



November 15, 2021

Submitted electronically to mentalhealthcare@finance.senate.gov

The Honorable Ron Wyden, Chairman
The Honorable Mike Crapo, Ranking Member
United States Senate
Committee on Finance
Washington, DC 20510-6200

RE: U.S. Senate Committee on Finance; Request for Information on Legislative Proposals To Improve Access to Behavioral Health Care Services

Dear Senators Wyden and Crapo:

Otsuka America Pharmaceutical, Inc. (Otsuka) appreciates the opportunity to respond to the request for information (RFI) and feedback on legislative proposals that will improve access to health care services for Americans with mental health and substance use disorders, issued by the Senate Committee on Finance on September 21, 2021.

Otsuka and its' affiliates oversee research and development and commercialization activities for innovative products in North America. At Otsuka, our driving philosophy is to defy limitation, so others can too. We seek to serve those with unmet medical needs in the central nervous system (CNS) which lead to mental illness. We respect the value within every mind—whether it's a grand idea that changes the world, a simple human connection that changes someone's life, or something in between.

GUIDING PRINCIPLES

Otsuka strives to make a difference in the lives of every patient we treat and is committed to helping patients gain access to treatments and the care they need. Otsuka's comments on the RFI derive from our experience working to expand access to innovative treatments in the mental health space. While the individual policy recommendations vary, the primary goal is the same—ensuring that all Americans have access to appropriate health care professional, pharmaceutical, and institutional supports when and where they need them. To that end, our comments on the RFI seek to identify ways to:

- **Promote pathways to behavioral health services and care** by strengthening the behavioral and long-term care workforce.
- **Improve patient access to care** by (1) creating a patient-centered coordinated system of care, (2) improving parity coverage and reimbursement for mental health services with respect to other services, and (3) expanding access to different modalities of care including, telehealth,

remote monitoring services and innovative digital health products such as prescription digital therapeutics (PDTs).

These principles inform our comments below.

A. Strengthening the Workforce

Otsuka is proud to be a leader in the development of innovative therapies in the mental health space. As part of that innovation, Otsuka is currently engaged in clinical trials to develop a treatment for agitation in Alzheimer's disease. We are dedicated to ensuring that these patients have access to the services they need by strengthening the behavioral health and long-term care workforce. We further are concerned about the challenges these patients may face in accessing appropriate services and treatment given the need for more behavioral health and long-term care workers in general.

Otsuka applauds President Biden's dedication to Alzheimer's disease research. While the nation and world continue to search for a cure to this heartbreaking disease, it is imperative we appropriately treat the symptoms of the disease. Neuropsychiatric symptoms of Alzheimer's disease, including agitation, have been shown to occur in roughly 82 percent of patients with mild or very mild Alzheimer's disease.¹ Agitation is commonly defined to include behavior consistent with emotional distress, excessive motor activity, verbal or physical aggression, and excess disability derived from such behaviors. It has been reported as the most common neuropsychiatric symptom among residents diagnosed with dementia living in care homes.² And the population of these patients is only growing, with an estimated 3.4 million patients newly diagnosed with Alzheimer's disease each year and an estimated 1.5 million likely to have agitation.³ Approximately 20 percent of persons with agitation are institutionalized and the incremental cost of agitation due to institutionalization is \$4.3 billion or \$50,588 per individual.⁴

As the number of patients with agitation continues to grow, it will continue to further strain caregivers, nursing homes, long-term care facilities, and related workforce. Yet the United States is already facing a shortage in long-term care staff and high turnover rates, exacerbated by low salaries, inadequate benefits, and little opportunity for promotion.⁵ With respect to behavioral health workers, this shortage is particularly acute in rural areas, and the population of these workers is further marked by a lack of racial and ethnic diversity.⁶ These shortages have only been exacerbated by the challenges of providing this care during the COVID-19 pandemic.

Inadequate staffing can lead to delays in patients receiving appropriate care and services.⁷ This is true for both the patients experiencing agitation and patients around them as significant staff resources

¹ Kristiina Karttunen et al., *Neuropsychiatric Symptoms and Quality of Life In Patients With Very Mild and Mild Alzheimer's Disease*, 26 Int. J. Geriatric Psych. 473 (May 2011), available at <https://pubmed.ncbi.nlm.nih.gov/21445998/>.

² Gill Livingston et al., *Prevalence of and Associations With Agitation In Residents With Dementia Living In Care Homes*, 3 British J. Psych. 171 (Jul. 2017), available at <https://pubmed.ncbi.nlm.nih.gov/28794896/>.

