



December 16, 2020

President-Elect Joseph Biden
Vice President-Elect Kamala Harris
c/o Presidential Transition Team
1401 Constitution Ave. NW
Washington, DC 20230

Re: Recommendations To Increase Access to Mental Health and Substance Use Services

Dear President-Elect Biden and Vice President-Elect Harris,

On behalf of the College of Psychiatric and Neurologic Pharmacists (CPNP), we are pleased to share with you and your colleagues at the Biden-Harris Presidential Transition Team our recommendations for improving the lives of Americans with mental health and substance use disorders. As the transition team develops its list of health care policy priorities for the Biden-Harris Administration, we urge you to consider actions to increase patient access to psychiatric pharmacists and the important services they provide.

CPNP and Psychiatric Pharmacists

CPNP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use and neurologic disorders, receive safe, appropriate, and effective treatment. Members are specialty pharmacists and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorder, psychopharmacology, and neurology.

Pharmacists today graduate with a Doctor of Pharmacy degree, a required six to eight years of higher education, and have more training specific to medication use than any other health care professional. Psychiatric pharmacy practice specializes in treating patients living with psychiatric, neurologic, and substance use disorders. Psychiatric pharmacists have extensive training and expertise in medication treatment and the psychosocial factors inherent within these illnesses. They are responsible for evidence-based patient-centered assessment, medication management of complex regimens, and comprehensive care plan development. Psychiatric pharmacists work collaboratively with medical and mental health interprofessional teams to improve patients' short- and long-term outcomes. They extend their reach by partnering with and educating patients, families, and providers and advocating for the appropriate use of medications.

Need For Behavioral Health Services

Prior to the COVID-19 pandemic, nearly one in five of U.S. adults (47 million) reported having a mental illness in the past year, and over 11 million had a serious mental illness, which frequently results in

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functional impairment and limits life activities. In 2017-2018, more than 17 million adults and an additional three million adolescents had a major depressive episode in the past year. Deaths due to drug overdose have increased more than threefold over the past 19 years (from 6.1 deaths per 100,000 people in 1999 to 20.7 deaths per 100,000 people in 2018). In 2018, over 48,000 Americans died by suicide, and in 2017-2018, nearly eleven million adults (4.3%) reported having serious thoughts of suicide in the past year.

The need for mental health and substance use services is greater than ever and services are not keeping up with demand. The COVID-19 pandemic and the resulting economic recession have negatively affected many people's mental health and created new barriers for people already suffering from mental illness and substance use disorders. With the increase in stressors related to COVID-19 there has been an increased demand for psychiatric services in which psychiatric pharmacists could better help fill that gap if there was payment for their services.

Policy Recommendations

CPNP respectfully requests consideration of the following recommendations as you and your transition team review the work of the federal agencies and implement plans to improve the health of Americans seeking behavioral health services:

Federal Leadership

1. Appoint leaders with behavioral health experience

We appreciate the recent announcement of personnel with behavioral health experience being added to the COVID-19 Advisory Board. We also urge that individuals with behavioral health expertise be included in bodies or discussions focused on intergovernmental coordination of the COVID-19 response. Behavioral health needs will continue to be acute long after the pandemic subsides.

In that vein, we believe that it is imperative to have leaders at the highest levels of HHS with behavioral health experience, including but not exclusively the Assistant Secretary of Health and Human Services for Mental Health and Substance Use. Further it is critical that policy solutions intentionally address behavioral health in concert with physical health. Far too often, behavioral health is addressed separately, rather than developing policies and programs to meet the holistic health needs of individuals. We also recommend reviving the leadership role of the Office of National Drug Control Policy to coordinate the federal response across government agencies to the nation's ongoing substance use crisis. We also urge that the Director of ONDCP have behavioral health expertise.

Centers for Medicare and Medicaid Services

2. Increase Access to Mental Health and Substance Use Services By Providing Reimbursement for Psychiatric Pharmacists' Services

Despite their central role in the health care system, pharmacists are not currently eligible to enroll in or bill Medicare. This lack of payment for psychiatric pharmacist services limits access to their services and their ability to increase the capacity of the care team, including psychiatrists, to see more patients. This impacts the financial sustainability of practices wanting to hire psychiatric pharmacists' and prevents psychiatric pharmacists from practicing at the top of their license. Many psychiatric pharmacists, working as team members often through collaborative practice agreements, provide all levels of care

including prescribing medications and managing all medications to optimize outcomes, addressing drug interactions, and promoting adherence to therapies. Psychiatric pharmacists are trained to perform mental status exams and identify symptoms of mental illnesses that respond to, or are poorly responsive to, psychiatric medications.

