APhA
American Pharmacists Association

November 1, 2021

The Honorable Ron Wyden
Chairman, Committee on Finance
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member, Committee on Finance
239 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Crapo:

The American Pharmacists Association (APhA) appreciates the opportunity to respond to the Finance Committee's RFI as you work to develop a bipartisan legislative package to enhance behavioral health care.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA thanks the Committee for issuing this RFI and holding important hearings on improving mental health and substance use disorder (SUD) and opioid use disorder (OUD) services.

Pharmacists' Role in Addressing Mental Health Care Needs

Pharmacists perform a wide variety of patient care services, provide safe and effective comprehensive medication management, and increase access to care for patients with mental health conditions. Pharmacists are currently providing the following in-person and telehealth-delivered mental health services--for a more complete list refer to Appendix 1 (attached to our comments) – Services and Activities Performed by Mental Health Clinical Pharmacists:

- Initial consult appointment through direct patient care via telehealth, face-to-face over video conference, typically lasting 60 minutes

- Comprehensive medication management to include:
    - Assess all of a patient's medications – prescription, nonprescription, vitamins, and supplements;

- Assess each medication to ensure that it is appropriate, effective, safe, and can be taken as intended;
- Identify and address medication-related problems;
- Develop individualized care plans with therapy goals and personalized interventions;
- Prescribe medications and order laboratory or other diagnostic tests (varies by state);
- Follow-up appointments at regular intervals (e.g., weekly, biweekly or monthly) to evaluate response, adverse effects, progress toward treatment goals, and to adjust medications as needed; typically lasting 30 minutes;
- Educate patient and family about medications and lifestyle modifications;
- Refer to other providers and specialists for services such as diagnostic clarification, psychotherapy, and dietary counseling; and
- Collaborate closely with other mental health team members to clarify diagnoses and discuss complex medication regimens.

Pharmacists' Role in Addressing SUD/OUD

Unfortunately, the COVID-19 pandemic has exacerbated the drug overdose crisis. According to the Centers for Disease Control and Prevention (CDC), during the period April 2020 through March 2021, there were more than 96,000 overdose deaths -- a record high.[1] As the Committee recognizes, additional steps need to be taken to address this crisis.

Pharmacists are important providers on the patient's health care team and play a critical role in caring for patients with acute and chronic pain and/or OUD including prescribing medications, as authorized; medication management; administering; dispensing; and educating patients about opioid and non-opioid pain medications, as well as talking to patients about nonpharmacologic therapies.

Pharmacists have more medication-related education and training than any other health care professional. As medication experts, pharmacists are uniquely qualified to provide opioid stewardship and medication management services including comprehensive medication management, dose optimization, appropriate tapering of opioids and other pain medications, and education on safe storage and disposal methods. In addition, pharmacists aid opioid overdose reversal efforts by furnishing naloxone and training patients and community members on its use.

[1] CDC National Center for Health Statistics. 12 Month-ending Provisional Number of Drug Overdose Deaths, based on data available for analysis on 10/3/2021, available at: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

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APhA Recommendations for Inclusion in the Committee's Legislative Package

In order to increase access to pharmacist-provided patient care services for patients with mental health conditions, SUD, and OUD, APhA urges the Committee to include the following in its legislative package:

S. 1362 / H.R. 2759, the *Pharmacy and Medically Underserved Areas Enhancement Act*

Despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care, Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. While over 90% of Americans live within 5 miles of a community pharmacy[2], and pharmacists are also present in clinics and physician office practices, many of our nation's seniors are medically underserved. As proven during the COVID-19 pandemic, pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care and the entire Medicare program.

Accordingly, APhA strongly urges the Committee to include S. 1362, the *Pharmacy and Medically Underserved Areas Enhancement Act*, introduced by Committee members Charles Grassley (R-IA), Robert Casey (D-PA), and Sherrod Brown (D-OH), and cosponsored by Debbie Stabenow (D-MI), in the Committee's legislative package to allow pharmacists to deliver vital patient care services in medically underserved areas to help break down the barriers to achieving health care equity in this country, improve patient care, health outcomes, the impact of medications,[3] and consequently, lower health care costs and extend the viability of the Medicare program.

