

**BEFORE THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
CENTERS for MEDICARE & MEDICAID SERVICES**

Agency Information Collection Activities;)	
Submission for HHS CMS Review;)	FR Doc. 2018-25945
Proposed Rule; Modernizing Part D)	Docket ID CMS-4180-P
and Medicare Advantage to Lower Drug)	
Prices and Reduce Out-of-Pocket Expenses)	

Submitted via www.regulations.gov

Attention: CMS-4180-P

COMMENTS OF WHITMAN-WALKER HEALTH

Whitman-Walker Health (WWH or Whitman-Walker) submits these comments in opposition to the changes to protected drug classes in Medicare Part D prescription drug plans that have been proposed by CMS, 82 Fed. Reg. 62152 (Nov. 30, 2019). Those proposed changes would thwart Congress’ intent, endanger patient health, weaken public health efforts to stop the spread of HIV, and very likely increase the costs to Medicare and the health system as whole. They should be withdrawn.

EXPERTISE AND INTEREST OF WHITMAN-WALKER HEALTH

Whitman-Walker Health is a community-based, Federally Qualified Health Center offering primary medical care and HIV specialty care, mental health and addiction treatment services, community health services and legal services to residents of the greater Washington, DC metropolitan area. WWH has a special mission to the lesbian, gay, bisexual and transgender members of our community, as well as to all Washington-area residents of every gender and sexual orientation who are living with or otherwise affected by HIV. In calendar year 2018, more than 20,000 individuals received health services from Whitman-Walker. Our patients rely on a wide range of private and public health insurance plans. A growing number of them rely on

Medicare – because of their age or because they have been on Social Security Disability for more than two years. In calendar year 2017, we had 1,215 Medicare patients.

Whitman-Walker has been a nationally recognized leader in HIV treatment and prevention for almost four decades. Our staff of almost 40 physicians, physician assistants, nurses and nurse practitioners, and medical assistants provided care to 3,505 people living with HIV in calendar year 2017. WWH has been at the forefront of the Nation’s response to the epidemic since the very beginning. Through direct care and participation in extensive research funded by the Federal Government and by pharmaceutical companies, we have participated in the breakthroughs in HIV treatment and prevention which have transformed HIV from a largely untreatable, terminal disease to a manageable chronic condition, and which have made it possible to envision an end to the epidemic in our lifetimes. The antiretroviral drug regimens which are one of the classes of drugs protected under the Part D program are at the heart of this success story. Our medical providers and community health workers – and our patients – are quite alarmed at the prospect that the guaranteed coverage on which our Medicare patients rely might be undermined. In 2017, 646 of our HIV patients were Medicare beneficiaries.

As part of WWH’s holistic approach to health, we offer a robust suite of behavioral health programs, including peer support, addiction treatment services, mental health and psychiatry services to adults and youth. Our behavioral healthcare team includes licensed psychotherapists, psychologists, psychiatrists, and trained peer counselors. In 2017, 1,842 people accessed mental health services from WWH; of those, 205 were Medicare patients. We also provided addiction treatment services to 222 patients, 35 of whom were Medicare patients. Many of our behavioral health patients rely on antidepressant and/or antipsychotic drugs that are among the Part D protected classes.

In 1986 Whitman-Walker established our Legal Services Program to provide *pro bono* legal assistance to people living with HIV on matters related to their diagnosis. From the beginning, our lawyers have assisted people secure Social Security disability and retirement benefits and Medicare. When Part D prescription drug coverage began, our lawyers launched legal clinics, and provided education and representation during annual open enrollment (or any period of need) to assist beneficiaries review and evaluate their prescription drug needs and the plans offered that would meet those needs with the least restrictions and lowest cost. In 2013, we launched a new initiative to meet the specific legal needs of older adults who are LGBT or living with HIV. In calendar year 2018, WWH staff and volunteer lawyers helped 479 clients with Part D matters. Just over 400 of those were during the Part D open enrollment season from October 15 through December 31, 2018. Our lawyers, like our medical and behavioral health providers, have extensive experience helping Part D beneficiaries navigate the complexities of the system – eligibility, enrollment, coverage, and access issues. Our comments are informed by both patient and practitioner experiences over the past four decades, and are well-grounded in actual hardships that result when plan enrollees encounter obstacles to coverage of the specific drugs that they need.