As to substance use disorders (SUDs), psychiatric pharmacists have a deep understanding of Medication Assisted Therapy (MAT) that extends beyond that of most other health care providers. When included in the provision of MAT services, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders; reduce per patient dosing of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs for treating patients with SUDs by relieving providers from delivering services including medication management, counseling, monitoring and follow-ups.

Because the Centers for Medicare & Medicaid Services (CMS) does not directly oversee pharmacists under Medicare, the agency often inadvertently excludes pharmacists during rulemaking. We urge your support for legislation such as the *Pharmacy and Medically Underserved Areas Enhancement Act* that would allow pharmacists to deliver care within their scope of practice to patients in federally defined medically underserved communities. This access is particularly vital to expanding access to mental health and SUD services during the public health emergency (PHE).

CPNP urges that CMS under the Biden-Harris Administration add psychiatric pharmacists as Qualified Health Professionals under Medicare to increase patient access to mental health and substance use disorder services.

3. Fund Psychiatric Pharmacist Training To Increase Pool of Mental Health and SUD Providers

The nation's need for quality health care services includes the services provided by pharmacy residency programs, which prepare pharmacists to work effectively as an integral part of a multidisciplinary health care team. Residency-trained pharmacists participate directly in clinical decisions regarding the use of medications and are leaders in improving patient outcomes. There continues to be a need for more pharmacy residency programs, and it is in the public's best interest that such programs be adequately funded. Due to scientific advancements and the evolution of care delivery models, pharmacy residencies are now essential to performing certain patient care services. CPNP specifically urges CMS to allow pass through funds to be used to fund all psychiatric residency training programs to increase the number of psychiatric pharmacists that are trained each year.

4. Maintain the Six Protected Classes Under Medicare Part D to Ensure Access to Mental Health Medications

Current policy requires insurers offering Medicare Part D plans to include on their formularies all or substantially all drugs in six medication classes. The "Six Protected Classes" include antidepressants and antipsychotics. The Six Protected Classes were put in place as acknowledgment that for some conditions individuals respond differently to different medications and formulations, and that individuals need access to a full range of options in achieving wellness. In recent years CMS has proposed creating exceptions to the Six Protected Classes policy to allow insurers to institute new prior authorization or step therapy requirements or exclude medications entirely under some circumstances. CMS, after concerns raised by Congress, ultimately abandoned their proposal. CPNP urges support for maintaining the Six Protected Classes' policy as it stands today. By having the Six Protected Classes in place, those

with Medicare are more likely to be able to access the medications they need for their mental health conditions at reasonable costs.

5. Permanently Authorize Pharmacist Telehealth Flexibilities

The rapid shift to telehealth services during COVID-19 has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. In order to accommodate the provision of telehealth services during the PHE, CMS relaxed its rule requiring physicians to provide “direct supervision” of auxiliary personnel, including pharmacists, in situation where direct supervision currently is required by regulation. In these situations, during the PHE, physicians may provide “virtual supervision” of pharmacists. Although pharmacists are fully capable and trained to provide pharmacist patient care services under general supervision, the flexibility provided during the PHE, at the very least, should be made permanent regardless of whether there is a declared PHE. Virtual supervision of pharmacist services, where supervision is required, will help meet the growing demand for telehealth services, which will likely extend beyond the COVID-19 pandemic. Finally, to ensure telehealth services are financially sustainable, physicians and other qualified practitioners must be able to bill for pharmacist-provided telehealth services at a level commensurate with the time and complexity of the services provided when the service meets all applicable billing requirements.

CPNP also urges support for the elimination of Medicare’s originating and geographic site restrictions so that patients can receive essential behavioral health services regardless where they are located including at home. There is also support in Congress for this, through the introduction of a number of bipartisan bills. Eliminating these restrictions is key to meeting individuals and families where they are, especially important in rural areas. Although the pandemic has so clearly demonstrated the tremendous value of providing telehealth to individuals and families in their homes during this crisis, the benefits transcend the goal of reducing the spread of COVID-19. Allowing telehealth from homes is enabling millions of people to receive care who, due to barriers to care such as transportation and scheduling difficulties, previously were unable to access services.

6. Test Models of Care Utilizing Pharmacist-Provided Patient Care Services

With the shift to value-based care, CPNP urges the development and testing of payment models through the Center for Medicare and Medicaid innovation in which psychiatric pharmacists manage medications through the process of comprehensive medication management. CPNP recommends CMS test a model that incentivizes psychiatric pharmacist involvement across relevant Medicare service lines, including in value-based models such as the Comprehensive Primary Care Plus (CPC+) primary care model. This advanced primary care model integrates pharmacists as part of the care team to provide medication management services, that includes evaluating medication regimens, providing medication self-management support for patients to help them adhere to their prescribed therapies, and promoting clinically-sound, cost-effective medication therapies.