By recognizing pharmacists as providers under Medicare Part B, S. 1362 would enable Medicare patients in medically underserved communities to better access health care – including mental health, SUD, and OUD care -- through state-licensed pharmacists practicing according to their own state's scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and the most accessible outside normal business hours. The ongoing COVID-19 pandemic has further illustrated how difficult it is for patients living in medically underserved communities to access care and achieve optimal medication therapy outcomes. S. 1362 recognizes that pharmacists can play an integral role in addressing these

[2] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.
[3] *See,* Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See,* Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

longstanding disparities to help meet health equity goals[4] and ensure that our most vulnerable patients have access to the care they need. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

S. 445 / H.R. 1384, the *Mainstreaming Addiction Treatment (MAT) Act*

Only 1 in 5 Americans with opioid use disorder receive buprenorphine.[5] The Department of Health and Human Services' (HHS) issuance of *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*[6] is a step in the right direction to increase patient access to buprenorphine, which has been proven to cut the risk of overdose death in half.[7] However, the *Practice Guidelines* exclude pharmacists – the most accessible healthcare providers – because pharmacists are statutorily ineligible to apply to the Substance Abuse and Mental Health Services Administration (SAMHSA) for a DATA 2000/X waiver[8] necessary to prescribe buprenorphine as medication-assisted treatment (MAT) for OUD.

Under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are unable to prescribe certain Schedule III medications, such as buprenorphine, because they are not eligible for a DATA waiver. When pharmacists partner with physicians and other healthcare providers to provide MAT, they streamline and improve care. Pharmacists' MAT-related services may include treatment plan development, patient communication, care coordination, and adherence monitoring and improvement activities, among others. Allowing pharmacists to prescribe buprenorphine according to their states' scope of practice laws will increase patients' access to MAT and help address treatment gaps.

Accordingly, APhA strongly urges the Committee to include S. 445, the *Mainstreaming Addiction Treatment (MAT) Act*, introduced by Committee member Maggie Hassan (D-NH) and Senator Lisa Murkowski (R-AK), in the Committee's legislative package to further

[4] The White House. Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. January 20, 2021, available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/
[5] Rebecca Haffajee, Ph.D., J.D., M.P.H. et al., Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment, 54 Am. J. Prev. Med. S230-42 (2019).
[6] HHS. Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. 86 FR 22439. April 28, 2021, available at: https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder
[7] National Academy of Sciences, Engineering, and Medicine. Consensus Study Report: Medications for Opioid Use Disorder Save Lives, Nat'l Acad. Press (2019), available at: https://www.nap.edu/catalog/25310/medications-for-opioid-use-disorder-save-lives
[8] 21 U.S.C. § 823(g)(2).

expand the number of practitioners – including pharmacists – who are ready, willing, and able to prescribe buprenorphine to patients in their jurisdictions.

Additional Recommendations and Responses to the RFI

Strengthening Workforce

- What public policies would most effectively reduce burnout among behavioral health practitioners?

The pharmacy profession has been concerned about pharmacists' well-being and burnout for more than 30 years. Over the last five years, these issues have become even more of a priority as burnout due to demanding workloads, staffing issues, and payment policies began approaching a crisis point. In 2019, the profession took action to address these issues through the 2019 *Enhancing Well-being and Resilience Among the Pharmacist Workforce* national consensus conference.[9] The 50 actionable consensus recommendations addressed pharmacist working conditions and patient safety; payment models; relations between pharmacists and employers; pharmacist and student pharmacist well-being; well-being education and training; and communications.