THE PART D PROTECTED DRUG CLASSES MEET CRITICAL TREATMENT NEEDS AND DO NOT IMPOSE UNNECESSARY COSTS ON THE HEALTH CARE SYSTEM

The six protected classes – antiretrovirals, immunosuppressants, antidepressants, antipsychotics, anticonvulsant agents, and antineoplastics – were established by CMS in 2003 through sub-regulatory guidance, affirmed by Congress in 2008, and further endorsed by Congress in the passage of the Patient Protection and Affordable Care Act in 2010. The consistent intent has been to ensure access to expensive and specific medications for diseases

with complex indications and disastrous consequences if beneficiaries are unable to access these life-saving medications consistently and without delay.¹

CMS asserts that a goal of the Proposed Rule is to give Part D plans greater flexibility to build their formularies so they are able to pressure drug manufacturers to keep their prices low.²

¹ See, e.g., the following exchange that occurred during the passage of the law that created the Part D program:

Mr. BAUCUS. ... One of the things I am particularly proud about in this bill is the strong beneficiary protections that will ensure that all Medicare beneficiaries get access to the appropriate medicine they need. You know, Senator Grassley, that there are certain diseases and conditions--like AIDS, and epilepsy--where having access to just the right medicine is especially important.

Mr. GRASSLEY. I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them.

Mrs. FEINSTEIN. Victims of HIV/AIDS are somewhat unique since the treatment for HIV/AIDS varies with the individual. To be clear, no low-income Medicare beneficiaries who have HIV/AIDS will be denied access to the drugs they need in Medicare Part D?

Mr. BAUCUS. Exactly. The bill asks the US Pharmacopeia to develop model formularies with therapeutic classes that can't be gamed. Then we require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry all clinically appropriate drugs.

Mr. GRASSLEY. I agree. And I am pleased with the backup protections in this bill. That if a plan doesn't carry or doesn't treat as preferred a drug needed by, say, a person with AIDS, a simple note from a doctor explaining the medical need for that particular drug could get that drug covered.

Mrs. FEINSTEIN. Will that apply to all covered drugs required by a person with HIV/AIDS and in all cases?

Mr. BAUCUS. That is correct. These beneficiary protections are crucial for these vulnerable Medicare beneficiaries. I would expect that the Secretary will take into account their special medication needs when he writes regulations on this provision and when he is evaluating plan bids. If a plan can't adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare.

Mr. GRASSLEY. I agree with my good friend.

149 Cong. Rec. S15887-8 (Nov. 25, 2003). Accessed via <https://www.congress.gov/crec/2003/11/25/CREC-2003-11-25-pt1-PgS15882-2.pdf>.

However, Part D plans already have substantial flexibility under current regulations and are aggressively managing their formularies to reduce unnecessary costs while maintaining patient access to the drugs that they need. According to an analysis of 2016 data by Avalere, Part D plans currently put 73% of the drugs in protected classes in a non-preferred or specialty category.³ This means that in 2016, 73% of protected class drugs were subject to utilization management techniques like prior authorization or increased co-pay and co-insurance requirements. Additionally, the vast majority (91%) of prescriptions in the protected classes as a whole are filled with generic medications. In the three classes of drugs that the Proposed Rule suggests will most use the proposed additional flexibility,⁴ the vast majority of prescriptions were generics in 2016: 90% of anticonvulsants, 97% of antidepressants, and 91% of antipsychotics.

CMS claims that current rules protecting patients who use protected class drugs are driving up the costs of pharmaceutical products,⁵ but the data show that Part D plans have the necessary flexibility to manage their formularies under the current rules. Across all six protected classes, only 67% of available drugs actually are actually included in plan formularies. Under current rules, only 46% of branded anticonvulsants, 37% of branded antidepressants, and 62% of branded antipsychotics are included in Part D plan formularies.