Health Resources and Services Administration

7. Safeguard the 340B Drug Pricing Program

At a time when budgets are stretched thin, the federal 340B drug pricing program helps maximize federal resources while providing access to lifesaving medications and supporting patient services that

might otherwise be unavailable. Absent discounts on 340B-purchased drugs, many covered entities and their contract pharmacies may struggle to keep their doors open, as they may be unable to absorb the cost of providing uncompensated care to the most vulnerable patients. CMS cuts to reimbursement for 340B Part B drugs and manufacturer actions to undercut the program, including unilateral cuts to contract pharmacies, threaten the program's stability. We strongly recommend that the Biden Administration take immediate action to safeguard the patient services and benefits enabled by 340B savings, including rescinding the CMS reimbursement cuts and intervening to ensure manufacturers comply with the law regarding contract pharmacies. Given the adverse impact of the pandemic on providers, they need every resource available to continue to care for their vulnerable and underserved communities.

8. Fund Behavioral Health Professions Training

CPNP urges you to invest resources that strengthen and grow the mental health workforce, including psychiatric pharmacists, and ensure there are enough inpatient and outpatient resources across the country to provide needed care to a broad array of patients. Specifically, we urge support for robust funding for Behavioral Health Workforce Education and Training program, the Loan Repayment Program for Substance Use Disorder Treatment Workforce, and the Mental and Substance Use Disorder Workforce Training Demonstration Program.

9. Inclusion of Pharmacists in the National Health Service Corps (NHSC)

Currently, pharmacists are not eligible to participate in most of the NHSC student loan repayment programs, which are open to primary care clinicians in a Health Resources and Services (HRSA)-approved service site in a Health Professionals Shortage Area. An exception is the Substance Use Disorder Workforce Loan Repayment Program. We recommend that pharmacists be eligible for additional NHSC loan repayment programs.

Drug Enforcement Agency

10. Eliminate X-Waivers for MAT or Allow Pharmacists to Receive Waiver

One of the most insidious effects of the COVID-19 crisis is its impact on efforts to fight the opioid epidemic. At the same time patients are facing external stressors that can trigger relapse, the PHE has upended existing medication-assisted treatment (MAT) programs, which were already, in many cases, struggling to meet patient need. To expand access to MAT, we urge the Administration to support elimination of the X- or DATA waiver requirement and allow buprenorphine to be utilized like other Schedule III drugs. There is bipartisan legislation in both chambers of Congress, the *Mainstreaming Addiction and Treatment Act*, to eliminate the requirement.

In the absence of the elimination of the waiver, we urge you to direct the Health & Human Services Secretary to use the authority granted in the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to revise the "qualifying other practitioner" requirements to allow for pharmacists to receive the requisite waiver (known as an "X- or DATA waiver") necessary to provide MAT services. In the alternative, we urge the Administration to explore using the Public Readiness and Emergency Preparedness (PREP) Act authority to allow pharmacists who meet certain requirements to provide MAT services during the opioid public health emergency. At present, the exclusion of psychiatric pharmacists from X-waiver eligibility has robbed patients of access to MAT at a time when demand for care far outstrips capacity. Psychiatric pharmacists play many different roles in helping patients receive opioid

use disorder treatment including working under expanded authority, such as a collaborative practice agreement that permits prescribing, to help expand patient access to MAT.

Substance Abuse and Mental Health Services Administration

11. Fund Mental Health and Substance Use Services

To address the wave of mental health and substance use triggered by the coronavirus pandemic, CPNP urges support for robust funding for SAMSHA's Community Mental Health Services Block Grant, Substance Abuse Prevention and Treatment Block Grant, Certified Community Behavioral Health Clinics Expansion Grants, and the National Suicide Prevention Lifeline. These programs are critical in providing necessary resources to assure access to mental health and substance use services for many Americans.

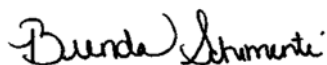
National Institutes of Health

12. Fund Mental Health and Substance Use Research

CPNP urges you to support substantial increases in medical research for mental health, suicide prevention, substance use disorders, and diagnostic tools to better understand the conditions and to provide better resources and more effective treatment for those struggling. Continued investments in research will aid in developing rapid, effective treatments for behavioral health disorders and facilitate early identification and intervention. Specifically, CPNP supports robust funding for the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse (NIAAA).

In closing, psychiatric pharmacists are a vital resource that should be recognized and utilized in the multidisciplinary approach to addressing the need for an affordable, accessible health care system. For their contributions to be fully realized and utilized, sufficient reimbursement is necessary. If you have any questions or require any additional information, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at laura.hanen@faegredrinker.com.

Sincerely,



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