwark against discriminatory plan design and ensures timely access to physician-directed care. It has successfully protected basic access for people who need noninterchangeable medications to treat and manage serious and often life-threatening conditions.

CMS proposes to expand plan flexibility to manage protected classes by 1) allowing broader use of prior authorization; 2) allowing plans to exclude a drug if new formulation does not provide unique route of administration; and 3) allowing plans to exclude a drug if it has cost increases above a certain threshold.

CCD is concerned that CMS's proposal to expand Part D plan flexibility to manage the costs of providing medicines in the protected classes may lead to significant unintended consequences. Specifically, we are concerned that the policy change could reduce patient access to life-saving and life-sustaining drugs, possibly leading to complications associated with an interruption of care. The proposed changes directly undermine Congressional intent for creating the protected classes. The 6 protected class policy has successfully allowed beneficiaries with cancer, HIV, transplant recipients, epilepsy, and mental illness, and other disabilities to receive the drugs their doctors prescribe.

Allowing plans to expand use of prior authorization and step therapy would hinder access and worsen patient outcomes. For example, the proposed rule would allow plans to implement a "fail first" policy, where beneficiaries prescribed a non-preferred alternative must first "fail" on a plan-preferred medication before the plan will pay for the original prescription. Such a policy would result in serious delays in needed therapy and increases in adverse health effects, potentially including long-term altered health status.

CCD specifically objects to several of the specific proposals within the overall changes to the 6 protected class policy.

1) People Currently on a Stable Therapy

The proposed changes would allow use of prior authorization or step therapy for people who are currently stable on a treatment therapy. This change is contrary to Congressional intent and would have real and negative impacts for people whose treatments are currently protected. For example, people with epilepsy who have been stable for years under a certain medication regime – a regime that likely took many attempts to perfect – may have to go back through step therapy and risk avoidable seizures and medical complications. People on immunosuppressants risk the failure of an organ transplant, at a huge cost to themselves, the Medicare program, and a society with thousands of people on organ transplant waiting lists. Step therapy is of even greater risk to people with HIV/AIDS, who may face a mutation of the virus, resistance to further treatment, and potentially transmitting a resistant form of the virus. Each of the protected classes was chosen for sound medical and public health reasons.

Introducing step therapy into the protected classes for people currently stable on a medication regime undermines these goals and subverts Congressional intent.

2) New Formulations

CCD believes the proposed changes related to new formulations will further hinder patient access to needed therapies. CMS proposes to permit Part D plans to exclude a drug if a manufacturer introduces a new formulation with the same active ingredient that does not provide a unique route of administration. However, new formulations can drastically increase individual quality of life and medication adherence by reducing side effects or providing long-acting formulations that require fewer administrations. The exclusion would be allowed even if the new formulation becomes the only option available.

3) Pricing Threshold for Protected Class Drug Formulary Exclusions

CMS proposes that, beginning in 2020, Part D plans could exclude any single-source drug or biologic that has a wholesale acquisition cost (WAC) increase, relative to the price in a baseline month or year, beyond the rate of inflation. CCD has concerns that this proposed policy would adversely affect beneficiary access to prescribed therapies—specifically those without any therapeutic equivalent. While we support CMS' efforts to address affordability concerns for beneficiaries, this policy may result in an unintended consequence of people losing access to a prescribed therapy. We would like CMS to provide more data and research on the potential impact of this policy before finalizing such a potentially sweeping change in a short time frame.

It is important to note that under the current 6 protected classes policy, Part D plans already have significant flexibility to apply prior authorization for select products within the protected classes. We do not believe that broader use of utilization management, including step therapy, is warranted. A 2018 Avalere Health study found that plans already apply utilization management tools (40% of the time) for drugs in the 6 protected classes, including a majority of branded drugs (54%) in the protected classes.

Moreover, Part D plans have applied prior authorization for almost half (49%) of branded drugs in the protected classes. The use of step therapy would likely present additional barriers and hurdles for people with disabilities and serious health conditions prior to receiving a critically-important treatment, threatening peoples' lives, safety, and medical stability. Therefore, we urge CMS to maintain the current requirements, rather than allow plans the flexibility to broaden use of these tools.