² News Release, *CMS Takes Action to Lower Prescription Drug Costs by Modernizing Medicare*, CENTERS FOR MEDICARE AND MEDICAID SERVICES. Nov. 26, 2018. Accessed via <https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-costs-modernizing-medicare>.

³ White Paper, *Medicare Part D's Six Protected Classes Policy*, PARTNERSHIP FOR PART D ACCESS. Accessed via <http://www.partdpartnership.org/resources/avalere-study-part-d-plans-aggressively-use-controls-to-keep-costs-low>.

⁴ 83 Fed. Reg. at 62,184.

⁵ 83 Fed. Reg at 62,156.

In contrast to the other protected classes, antiretrovirals are mostly branded rather than generic drugs: according to an analysis of 2015 Medicare data by Pew Charitable Trusts, 91% of these prescriptions are for branded drugs, accounting for 97 % of spending in that class.⁶ While a relatively new but still limited number of generic antiretrovirals are available, federal clinical guidelines for treatment of HIV recommend the use of newer brand drugs based on effectiveness.⁷ Current CMS regulations for Part D expressly provide that formulary decisions must be based on HIV treatment guidelines.⁸ The Proposed Rule, appropriately, maintains this requirement.⁹

Under existing regulations, therefore, Part D plans are able to manage their costs by restricting patient access to a number of drugs, even those in the protected classes (with the exception of antiretroviral drugs). The existing system already imposes significant burdens on many patients and on the providers that care for them – including Whitman-Walker providers and our lawyers and paralegals who serve as patient advocates and handle appeals. Despite the fact that the current regulatory system already favors Part D plans and presents many challenges for patients, the Proposed Rule would further skew the balance by permitting Part D plans to exclude drugs in the protected classes from their formularies in three circumstances:¹⁰

⁶ Fact Sheet, *Policy Proposal: Revising Medicare's Protected Classes Policy*, PEW CHARITABLE TRUSTS, March 2018. Accessed via <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy>.

⁷ Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, last updated Oct. 25, 2018. Accessed via <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0>.

⁸ 42 CFR §423.120(b)(2)(vi)(C).

⁹ The Proposed Rule re-designates this provision as §423.120(b)(2)(vi)(F).

¹⁰ 83 Fed. Reg. at 62152

The first proposed exception would allow Part D sponsors to use PA [prior authorization] and ST [step therapy] for protected class drugs, including to determine use for protected class indications, without distinguishing between new starts and existing therapies, as is currently allowed for all other drug categories and classes. We would also allow indication-based formulary design and utilization management for protected class drugs. ...

The second proposed exception would permit Part D plans to exclude from the formulary protected class drugs that are a new formulation of a protected class Part D drug, even if the older formulation is removed from the market. That is, Part D plans would be permitted to exclude from their formularies a protected class drug that is a new formulation that does not provide a unique route of administration, regardless of whether the older formulation remains on the market.

The third proposed exception is to permit Part D sponsors to exclude from the formulary any protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. ...

As explained below, these proposals would cause considerable harm to patients living with complex health care needs; would undercut local, state, and national efforts to prevent new HIV infections through evidence-based community initiatives, as highlighted by the Administration's own National HIV Strategy; would very likely result in increased costs to the Medicare program and increased health care costs generally; would exacerbate health disparities and inequities that persist on our communities; and would result in ill-conceived cost-containment policies in drug coverage that will have adverse consequences for the patients we serve.

INCREASED UTILIZATION MANAGEMENT FOR PART D PROTECTED CLASSES WOULD HARM PATIENTS, ENDANGER PUBLIC HEALTH, AND BURDEN THE ENTIRE HEALTHCARE SYSTEM

The extensive experience of Whitman-Walker's medical and mental health providers is that broader use of prior authorization and step therapy for HIV and behavioral health patients is medically inappropriate and would result in substantial harms to our patients. As is true for Medicare beneficiaries generally, WWH's Medicare patients – who are eligible for that program because of advanced age or extended, serious disability – tend to be sicker and to struggle with

more complex medical conditions, which make individually calibrated therapies, and access to the full range of available drugs, particularly important.