The final recommendation category identified the need for pharmacist well-being data and research. Research on the effect of burnout in health care practitioners has traditionally focused on physicians and nurses. Very recently and only sporadically has it included pharmacists. Over the last two years, the profession began to make research on pharmacists' burnout and well-being a priority, but more needs to be done. As the health care practitioner that consumers access in their neighborhoods each day, it is imperative that pharmacists are included in any public policy efforts and funding for burnout/well-being research and programs to ensure they continue to be there for the nation's consumers.

APhA began to address the need for pharmacists' well-being data in 2019 through the Well-being Index (WBI) for Pharmacy Personnel.[10] Through the WBI aggregate data, APhA tracks the percentage of pharmacy personnel WBI assessors whose scores indicate that they are at risk for

[9] APhA. Enhancing Well-Being and Resilience Among the Pharmacist Workforce: A National Consensus Conference (2019), available at: https://aphanet.pharmacist.com/enhancing-well-being-and-resilience-among-pharmacist-workforce-national-consensus-conference?is_sso_called=1

[10] The Well-being Index for Pharmacy Personnel is an online screening tool, invented by the Mayo Clinic, to assess an individual's well-being by evaluating fatigue, depression, burnout, anxiety/stress, and mental/physical quality of life. The WBI tool was invented by the Mayo Clinic and offered to all pharmacy personnel, regardless of APhA membership, free of charge (www.pharmacist.com/wellbeing).

high distress. Over the last two years, the percentage has fluctuated between 32-36%. It has been as high as 52% for those in community pharmacy practice. Researchers at the Mayo Clinic have determined that the risk of high distress is accompanied by a corresponding higher risk of personal and professional consequences including a two-fold increase in the risk of a medication error.

A 2019 study[11] published in the *Journal of the American Pharmacists Association* concluded that focusing on both external and individual factors pharmacists face in practice are critical to addressing pharmacists' burnout. A subsequent 2021-published study validated this multifaceted approach.[12] Working conditions are often cited as the major contributor to pharmacists' burnout. The 2021 study asked pharmacists what policy solutions would be needed to address working conditions specific to community pharmacy practice. It concluded that working conditions are affected by multiple factors that are often interdependent and thus require a multifaceted public policy approach.[13] These interdependent factors are both under the control of the pharmacy organization (e.g., staffing, metrics, workflow) and external to the pharmacy organization (e.g., regulations, laws, payment).

One external factor that can be addressed by Congress is payment reform. The 2021 study concluded that payment for pharmacists' patient care services and dispensing reimbursement rates, along with restricting the harmful practices of pharmacy benefit managers (PBMs), would provide more resources to the pharmacy practice that could then be available to increase staffing to meet workload demands and enhance patient safety.

Increasing Integration, Coordination, and Access to Care

- What programs, policies, data, or technology are needed to improve access to care across the continuum of behavioral health services?

Physicians, pharmacists, and other health care practitioners are challenged to meet the growing demand for behavioral health services. The Association of American Medical Colleges (AAMC) projects a shortfall of up to 139,000 physicians by 2030.[14] The physician workforce shortages that

[11] Schommer JC, Gaither CA, Goode JR, Owen JA, Scime GM, Skelton JB, Cernasev A, Hillman LA. Pharmacist and student pharmacist views of professional and personal well-being and resilience. J Am Pharm Assoc (2003). 2020 Jan-Feb; 60(1):47-56. doi: 10.1016/j.japh.2019.09.006. Epub 2019 Oct 25. PMID: 31669419, available at: https://pubmed.ncbi.nlm.nih.gov/31669419/
[12] Beal, JL et al. Policy solutions to address community pharmacy working conditions. J Am Pharm Assoc. 2021 July; 61(4): 450–461. doi: 10.1016/j.japh.2021.02.011, available at: https://www.japha.org/article/S1544-3191(21)00079-0/fulltext
[13] Id.
[14] AAMC. The Complexities of Physician Supply and Demand: Projections from 2018-2033. June 2020, available at: https://www.aamc.org/media/45976/download

our nation is facing are being felt even more acutely as health care providers, including our nation's pharmacists, have been mobilized on the front lines to combat the COVID-19 public health emergency (PHE). The effects of workforce shortages are only exacerbated in rural communities which already struggle to meet patient needs.[15] One important mechanism physician practices can employ to greatly increase their capacity to meet patient demand is to use a coordinated, team-based, patient-centered approach to care and delegate appropriate clinical responsibilities to non-physician providers, including pharmacists.[16]