³ An analysis of OPTUM Claims Data showing the growth in diagnoses of patients with Alzheimer's Disease, and the likely corresponding increase in agitation, is on file with Otsuka.

⁴ Martin Cloutier et al., *Institutionalization Risk and Costs Associated With Agitation in Alzheimer's Disease*, 5 Alzheimer's Association 851 (2019), available at <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1016/j.trci.2019.10.004>.

⁵ Lauren Weber, *Nursing Homes Keep Loosing Workers*, WALL STREET JOURNAL (Aug. 25, 2021).

⁶ Ryan K. McBain et al., *How to Transform the U.S. Mental Health System: Evidence-Based Recommendations*, RAND at Recommendation 9 (2021), available at https://www.rand.org/pubs/research_reports/RRA889-1.html (hereinafter "RAND Report").

⁷ Lauren Weber, *Nursing Homes Keep Loosing Workers*, WALL STREET JOURNAL (Aug. 25, 2021).

are spent treating agitated patients. It is therefore imperative that Congress take steps to preserve and expand the workforce for patients in long-term care settings, including those with agitation in Alzheimer's disease and other illnesses.

To that end, Otsuka supports the following steps:

- ***Integrating behavioral health expertise into primary and other health care settings treating patients with agitation in Alzheimer's disease in the community***, to help these professionals better recognize and treat patients with agitation in Alzheimer's disease.⁸ Training should include improving understanding of appropriate therapeutic and non-therapeutic interventions and how to best integrate behavioral health and related services into the patient's care plan, thereby helping patients and caregivers better access these services.
- ***Improving on the availability and quality of peer support services, i.e., services offered by individuals already living with Alzheimer's disease***. Peer-support services for patients with agitation in Alzheimer's disease could include support groups or mentorship programs that allow patients and caregivers to learn from others who have experienced similar diagnoses. Such programs have been found to improve quality of life and feelings of self-control, among other issues, for patients with a variety of mental health conditions.⁹ Congress should support the expansion of these services through supporting the development of peer-support services certification programs.

The above proposals could be operationalized through grant programs, including grants to state Medicaid agencies as well as patient and professional advocacy organizations to expand on the training for behavioral health and long-term care workers available in the state.

B. Increasing Integration, Coordination, and Access to Care

As part of our continued dedication to treatments in the mental health space, Otsuka is engaged in clinical trials studying a new treatment for post-traumatic stress disorder (PTSD). The Department of Veterans Affairs (VA) is at the forefront of developing treatment guidelines for PTSD. These guidelines, however, are often perceived as specific to one population (i.e., veterans) and not widely integrated into care. Further, while there is some consensus with respect to recommendations for PTSD treatment,¹⁰ there has not been a new pharmacological treatment for PTSD in two decades. With a potential new treatment forthcoming, patients could benefit from improvements in treatment and coverage through the development of coordinated systems of care that enable all patients, veterans and otherwise, to access high quality mental health services across the continuum of care, consistent with established guidelines. Coordination is essential for patients living with any serious mental illness, as adherence to clinical guidelines across providers remains scattered and inconsistent.

To that end, Otsuka supports the following steps to improve integration, coordination, and access to care for patients with PTSD and other mental health conditions:

⁸ RAND Report at Recommendation 2.

⁹ *Id.* at Recommendation 10.

¹⁰ Jessica L. Hamblen, A Guide to Guidelines For the Treatment of Posttraumatic Stress Disorder in Adults: An Update, 56 *Psychotherapy* 359 (2019), available at <https://pubmed.ncbi.nlm.nih.gov/31282712/>.

- **Congress should support state Medicaid program efforts to establish a continuum of integrated, coordinated care to optimize spending and improve patient access to mental health services.** Such a continuum could coordinate and integrate services from primary care to inpatient hospitals, nursing homes, long-term care facilities, and community benefit organizations, relying on guidelines such as the Level of Care Utilization System developed by the American Association of Community Psychiatrists.¹¹ It further could include treatment for patients in temporary housing, correctional facilities, and other institutions that disproportionately serve patients with mental illness, including those with PTSD and those being treated with antipsychotics. Congress would need to establish funding for and delegate authority to states to develop this continuum and to contract or engage with appropriate entities to do so, including through Medicaid managed care organizations. Entities, including state Medicaid programs and other agencies that effectively coordinate care should also be eligible for bonus payments and to enter into shared savings agreements to create further incentive to facilitate a holistic approach.
- **Establish a national care coordination initiative.** To support the above effort, Congress should establish a national care coordination initiative, which should be based on the Centers for Medicare & Medicaid Services' (CMS's) Transforming Clinical Practices Initiative. Doing so would help reform the mental health care delivery system to ensure that there is consistent, robust, coordinated care across states.¹²

We encourage Congress to consider and adopt these proposals.