Antiretroviral medications. CMS' proposal to enable Part D plans to impose restrictions on coverage of antiretroviral drugs, or to exclude some antiretroviral drugs from their formularies in certain circumstances, would thwart the goals of the National HIV/AIDS Strategy endorsed by this Administration: to get everyone diagnosed with HIV on effective antiretroviral therapy and to achieve full viral suppression for all people living with HIV, in order to improve their own health and to reduce or eliminate new transmissions.¹¹

Treatment of HIV infection is not like treatment of many medical conditions, such as high blood pressure or high cholesterol. Getting an individual diagnosed with HIV on an effective antiretroviral regimen that is well-tolerated and ensuring that the patient consistently adheres to that regimen, is critical to achieving viral suppression. Achieving and maintaining viral suppression is correlated with longer life and better overall health outcomes for people living with HIV and is essential for obtaining the preventative public health benefit of reducing HIV transmission.¹² Overwhelming evidence has led to the conclusion that an undetectable viral load renders an individual with HIV unable to transmit the virus to others.¹³

¹¹ HHS Office of HIV/AIDS and Infectious Disease Policy, *National HIV/AIDS Strategy for the United States: Updated to 2020; 2017 Progress Report*, NATIONAL HIV/AIDS STRATEGY FEDERAL INTERAGENCY WORKGROUP. Accessed via https://files.hiv.gov/s3fs-public/NHAS_Progress_Report_2017.pdf.

¹² Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEPARTMENT OF HEALTH AND HUMAN SERVICES. last updated Oct. 25, 2018, accessed via <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/10/initiation-of-antiretroviral-therapy>.

¹³ Anthony S. Fauci, *HIV Viral Load and Transmissibility of HIV Infection; Undetectable Equals Untransmittable*. JAMA. January 10, 2019. doi:10.1001/jama.2018.21167.

Drug therapies to treat HIV must be determined by the physician and patient based on the individual's unique genetic make-up and virus genotype.¹⁴ The physician and patient must have access to the full range of approved antiretroviral drugs. Patients and providers, not insurers and drug manufacturers, should determine which treatment modality is appropriate for the patient. Step therapy and prior authorization requirements threaten delays in the initiation of effective therapy – or even worse, interruptions in a therapy that is working – that may delay or interrupt viral suppression.¹⁵ HIV treatment guidelines provide that changes in antiretroviral regimens must be based on the patient's full history of virologic responses and past intolerances, not on cost considerations.¹⁶ Step therapy is completely inappropriate for HIV treatment, even for a patient who is recently diagnosed or otherwise new to treatment – it could result in dangerous delays in effective treatment, or even viral mutations, rendering effective treatment more difficult. Imposing step therapy or prior authorization requirements on patients who already are on a successful regimen would be even more dangerous: patients whose HIV had been well-managed could experience harmful treatment disruptions, resulting in increased viral load or even viral mutations.

¹⁴ Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEPARTMENT OF HEALTH AND HUMAN SERVICES. last updated Oct. 25, 2018, accessed via <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/10/initiation-of-antiretroviral-therapy>.

¹⁵ Rashad I. Carlton, *Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy*, AMERICAN JOURNAL OF PHARMACY BENEFITS 2010;2(1):50-58. Accessed via https://www.ajpb.com/journals/ajpb/2010/vol2_no1/review-of-outcomes-associated-with-formulary-restrictions-focus-on-step-therapy.

¹⁶ Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEPARTMENT OF HEALTH AND HUMAN SERVICES. last updated Oct. 25, 2018. Accessed via <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/16/optimizing-antiretroviral-therapy-in-the-setting-of-virologic-suppression>.

Imposing step therapy or prior authorization requirements on patients living with HIV not only would threaten their own long-term health; it also would create public health risks. The scientific consensus is that an undetectable viral load renders an individual with HIV unable to transmit the virus. Viral load suppression, therefore, is at the center of the National HIV/AIDS Strategy goals to reduce the spread of HIV.¹⁷ Taking medications as prescribed is essential to maintaining viral suppression.¹⁸ Even brief interruptions of HIV therapies may lead to rapid increases in HIV RNA and a decrease in CD4 count, leading to greater risk of opportunistic infections and potential for viral transmission.¹⁹ Moreover, increases in viral load resulting from interruptions in care increase the risk of transmission to others. Setbacks in the progress we have achieved in getting more people living with HIV into care, adhering to care, and achieving viral suppression could lead to increases in HIV transmissions and undercut the fight against HIV. The current protected status of antiretroviral formularies recognizes the heightened consequences for public and individual health should patients be unable to access all or substantially all the treatment options throughout the course of their care.