There are more than 300,000 pharmacists in the U.S., many of whom are underutilized in their capacity to contribute to addressing unmet health care needs.[17] Pharmacists currently receive doctoral-level education and/or practice experience and training, with some pharmacists furthering their training to become specialists with residencies and board certification in Psychiatric Pharmacy[18] and other specialties.

Pharmacists' participation on patient care teams has been shown to reduce adverse drug events and improve outcomes for patients.[19] Given pharmacists' ability to reduce the estimated $672 billion spent annually on medication-related issues,[20] pharmacists are critical to bending the cost curve by encouraging the delivery of high-quality, low-cost care. In addition, research has shown coordinated care models involving other health care practitioners, including pharmacists, are essential for realizing the maximum impact of patient care delivery.[21] Improving the utilization of pharmacists in coordinated care models, particularly in rural and medically underserved areas, will help address the need for health care practitioners to provide access and care in rural settings and improve quality.

The COVID-19 pandemic has highlighted how accessible pharmacists are and how they can be leveraged to improve the health of communities. Many of the new authorities and flexibilities provided related to pharmacists' patient care services during COVID-19 will end when the

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[15] Petterson S.M., Phillips R.L., Jr., Bazemore A.W. & Koinis G.T. (2013). Unequal distribution of the U.S. primary care workforce. American Family Physician, 87(11), available at: http://www.aafp.org/afp/2013/0601/od1.html

[16] Bodenheimer, T.D. & Smith, M.D. (2013). Primary Care: Proposed Solutions to the Physician Shortage Without Training More Physicians, Health Affairs, available at: https://doi.org/10.1377/hlthaff.2013.0234 4

[17] Gums, John. Can pharmacists help fill the growing primary care gap? UF News. January 5, 2016, available at: http://news.ufl.edu/articles/2016/01/can-pharmacists-help-fill-the-growing-primary-care-gap.php

[18] Board of Pharmacy Specialties (BPS). Psychiatric Pharmacy. Available at: https://www.bpsweb.org/bps-specialties/psychiatric-pharmacy/

[19] Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment

[20] Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy*, available at: https://doi.org/10.1177/1060028018765159

[21] Mitchell, Pamela. Et. al. Core Principles & Values of Effective Team-Based Health Care. Institute of Medicine. October 2012, available at: https://www.nationalahec.org/pdfs/VSRT-Team-Based-Care-Principles-Values.pdf

public health emergency is over. **Thus, as the Committee understands, Congress needs to act immediately to ensure these pharmacist patient care services authorities are maintained as they have significantly increased patient access and improved care while lowering health care costs and saving lives.**

In addition, as noted above, APhA strongly urges the Committee to include S. 1362, the *Pharmacy and Medically Underserved Areas Enhancement Act*, in the Committee's legislative package to allow pharmacists to deliver vital patient care services in medically underserved areas to help break down the barriers to achieving health care equity in this country, improve patient care, health outcomes, the impact of medications,[22] and consequently, lower health care costs and extend the viability of the Medicare program.

Ensuring Parity

- How could Congress improve mental health parity in Medicaid and Medicare?

APhA recommends that Congress extend mental health and substance use treatment parity to Medicare, Medicaid fee-for-service (FFS), and TRICARE. More than 60 million Medicare beneficiaries, 20 million enrollees in traditional Medicaid, and 10 million TRICARE enrollees have limited coverage for mental health and substance use disorder services. Extending mental health parity to Medicare, Medicaid FFS, and TRICARE will help to expand access to mental health and SUD treatment services to these populations.