In this proposed rule CMS asserts beneficiary access will be protected under this new policy through the current appeals and exceptions process in Part D. CCD believes this assertion is not warranted. Beneficiaries and providers cannot rely on these processes alone if CMS implements broader plan flexibility to manage drugs in the protected classes. While there is an appeals process, frankly, we do not believe it is a sufficient safeguard against the decreased access that will result from stricter formularies. Instead, CCD recommends that CMS to continue working to improve the appeals process, particularly around beneficiary communication at the point-of-sale and electronic prescribing/prior authorization.

In a 2018 report to Congress MedPAC made a similar recommendation to CMS, noting frustrations with Part D determinations, exceptions and appeals process by beneficiaries, providers, plan sponsors, and CMS itself. For example, there was one more civil monetary penalty imposed on a plan for program

audit in 2017 compared to 2016. Additionally, a September 2018 Office of Inspector General (OIG) report found that Medicare Advantage plans had significantly high rates (75%) of denials overturned for services and payments (for beneficiaries enrolled in Part C and Part D programs) that should have initially been provided. OIG found this especially concerning because from 2014 to 2016, only 1% of denials were brought to the first level of appeals, so the system designed to ensure access to care is not working.

CCD therefore urges CMS to engage with the relevant stakeholders—particularly beneficiary advocacy groups—to implement improvements to the exceptions and appeals processes, with the strong focus on ensuring these processes work for beneficiaries, while still offering plan flexibility.

In addition to maintaining the current protected class policy, we encourage CMS to implement other beneficiary protections related to formulary coverage. In particular, CMS should consider requiring plans to manage a more transparent formulary review process. Additionally, plans should be required to have a robust formulary, including the 6 protected classes of drugs and any additional classes where restricted access to those drugs would have a significant health impact. CMS should also require that plans provide coverage for a variety of medications in each drug class or category, as well as provide beneficiaries with timely information about any changes. CMS should analyze formularies, both prior to and during the plan year, to determine whether appropriate access is afforded to needed drugs and classes of drugs.

Explanation of Benefits Requirements

CMS seeks to require plans to communicate negotiated drug pricing information and lower cost alternatives in the Part D plan's Explanation of Benefits (EOB).

CCD appreciates the step toward transparency; however, we are concerned that the provided information is not actionable for the beneficiary to make better and timely health care decisions. A beneficiary would not be able to change plans midyear, so the information may be confusing to them and may not be helpful. For example, when a beneficiary receives an EOB after they have received treatment, they cannot use pricing information to change out-of-pocket costs that they have already incurred.

Instead, we believe that CMS should require plans to use clear and concise language to communicate plan benefits, coverage levels, and out-of-pocket costs, and this information should be included in EOBs in different ways (e.g., using graphs or bullet point summaries) and in a manner and format to ensure that beneficiaries understand the benefits provided in a plan. Instead of moving forward with the proposed changes, CMS should work to improve beneficiaries' online shopping experience and ability to compare formularies and out-of-pocket costs across plans. We recommend that Medicare Plan Finder display costs with more precision, so that enrollees could view actual premium and out-of-pocket costs more accurately. This would help them make informed decisions when choosing a plan.

Application of Step Therapy for Part B Drugs by Medicare Advantage Plans

CMS proposes new requirements for when Medicare Advantage plans may apply utilization management (including step therapy) for Medicare Part B drugs. CCD has consistently opposed widespread use of step therapy, as it is an impediment to a prescribed therapy, particularly for

beneficiaries who require timely and often personalized Part B medications. We are disappointed that CMS did not seek any formal or informal stakeholder comments before releasing guidance on August 7, 2018. This is allowing Medicare Advantage plans to use these same tools for Part B drugs in 2019 under certain circumstances. While we appreciate CMS's callout regarding protections currently in place for beneficiaries, we do not believe that these callouts are sufficient to adequately protect beneficiary access.

These recently enacted and proposed policies weaken beneficiary protections in favor of health plan flexibility and outline a number of program features that hinder beneficiaries' ability to appropriately access needed prescription drugs, particularly those in the protected classes, including drugs for people with cancer, HIV, and organ transplant recipients. Utilization management practices, such as step therapy, pose significant safety issues that could threaten peoples' lives, safety, and medical stability.

The Health Task appreciates the opportunity to provide comments and urges HHS not to provide plans additional flexibility in the Part D 6 protected class policy. The Task Force urges HHS to focus on improving beneficiary protections in order to ensure that people will receive needed medications. For more information please contact Rachel Patterson rpatterson@efa.org.

Sincerely,

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