Any potential cost savings associated with imposing step therapy and prior authorization requirements on patients in need of antiretroviral therapy would be outweighed by the increased costs – to Medicare, to the health care system generally, and to the fight against the HIV epidemic – resulting from increases in patient viral load and corresponding immune system

¹⁷ HHS Office of HIV/AIDS and Infectious Disease Policy, *National HIV/AIDS Strategy for the United States: Updated to 2020; 2017 Progress Report*, NATIONAL HIV/AIDS STRATEGY FEDERAL INTERAGENCY WORKGROUP. Accessed via https://files.hiv.gov/s3fs-public/NHAS_Progress_Report_2017.pdf.

¹⁸ Anthony S. Fauci, *HIV Viral Load and Transmissibility of HIV Infection; Undetectable Equals Untransmittable*. JAMA. January 10, 2019. Accessed via doi:10.1001/jama.2018.21167.

¹⁹ *Id.*

damage and long-term inflammation caused by high levels of immune system activation. Failure to virally suppress HIV is correlated not only with increased risk of opportunistic infections which are very expensive to treat, but also with long-term increased risks of heart disease, liver disease, kidney disease, and neurological complications.²⁰ Moreover, overall HIV treatment costs would increase substantially because of increases in infection rates resulting from setbacks in viral suppression among patients living with HIV.

Antidepressant and antipsychotic drugs. The harms to patient health, to public health, and to Medicare and the health care system overall that would result from coverage restrictions on antiretroviral drugs also would result from allowing Part D plans to impose additional restrictions on antidepressant and antipsychotic drugs. Mental illness and substance use disorder are leading causes of disease burden in the U.S.²¹ Untreated or ineffectively treatment mental illness causes substantial harm to the individuals involved, but also to their families and communities, and to the public health and to the economy generally. Effective mental health services are particularly critical for people living with HIV; approximately one-half of individuals with HIV have been diagnosed with a comorbid mental health condition.²²

Antipsychotic and antidepressant medications are required to treat and stabilize those with severe illnesses that may otherwise require institutionalization and long-term

²⁰ Panel on Antiretroviral Guidelines for Adults and Adolescents, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*, DEPARTMENT OF HEALTH AND HUMAN SERVICES. last updated Oct. 25, 2018, accessed via <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/10/initiation-of-antiretroviral-therapy> .

²¹ *Costs and Outcomes of Mental Health and Substance Use Disorders in the U.S.*, KAISER FAMILY FOUNDATION, Aug 01, 2017. Accessed via <https://www.kff.org/slideshow/costs-and-outcomes-of-mental-health-and-substance-use-disorders-in-the-u-s/>.

²² Bing, E.G, et al., *Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States*, ARCHIVES OF GENERAL PSYCHIATRY. 2001 Aug;58(8):721-8. Accessed via <http://archpsyc.jamanetwork.com/article.aspx?articleid=205826>.

hospitalization, which can contribute to costs and burden the health care system. Imposing additional step therapy and prior authorization requirements for the drugs used to treat severe depression, psychosis or other mental disorders – particularly for patients already stabilized on a drug therapy – would be immensely burdensome and would endanger the health of many patients, who cannot tolerate interruption of a therapy that is working for them. Untreated mental illness or inappropriately treated mental illness contributes to additional economic and social costs and interfere with daily life and function. Untreated mental illness will place patients at greater risk of disability, suicide, and death.

The mental health system, which is severely stretched and woefully unable to meet the existing need for services, lacks the capacity to deal with the burden of obtaining prior authorizations for patients already stabilized on antidepressant or antipsychotic drugs, or to meet substantial new administrative burdens imposed by an increase in step therapy and prior authorization requirements generally. New plan restrictions would impose additional administrative burdens on providers, which would inevitably detract from essential duties such as providing direct clinical care. These burdens would disrupt many behavioral health delivery settings, including outpatient clinics, inpatient hospitals, urgent care centers, emergency rooms, nursing homes, substance treatment centers, and Veterans Affairs mental health treatment centers.