Expanding Telehealth

The rapid shift to telehealth services during the COVID-19 public health emergency has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. Prior to the PHE, pharmacists were already actively involved in virtual care delivery for Medicare beneficiaries through provision of Part B services such as Chronic Care Management (CCM), Transitional Care Management (TCM), Continuous Glucose Monitoring (CGM), Remote Patient Monitoring (RPM), and Behavioral Health Integration (BHI), as well as Medication Therapy Management Services in the Part D program. The onset of the COVID-19 pandemic has brought about additional opportunities to leverage pharmacists in telehealth services, including medication management services, chronic

[22] *See,* Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See,* Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

disease management, education on healthy lifestyle interventions, interpretation of, and patient counseling on point of care diagnostic tests, and more.

In response to the Committee's RFI, APhA offers the following recommendations to enhance patient access to telehealth services:

- How can Congress craft policies to expand telehealth without exacerbating disparities in access to behavioral health care?

Telehealth can help address existing health disparities. According to GAO's May 2021 report, *MEDICARE AND MEDICAID: COVID-19 Program Flexibilities and Considerations for Their Continuation*, the proportion of Medicare beneficiaries utilizing telehealth was similar across racial and ethnic groups.[23] To avoid both the inequities in access to modes of care and potentially problematic interruptions to care or the negative consequences of fragmented care, Congress should revise the requirement that a rural health clinic (RHC) or federally qualified health center (FQHC) mental health visit must be a face-to-face (that is, in person) encounter between a RHC or FQHC patient and a RHC or FQHC practitioner to also include encounters furnished through audio/video telehealth as well as audio-only communications technologies. As stated in the CY 2022 Medicare Physician Fee Schedule proposed rule, CMS believes that mental health telehealth services furnished via audio-only communications technology would increase access to care, especially in areas with poor broadband infrastructure and among patient populations that either are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction.[24] APhA also recommends that Congress act to ensure that Critical Access Hospitals can bill for behavioral health services via telehealth just as they do for in-person services.

- How should Medicare pay for the practice expense portion of Medicare's telehealth payment for mental and behavioral health services? Should the practice expense resources needed for telehealth forms of these services be independently measured, or should Medicare rely on the practice expense values used for in-person forms of Medicare payment for the services?

[23] GAO. MEDICARE AND MEDICAID: COVID-19 Program Flexibilities and Considerations for Their Continuation. P. 14. May 19, 2021, available at: https://www.finance.senate.gov/imo/media/doc/Jessica%20Farb%20GAO%20Testimony.pdf
[24] CMS. Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Proposed Rule (RIN 0938-AU42), 86 FR 39104, 39235-39238. July 23, 2021, available at: https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf

- Ensure Medicare Payment for Pharmacist-provided Telehealth and In-Person Services is Commensurate with the Time and Complexity of the Services Provided

To ensure telehealth services are financially sustainable, physicians and other non-physician providers (NPPs) must be able to bill for pharmacist-provided telehealth and in-person services at a level commensurate with the time and complexity of the services provided. However, the 2021 Medicare physician fee schedule rule[25] only allows payment to physicians and other NPPs for pharmacists' evaluation and management (E/M) services at the least complex services level (CPT Code 99211 - limited to 7 minutes). Such a provision eliminates any incentive and/or ability for physicians/NPPs and pharmacists to partner to provide complex health care services. This misaligned Medicare payment policy for pharmacists' services performed in incident to physician services arrangements continues to be a significant barrier to broad use of pharmacists in team-based care models during the COVID-19 public health emergency and beyond.

Accordingly, APhA strongly urges the Committee to ensure that physicians and other qualified practitioners can bill for pharmacist-provided "incident to" services provided both in-person and via telehealth to Medicare beneficiaries at higher E/M codes within their state scope of practice and training (CPT Codes 99212-99215) when the service provided meets the billing requirements for a specific E/M code.

