November 1, 2021

Via Electronic Communication
mentalhealthcare@finance.senate.gov

Senator Ron Wyden
Chairman, Committee on Finance
221 Dirksen Senate Office Bldg.
Washington D.C., 20510

Senator Mike Crapo
Ranking Member, Committee on Finance
239 Dirksen Senate Bldg.
Washington D.C., 20510

Re: Improving Mental and Behavioral Health Access for Patients

Dear Senators Wyden and Crapo:

We, the undersigned organizations, that advocate on behalf of patients with mental health disorders and other complex and chronic conditions, commend the Senate Committee on Finance for showcasing leadership to address critical issues pertaining to the mental health and behavioral health of American communities. As Congress works towards developing a bipartisan legislative package on mental and behavioral health, we believe it is pivotal to ensure that patients have broad and consistent access to the medications they rely on to manage their mental health – and that patients are adequately protected from the harmful insurance practice of non-medical switching. As you embark on these efforts, we ask that you address the practice of non-medical switching and protect patient communities by:

(1) Calling for the enforcement of the guaranteed renewability provision in the Patient Protection and Affordable Care Act (ACA);
(2) Prohibiting demonstration projects that would remove protections in the Six Protected Classes; and
(3) Authorizing a report exploring the impact of non-medical switching on patients with mental health conditions.

I. Background on Non-Medical Switching

Non-medical switching occurs when a health insurer or pharmacy benefit manager ("PBM") requires a stable patient to switch from his or her current, effective medication to an alternate drug by excluding the original medication from coverage, elevating the drug to a higher cost tier, or otherwise limiting access to treatment or increasing the patient's out-of-pocket costs. These policies result in patients changing medications for financial rather than medical reasons.

For patients with mental health conditions, non-medical switching can result in many avoidable complications, including a lack of adherence to their treatment plan, harmful side effects, medication errors, increased office visits, and additional lab testing and medication use.[1] Lack of treatment adherence can be especially impactful for patients with mental health conditions who may already struggle with medication adherence. Specifically, a 2020 study reported that "at least 61% of patients with schizophrenia, 57% of patients with bipolar disorder, and 52% of patients with depression had problems with adherence."[2] Nonadherence can worsen patient symptoms and result in hospitalization or re-hospitalization, reduce effectiveness of subsequent treatments, and result in an increased risk of suicide.[3]

Non-medical switching policies are against the clinical practice recommendations. Notably, the American Medical Association (AMA) recognized that "unanticipated changes to formularies and coverage restrictions throughout the plan year can negatively impact patients' access to needed medical care."[4] The AMA adopted Principle 5, which states "[a] drug or medical service that is removed from a plan's formulary or is subject to new coverage restrictions after the beneficiary enrollment period has ended should be covered without restrictions for the duration of the benefit year."[5] Therefore, we ask that Congress take action to prohibit non-medical switching and ensure patients have consistent access to necessary medications to manage their mental and behavioral health needs.

II. Congress Should Encourage Enforcement of the Guaranteed Renewability Provision

Non-medical switching policies violate the guaranteed renewability provision of the ACA. The ACA's guaranteed renewability provision states that individual, small group, and large group plans may only "modify the health insurance coverage for a product" at the time of renewal.[6] Further, in the 2016 Notice of Benefit and Payment Parameters (NBPP), the Department of Health and Human Services (HHS) stated:[7]

> We are also concerned about issuers making mid-year formulary changes, especially changes that negatively effects enrollees. . . . We also note that, under guaranteed renewability requirements and the definitions of "product" and "plan," issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal.[8]

The NBPP is explicit that mid-year formulary changes should not occur at a time other than plan renewal, unless for reasons of drug availability.[9] Despite this clear statement from

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7144249/
[2] https://www.psychiatrictimes.com/view/treatment-nonadherence-epidemic-hidden-plain-sight
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778728/
[4] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf
[5] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf
[6] 45 CFR Section 146.152 (a) and (b).
[7] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[8] https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf at p. 74.
[9] https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf at p. 74.

HHS, insurers have openly disagreed and have continued to implement non-medical switching policies.[10]

While some states have taken action to pass their own laws to address non-medical switching, these laws do not protect patients in employer-sponsored plans due to ERISA preemption.[11] Thus, Congress should clarify that mid-year formulary changes violate the ACA's guaranteed renewability provision and call on HHS to enforce the provision.

III. Congress Should Prohibit Demonstration Projects that Would Remove Protections in the Six Protected Classes

Currently, Medicare Part D plan sponsors are required to cover all or substantially all drugs in six categories or classes, referred to as the "Six Protected Classes."[12] The Six Protected Classes include antidepressants and antipsychotics, among others.[13] The Six Protected Classes were adopted because it is widely recognized that conditions, such as mental health disorders often require specialized treatment that is targeted to a patient's specific needs. The treatments within these Six Protected Classes are often not interchangeable, meaning that if a stable patient is switched from one medication to another, that patient may not achieve the same success on the new medication. Yet, according to a 2021 analysis conducted by Avalere Health, Medicare Part D plans are increasingly leveraging formularies and utilization management tools across drugs in the protected classes – including antidepressants and antipsychotics – that present significant barriers to medically necessary medications.[14]

On January 19, 2021, the Center for Medicare and Medicaid Innovation (CMMI) launched the PDM Model, a demonstration project to test a new Medicare Part D design.[15] The changes included removing protections for the Six Protected Classes. As of CY 2022, participating Part D sponsors would have been permitted to "treat five of the six protected classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would other Part D drugs in other classes.[16] Additionally, as of CY 2022, regarding all other classes of drugs aside from the Six Protected Classes, participating Part D sponsors would have been permitted to include only one drug per drug class on their formulary rather than a minimum of two drugs per classes, as is currently required.[17] These changes may have resulted in non-medical switching of patients with mental health conditions.