The Proposed Rule suggests that any barriers to the care needed by an individual patient, if a Part D plan is permitted to exclude drugs in a protected class or restrict access through prior authorization or step therapy, can be addressed by recourse to the existing appeals process, or an

improved appeals process.²³ However, many if not most Medicare patients – especially those who are very sick or disabled, and those who are lower-income and otherwise marginalized – lack the resources, knowledge, and energy to navigate the complex Part D appeals process. Due to nature of mental illness, including difficulties remembering and focusing, patients themselves are often unable to advocate for themselves. Low-income patients who are enrolled in Low Income Subsidy plans – basic plans – or who cannot afford enhanced coverage will suffer the most and are least likely to be able to navigate time-consuming and complicated prior authorization, step therapy, and appeals processes. The burden on providers of obtaining prior authorization and navigating step therapy would create additional administrative costs that would stretch providers’ already-limited resources and reduce their capacity to care for their current patient loads. The cost estimates for appeal and formulary design included in the Proposed Rule fail to consider how the added time and energy necessary to process appeals will affect the safety-net organizations and providers, including the impact on public health and healthcare system of the limitations in services due to the additional administrative burdens.

We also are concerned with the proposal to authorize Part D plans to restrict off-label uses of drugs that may be effective to treat mental illness. For example, Gabapentin, an anticonvulsant, is frequently used for anxiety, and certain antipsychotics may be used as off-label but effective treatments for anxiety or PTSD. Certain antipsychotics also are known to lead to weight gain and contribute to high cholesterol and high blood pressure, which can increase the risk of other medical outcomes such as stroke and heart diseases. Newer medications, such as Latuda or Abilify, are required for long-term stabilization while minimizing other medical complications. Such medications also are indicated to treat multiple mental health conditions,

²³ 83 Fed Reg. at 62,163: “Finally, we note that existing enrollee protections, namely the coverage determination and appeal process, and the Part D formulary requirements as discussed elsewhere in this preamble, provide safeguards to access to all prescription drugs.”

such bipolar depression and depression augmentation. Permitting drug plans to impose prior authorization or step therapy on prescriptions for these drugs, or to limit coverage to “on-label” uses, would remove valuable medications from the provider’s toolkit. Contrary to assertions in the Proposed Rule, our providers have not seen “adverse effects that can harm the beneficiary and require medical treatment that would otherwise not have been necessary” or “overutilization, particularly off-label overutilization, of some of these drugs.”²⁴ On the contrary, our providers report that physicians try not to prescribe these drugs unless medically necessary because of adverse side effects.

ALLOWING MEDICARE PART D PLANS TO EXCLUDE PROTECTED CLASS DRUGS FROM THEIR FORMULARIES WOULD DISCOURAGE ADVANCES IN CARE

The Proposed Rule would allow a Medicare Part D plan to exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, even if the older formulation is no longer on the market. As applied to antiretroviral, antidepressant and antipsychotic drugs – drugs whose use is at the heart of WWH’s HIV and behavioral health practices – this proposal threatens to impede effective treatment of people living with HIV and many suffering from mental illness.

Recent incremental advances in co-formulations and delivery innovations of previously existing HIV treatments often decrease the disease burden and increase patient adherence and retention in care. There are real medical benefits from co-formulations that simplify treatment regimens, and from moiety-specific drugs that reduce side effects. These advantages contradict the notion that all new releases of medications are simply attempts by pharmaceutical manufacturers to hold onto market share and prevent the introduction of generics. Innovations that allow for new dosing schema like extended release tablets can lead to advancements in

²⁴ 83 Fed. Reg. at 62,156.

pediatric care, improved shelf life, decreased side effects, and ultimately improved health outcomes. New formulations in antiretroviral, antidepressants, and antipsychotics that result in advances in efficacy, safety, and patient outcomes should be welcomed by plan sponsors because they ultimately reduce the care burden, increase adherence, reduce incidences of co-morbidities, and prevent future health care costs.