- Pharmacists Providing Mental Health and SUD/OUD Services Should Receive Attribution, Recognition, and Compensation by CMS

Many pharmacists are actively caring for patients with OUD at Opioid Treatment Programs (OTPs), yet many barriers prevent patients from receiving care. APhA believes pharmacists can help meet treatment demands but their ability to do so is dependent, in part, on coverage frameworks that encourage better optimization of resources, such as pharmacists. Congress and CMS should take action to acknowledge, attribute, and reimburse pharmacist-provided patient care services that can be provided through OTP programs.

Patients receiving care in an OTP may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners outside of the OTP. APhA encourages the Committee to specifically consider how pharmacists' time devoted to treatment planning and modification, and care coordination can be included among the services covered by Medicare Part B. Pharmacists provide SUD and OUD services at OTPs,

[25] 85 Fed. Reg. 84472

specialty, and primary care offices, including medication assisted treatment (MAT), and, as noted above, some pharmacists receive additional education and credentialing relevant to SUD/OUD, such as board certification as a psychiatric pharmacist.[26,27,28,29,30,31,32] Pharmacists providing mental health and SUD/OUD services should receive attribution, recognition, and compensation by CMS for providing these services.

- Should Congress make permanent the COVID-19 flexibilities for providing telehealth services for behavioral health care? If so, which services, specifically?

    - Designate Pharmacists as Practitioners (Providers) for the Medicare Telehealth Benefit, and Add Patient Care Services Provided by Pharmacists Using Telehealth to the Medicare Telehealth List

The Coronavirus Aid, Relief, and Economic Security Act (CARES) Act (P.L. 116-136) under Sec. 3703. Expanding Medicare Telehealth Flexibilities eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123) and allows the Secretary of Health and Human Services to waive telehealth restrictions under 1834(m) to enable beneficiaries to access telehealth, including in their home, from a broader range of providers—including pharmacists. Given the significant burdens on the health care system posed by the COVID-19 public health emergency, APhA urges Congress to designate pharmacists as practitioners (providers) for the Medicare Telehealth Benefit in order to fully utilize their expertise both during and after the end of the PHE.

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26 DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. J Am Pharm Assoc. 2015; 55: 187-192. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

27 Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. Journal of the American Pharmacists Association. 57 (2017), S135-S140. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28292501

28 Lagisetty, P., Klasa, K., Bush, C., Heisler, M., Chopra, V. & Bohnert, A. Primary care models for treating opioid use disorders: What actually works? A systematic review. PLOS One. Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0186315

29 Gilmore Wilson, C. & Fagan, B. Providing Office-Based Treatment of Opioid Use Disorder. Annals of Family Medicine. 2017; 15(5). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5593733/

30 Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, Mental Health Clinician, 2013, 3(6), 290-291. Available at: http://mhc.cpnp.org/doi/abs/10.9740/mhc.n183353?code=cpnp-site

31 Suzuki et al., Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically, Journal of Opioid Management, 10(3), 159-168. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4085743/

32 McCarty et al., Training rural practitioners to use buprenorphine: Using The Change Book to facilitate technology transfer, Journal of Substance Abuse Treatment, 2004, 26(3); 203-8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/15063914

In addition, APhA urges Congress to add patient care services provided by pharmacists using telehealth, particularly services provided outside of inpatient settings, to the Medicare Telehealth List.[33] Many patient care services provided by pharmacists are clinically appropriate for telehealth, including medication management services, chronic condition management, pharmacogenomics, interpretation of point of care diagnostic tests and providing patient counseling on test results, and consultations with patients and health care providers.