C. Ensuring Parity

In light of the continued mental health crisis, which has only been exacerbated by the pandemic, it is more important than ever that we achieve mental health parity in terms of coverage of behavioral health and related services. Despite years of efforts, we have still not achieved parity; and health insurers, particularly in the private commercial landscape, continue to place restrictions on mental health treatment options.

Procedural requirements like step therapy, also known as “fail first policies,” continue to limit patient access to necessary mental health treatments, often while failing to achieve their stated goal of reducing costs by favoring lower cost medications. In one study, the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California found that many formulary restrictions and step therapy requirements instituted by state Medicaid programs increased Medicaid spending, because patients with schizophrenia or bipolar disorder were more likely to be hospitalized and had higher inpatient and total medical costs, and increased incarceration rates among people with serious mental illnesses.¹³ Limiting access to antipsychotic medications therefore harmed patients by limiting their ability to access needed therapies without any corresponding reduction in costs.

¹¹ *Id.* at Recommendation 13.

¹² *Id.* at Recommendation 14.

¹³ Seth A. Seabury et al., *Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid*, 20 AM. J. MANAGED CARE e52 (2014), available at <https://www.ajmc.com/view/formulary-restrictions-on-atypical-antipsychotics-impact-on-costs-for-patients-with-schizophrenia-and-bipolar-disorder-in-medicare>. See also Dana Goldman & Seth Seabury, *Medicaid Access Restrictions on Psychiatric Drugs: Penny-Wise or Pound-Foolish?* USC LEONARD D. SCHAEFFER CENTER FOR HEALTH POL'Y & ECON. (2015), available at <https://www.healthpolicy.usc.edu/research/medicaid-access-restrictions-on-psychiatric-drugs-penny-wise-or-pound-foolish/>.

We were supportive of Congress' extensive progress in expanding mental health parity through the adoption of the Mental Health Parity and Addiction Equity Act of 2008, which prohibits many group health plans and health insurance issuers from imposing less favorable conditions on mental health and substance use disorder services, including through Medicare and Medicaid. However, additional steps are necessary to ensure that congressional intent of this important Act achieves its goals and patients truly have parity in access to the mental health services and therapy they need, including:

- ***Strengthening mental health parity regulation and enforcement.***¹⁴ Congress should require CMS to adopt additional evidence-based standards and guidelines to implement the mental health parity statutes. These standards should explicitly limit the use of step therapy and other limitations on protected classes of drugs, such as antipsychotics. Congress should further expand resources for enforcement of these requirements in Medicare and state Medicaid programs to ensure that standards are actually being adopted in practice.
- ***Reimbursing evidence-based behavioral health treatments at their true costs.*** Medicaid is the nation's largest payer of behavioral health care services, but reimbursement rates for behavioral health services are consistently low, even when compared with Medicaid payments for other types of health services.¹⁵ Due to low reimbursement, many behavioral health providers choose not to participate in the Medicaid program, limiting their patient population to those who can afford to pay out-of-pocket or who have more comprehensive private insurance options. To ensure parity with respect to reimbursement for mental and behavioral health services, Congress should consider increasing the federal role with respect to reimbursement for mental health services under Medicaid. For example, Congress could increase the availability of federal matching dollars for patients being treated with serious mental illness, on the condition that states establish more appropriate rates.
- ***Establishing an evidence-based mental health crisis response system***¹⁶. While most communities have local responders for medical crises, additional resources are needed to ensure that states and local communities are prepared to respond to mental health crises, including training for local and regional responders. To that end, Congress should consider providing grant programs to states and local communities to prepare for the implementation of the national mental health crisis 988 hotline in 2022, as well as establish mental health crisis response teams when an issue has been identified.
- ***Establishing a national strategy to finance and disseminate earlier intervention for serious mental illness.*** Early intervention for schizophrenia and other serious mental illnesses can improve the ability of patients with mental illness to participate in society. For example, many mental health disorders commonly begin during a patient's teen or young adult years, and if the illness is not appropriately diagnosed and addressed, it may be challenging for these individuals to progress on developmental and other goals.¹⁷ Congress should help support the development of grant programs and funding opportunities that are designed to address early intervention in serious mental illness.
- ***Promoting access to mental health education in public schools, to improve mental health literacy,*** through guidelines and grants issued by the U.S. Department of Education.