Whitman-Walker recognizes the problem of ever-greening patents to maintain a monopoly on the market for a particular type of medication. We welcome efforts to reform our current system of drug licensing to that issue. However, allowing insurance companies operating Part D plans to restrict coverage based on their conclusion that a new formulation “does not provide a unique route of administration”²⁵ would threaten the care needed by too many patients.

THE PROPOSED RULE WOULD IMPOSE PARTICULAR HARMS ON LOWER-INCOME PATIENTS AND LIKELY EXACERBATE EXISTING HEALTH INEQUITIES IN OUR COMMUNITIES

By allowing Part D plans the discretion to exclude specific drugs from their formularies that are currently protected, the Proposed Rule threatens not only to impede treatment of HIV and many mental illnesses and addiction issues, but also to exacerbate existing health disparities and inequities by imposing particular burdens on lower-income, marginalized patients. A major unintended consequence of this proposed rule is to incentivize health plans to exclude Part D patients with complex health care through a variety of market/risk segmentation efforts.

The Proposed Rule assumes that beneficiaries would have the option to choose among various Part D plans. However, many patients – regardless of capacity or education level – find it difficult to understand the differences between Part D plans. Only those particularly savvy or who get assistance from advocates with Medicare expertise – which many health care providers and institutions lack – can sufficiently grasp the details of the current system to fully understand

²⁵ 83 Fed. Reg. at 62152

which plan is best for them given their medical needs and financial situation. Medically vulnerable patients – particularly patients with mental illness or those suffering from dementia or HIV or cancer – all with protected drug class drug needs – will face yet another barrier to access.

Moreover, if some plans exercise a right to exclude certain high-cost but much-needed drugs from their formularies, or to employ prior authorization and step therapy to limit coverage of those drugs, other Part D plans would have an incentive to do the same – in order to avoid attracting disproportionate numbers of high-cost patients who need those drugs. If some Part D plans chose to maintain full coverage of the drugs in protected classes, patients needing those medications would be more likely to choose those plans. The plan working to promote access and health may find itself disproportionately bearing financial burdens, in contrast to the current system, in which all Part D plans are required to bear the costs of the treatments that patients living with HIV, cancer, mental illness and other high-cost conditions with critical public health implications. A “race to the bottom” would likely result. Further, sponsored plans that provide coverage for new medications will have higher costs as beneficiaries seek to avoid the “race to the bottom” plans. Eventually, the few generous plans that offered all or substantially all available treatment modalities would increase their premiums or abandon their fuller coverage approach.

By allowing Part D plans the discretion to exclude specific drugs from their formularies that are currently protected, the Proposed Rule threatens not only to impede treatment of HIV and many mental illnesses and addiction issues, but also to exacerbate existing health disparities by imposing particular burdens on lower-income, marginalized patients. The communities most likely to negatively affected by plans that restrict coverage of some drugs needed to treat HIV, cancer, mental illness and other particularly complex and serious condition would be

economically depressed racial, sexual and gender minorities. Disparities in health care, and in health, that particularly burden these communities would likely be exacerbated – a result which would run counter to the Nation’s commitment to reducing or eliminating those disparities. The National HIV/AIDS Strategy goals recognize the role that health disparities play in the spread of HIV and include reducing HIV-related health disparities and health inequities as a core goal.²⁶

ALLOWING PART D PLANS TO RESTRICT ACCESS TO PROTECTED DRUGS IS AN INEFFECTIVE AND BLUNT COST CONTAINMENT APPROACH THAT WILL HARM PATIENTS

WWH generally supports continued efforts to reduce ever-increasing drug costs on patients, public and private payers, and society at large. We recognize that the prices of prescription medications have risen far faster than inflation for many years. We encourage HHS, the Administration generally, and Congress to seek cost transparency from pharmaceutical manufacturers and pharmacy benefit managers; to empower public and private payers to negotiate prices with drug manufacturers and pharmacy benefit managers; and to continue to investigate incentive structures that may help to constrain drug costs. Our support of such efforts reflects a core value of “first, do no harm.” While cost containment in Part D is a laudable goal, it should not be pursued in a manner that imposes predictable and substantial harms on patients.