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[10] *See* America's Health Insurance Plans Comment Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019 Proposed Rule, https://www.regulations.gov/document/CMS-2019-0006-23013 at p. 12.

[11] http://www.uspainfoundation.org/wp-content/uploads/2017/01/NAIC-Midyear-Formulary-Changes.pdf at pp. 2-3.

[12] https://www.medicarefaq.com/faqs/six-protected-classes/

[13] https://www.medicarefaq.com/faqs/six-protected-classes/

[14] http://www.partdpartnership.org/uploads/8/4/2/1/8421729/avalere_report_on_six_protected_classes_--_february_2021.pdf

[15] https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet

[16] *Id.*

[17] *Id.*

While we are thankful that this Administration revoked the planned demonstration project, CMMI still has the authority to offer similar demonstration projects in the future.[18] As such, Congress should revoke CMMI's authority to implement demonstration projects that impact the Six Protected Classes.

IV. Congress Should Authorize a Report on the Impact of Non-Medical Switching on Patients with Mental Health Disorders

We recommend that Congress authorize a report on the impact of non-medical switching on patients with mental health disorders in the United States. As noted, non-medical switching is becoming more common.[19] One study found that 41 of 82 plans had a mid-year formulary change.[20] In addition, a separate New York study found that 64.8 percent of patients surveyed had been subject to non-medical switching, and that two-thirds of these switches derived from mid-year formulary changes.[21] While these changes can be beneficial to the plan profits in the short term, these changes harm patients with mental health conditions and increase their risk for negative health outcomes.[22] Specifically, for patients with mental health conditions, non-medical switching can leave vulnerable patients without access to medications during increasingly stressful times.[23] For example, at the end of 2020, CVS Caremark announced that it would eliminate coverage for certain antidepressant medications.[24] CVS implemented this change in the midst of the COVID-19 pandemic, exacerbating mental health conditions and rates of anxiety and depression.[25]

Some states have already produced similar reports. For example, in 2017 the Massachusetts state legislature established a Special Commission to study medical switching by health plans and pharmacy benefit manager.[26] The Special Commission found that non-medical switching was a frequent occurrence, and that chronic conditions, auto-immune disorders, and mental health conditions were most frequently subject to non-medical switching policies.[27] Further, the Special Committee report recommended rules, guidelines, or potentially legislation

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[18] The Social Security Act states that Part D sponsors shall be required to include all covered Part D drugs for the Six Protected Classes. The statutes also states that HHS may establish exceptions that permit a sponsor to exclude certain drugs within the protected classes from its formulary. However, in order to do so, HHS is required to ensure that any exception is 1) based upon scientific evidence and medical standards of practice; and 2) includes a public notice and comment period. 42 U.S.C. § 1395w-104I (G)(i)(I), (iv); 42 C.F.R. 423.10. However, 42 U.S.C. 1315a gives CMMI authority to waive 42 U.S.C. § 1395w-104I in order to implement demonstration projects

[19] https://www.mass.gov/files/documents/2018/06/06/final-report-special-commission-report-on-medication-switching.pdf

[20] https://catalyst.phrma.org/new-analysis-midyear-formulary-changes-in-marketplace-plans-can-significantly-reduce-access-to-needed-medications-for-patients

[21] https://creakyjoints.org/advocacy/new-york-patient-sentiment-toward-non-medical-drug-switching/

[22] https://advocacy.consumerreports.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf at p. 69.

[23] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778728/

[24] https://www.realclearhealth.com/articles/2020/12/24/cvs_dont_leave_depression_patients_in_the_dark_during_the_worst_days_of_the_pandemic_111152.html

[25] https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm#:~:text=What%20is%20added%20by%20this,from%209.2%25%20to%2011.7%25.

[26] https://www.mass.gov/files/documents/2018/06/06/final-report-special-commission-report-on-medication-switching.pdf

[27] *Id.* at p. 18.

should be developed to ensure formulary changes do not harm patients; patients should receive timely notifications of formulary changes; there should be an adequate appeals process; and that state agencies should monitor formulary appeals.[28] Congress could conduct a similar study and use that as the basis for future legislative work on non-medical switching.

V. Conclusion

In conclusion, the undersigned organizations fully support the Senate Committee on Finance's efforts to improve access to mental and behavioral health services. We strongly encourage the Committee to take action to protect patients with mental health disorders from harmful non-medical switching policies and ensure that Americans living with a mental health condition can have the confidence and peace of mind that they can access their medications to manage their health. We appreciate the opportunity to share these recommendations and look forward to working with the Committee as this effort continues.

Sincerely,

Aimed Alliance
Alliance for Patient Access
Anxiety & Depression Association of America
Caregiver Action Network
Center for U.S. Policy
Depression and Bipolar Support Alliance
Easterseals Iowa
Families for Depression Awareness
HealthyWomen
Hemophilia of Iowa Inc
Infusion Access Foundation
The Kennedy Forum
Maternal Mental Health Leadership Alliance
NAMI Texas
National Infusion Center Association (NICA)
National Organization for Tardive Dyskinesia
The Trevor Project

[28] *Id.* at p. 21.