¹⁴ RAND Report at Recommendation 5.

¹⁵ *Id.* at Recommendation 6.

¹⁶ *Id.* at Recommendation 7.

¹⁷ *Id.* at Recommendation 8.

These efforts should support school-based mental health awareness programs that have been shown to help improve knowledge, attitudes, and willingness to seek behavioral health support.¹⁸ Such education would help improve awareness and opportunities for seeking treatment.

Otsuka encourages Congress to consider and adopt all of these programs to improve access to services for patient with mental illness in the United States.

D. Congress Should Codify Changes to Reimbursement for Telehealth Services to Ensure that Expanded Access is Maintained.

The COVID-19 pandemic spurred unprecedented expansion of coverage for telehealth services, allowing not only for patients to access care during lockdowns but also expanding access to previously underserved patients. Unfortunately, much of the expanded coverage of these services was authorized through waivers enabled by CMS's expanded authority during the COVID-19 public health emergency and will terminate once the pandemic is over. If Congress wishes to see access to these services continue as during the pandemic, where appropriately prescribed by a patient's health care professional, it will need to take additional steps to modify existing telehealth statutes.

In addition, in recent years, CMS has begun expanding coverage of what it deems to be digital but non-telehealth services, including remote patient monitoring services and remote therapeutic monitoring services (the codes for which were finalized in this year's physician fee schedule Final Rule). This expansion coincided with the growth of products like drug/device combinations that include a digital component and of Food and Drug Administration (FDA) regulated prescription digital therapeutics (PDTs), i.e., digital therapies prescribed by health care professionals to help treat a patient's illness.

Otsuka has been at the forefront of digital therapeutic innovations in mental health, including through the company's 2017 launch of ABILIFY MYCITE® (aripiprazole tablets with sensor), FDA's first-ever approved drug with a digital ingestion tracking system. Otsuka continues to break ground in innovative digital treatments through our efforts to develop PDTs to treat illnesses such as major depressive disorder when prescribed in addition to a patient's existing medical regimen. Congress must establish a new benefit category for the Medicare and Medicaid programs in order for PDTs to become a relevant part of patients' treatment journey.¹⁹

These innovative products have the potential to expand the ability of health care professionals to interact with and monitor their patients remotely, along with expanded access to real-time audio or virtual face-to-face telehealth services. Therefore, Otsuka urges Congress to both:

- ***Open up the Medicare telehealth statute***, by making it more feasible for patients to access telehealth services in the home, where deemed appropriate in the judgment of a health care professional.
- ***Expand and promote access to innovative digital therapies, such as PDTs***. Congress should support the establishment of a benefit category for these services under both Medicare and Medicaid and adopt an appropriate reimbursement mechanism to support them.

¹⁸ RAND Report at Recommendation 1.

¹⁹ Data on file with Otsuka.

E. Additional Recommendations

In addition to the recommendations outlined above, Otsuka recommends that Congress continue to explore how issues outside of direct medical care also play a significant role in the lives of those living with mental illness including:

- ***Connecting homeless individuals with mental health issues to more affordable housing.***
An estimated 2 million people experience homelessness every year, a quarter of which have a serious mental illness.²⁰ Moreover, being homeless itself can exacerbate these conditions. Congress should support these efforts by increasing existing funding for housing support services, including the Substance Abuse and Mental Health Services Administration's Projects in Assistance in Transition from Homelessness project and the VA's and Department of Housing and Urban Development's Housing First program.
- ***Improving strategies to address mental illness in the criminal justice system,*** by ensuring that currently or previously incarcerated patients are connected with mental health programs at an early phase of the criminal justice process. Such programs could include agreements between police and mental health departments to coordinate services and connecting previously incarcerated individuals with specialized case management services.²¹

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Advancing policy solutions to improve mental and behavioral health in this country is a priority for Otsuka. We will continue to lead within this area in our industry and welcome opportunities to work with you and your colleagues in Congress. Should you have any questions, please contact Otsuka's Director, Federal Affairs and Advocacy, Michelle Mathy at michelle.mathy@otsuka-us.com or 202-374-4886.

Sincerely,



Debra Barrett
Vice President, Corporate Affairs
Otsuka America Pharmaceutical Inc.

²⁰ *Id.* at Recommendation 3.

²¹ *Id.* at Recommendation 4.