The proposed restrictions on access to drugs needed by Medicare Part D participants to treat their HIV, cancer, mental illness, epilepsy or organ transplants are an ineffective as well as unjust solution to the problem of high drug prices. The cost reductions estimated by CMS from the proposed cutbacks in access to protected class drugs are miniscule compared to the problem of drug overpricing. CMS estimates that the combined savings to the Medicare Trust Fund in

²⁶ HHS Office of HIV/AIDS and Infectious Disease Policy, *National HIV/AIDS Strategy for the United States: Updated to 2020; 2017 Progress Report*, NATIONAL HIV/AIDS STRATEGY FEDERAL INTERAGENCY WORKGROUP, page 18. Accessed via https://files.hiv.gov/s3fs-public/NHAS_Progress_Report_2017.pdf.

2020, resulting from allowing Part D plans to restrict coverage of drugs in the protected classes, at \$141 million.²⁷ The projected savings are approximately one thousandth (0.012%) of total Medicare Part D spending projected for 2019.²⁸

We encourage HHS and the Administration to work with Congress to explore effective solutions that do not penalize patients who are struggling with complex health conditions – especially those who live with life-threatening diseases that are particularly sensitive to specialized drugs. National discussions of potentially promising policies include importing pharmaceuticals manufactured abroad,²⁹ tying Medicare drug reimbursement to an international index,³⁰ allowing Medicare to negotiate directly with drug companies,³¹ and mandating increased transparency of drug manufacturing costs.³²

²⁷ Table 4. 83 Fed. Reg. at 62,185

²⁸ \$116 billion in projected Medicare Part D spending in 2019. *See* 2017 Annual Report, *2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, CENTERS FOR MEDICARE & MEDICAID SERVICES. Accessed via <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>. Pg 105

²⁹ Laurie McGinley, *Trump administration to explore drug imports to counter price hikes*. THE WASHINGTON POST. July 19, 2018. Accessed via https://www.washingtonpost.com/news/to-your-health/wp/2018/07/19/trump-administration-to-explore-drug-imports-to-counter-price-hikes/?utm_term=.13de0ed95cae.

³⁰ News Release, *HHS Advances Payment Model to Lower Drug Costs for Patients*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES. Oct. 25, 2018. Accessed via <https://www.hhs.gov/about/news/2018/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html>.

³¹ Paige Winfield Cunningham and Felicia Sonmez, *Trump says he's taking 'revolutionary' action to lower drug prices*, THE WASHINGTON POST. October 25, 2018. Accessed via https://www.washingtonpost.com/politics/trump-to-address-drug-prices-in-speech-shifting-focus-to-health-care-before-midterm-elections/2018/10/25/88e16e0a-d84b-11e8-a10f-b51546b10756_story.html?utm_term=.829e75214f55.

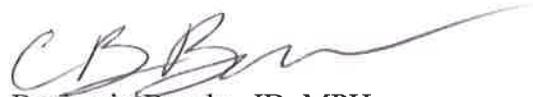
CONCLUSION

For the above reasons, Whitman-Walker Health submits that the proposals to allow Medicare Part D Plans to reduce coverage of drugs in the protected classes should be withdrawn. These provisions in the Proposed Rule would undercut Congress' goal of ensuring that patients struggling with particularly challenging diseases have access to individually calibrated treatment options on the forward edge of medical innovation.

Respectfully submitted,



Daniel Bruner, JD, MPP
Senior Director of Policy
dbruner@whitman-walker.org
(202) 939-7628



Benjamin Brooks, JD, MPH
Assistant Director of Policy
bbrooks@whitman-walker.org
(202) 797-3557

WHITMAN-WALKER HEALTH
1342 Florida Avenue NW
Washington, DC 20009

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³² Thomas Sullivan, *Vermont: First State to Pass Pharmaceutical Cost Transparency Bill*, POLICY AND MEDICINE. May 5, 2018. Accessed via <https://www.policymed.com/2016/05/vermont-first-state-to-pass-bill-on-pharmaceutical-cost-transparency.html>.