- Make Permanent the Removal of Geographic Location Requirements

APhA strongly supports the removal of geographic location requirements in order to allow patients' homes as originating sites to access telehealth services for the diagnosis, evaluation, and treatment of mental health disorders and other health conditions. During the COVID-19 PHE, telehealth has enabled both providers and patients to stay safe. Allowing patients to receive telehealth services at home greatly enhances access to care by removing barriers such as transportation challenges, childcare needs, or an inability or unwillingness to attend an in-person visit, such as for agoraphobic patients or those with anxiety disorders.

- Remove the CAA's Requirement for an In-person Visit, Without the Use of Telehealth, Within 6 Months Prior to the First Time the Physician or Practitioner Furnishes a Telehealth Service to the Beneficiary

APhA strongly supports telehealth for mental health services as established in the Consolidated Appropriations Act of 2021 (CAA). However, we believe that requiring an in-person visit within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary might hinder access to care for beneficiaries in need of mental health or substance use disorder services. There is no clinical evidence for an arbitrary in-person requirement before a beneficiary can access telehealth services.[34] Requiring an in-person visit often discourages patients from seeking out mental health care due to stigma. For example, patients that live in small rural communities might not want to be seen entering a behavioral health clinic. In addition, patients experience barriers to in-person visits, including transportation challenges, the need to make childcare arrangements, and simply accessing a local mental health provider. Therefore, APhA strongly urges Congress to remove the requirement for an in-person visit within six months prior to the furnishing of a telehealth service. In addition, APhA opposes requiring an in-person visit at least once within six months

[33] Medicare List of Telehealth Services, available at https://www.cms.gov/Medicare/Medicare-General Information/Telehealth/Telehealth-Codes

34 American Telemedicine Association. Overview of In-Person Requirements, available at https://www.americantelemed.org/wpcontent/uploads/2021/06/ATA-Overview-of-In-Person-Requirements-1.pdf

before any subsequent Medicare mental health telehealth service. The appropriate visit interval – whether in-person or via telehealth – is patient specific.

- Make Permanent Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

During the COVID–19 PHE, CMS used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology.

In the CY 2022 Medicare Physician Fee Schedule proposed rule, CMS states:"[g]iven the generalized shortage of mental health care professionals (https://bhw.hrsa.gov/sites/default/files/bureau-healthworkforce/data-research/technicaldocumentation-health-workforcesimulation-model.pdf), and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, we believe beneficiaries may have come to rely upon the use of audio-only communication technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care."[35]

We agree. Accordingly, we support amending 42 CFR § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders when the originating site is the patient's home, including therapy, counseling, and periodic assessments provided by Opioid Treatment Programs (OTPs).

Pharmacists are using audio-only communications to deliver telehealth services, especially during the PHE. APhA's May 2021 Pharmacist Experience in Telehealth Survey found that 86% of respondents were using audio-only communications to deliver telehealth services.[36] Audio-only communications were used 60% of the time to deliver telehealth services, compared to 36% for audio/video technology.[37]

Audio-only tele-mental health services provided by pharmacists have been proven effective. For example, a 2018 pilot study found that a pharmacist-conducted telephonic assessment of

35 86 FR 39104, 39148
36 American Pharmacists Association. May 2021. Pharmacist Experience in Telehealth Survey, Data on file.
37 Id.

mental health patients' current nutrition, physical activity, and sleep status and subsequent counseling and education improved Duke Health Profile (Duke) scores.[38] Specifically, patients experienced higher Duke physical scores ($p = 0.007$) and significantly lower anxiety ($p = 0.025$), depression ($p = 0.001$) and anxiety-depression scores ($p = 0.005$) at follow-up.[39]

- Make Permanent the Authority Allowing Direct Supervision to be Provided Using Real-Time Interactive Audio and Video Technology under Incident to Physician Services Arrangements

In order to accommodate the provision of telehealth services during the COVID-19 PHE, CMS relaxed its rule requiring physicians to provide "direct supervision" of auxiliary personnel, including pharmacists, in situations where direct supervision currently is required by regulation.[40] In these situations, during the PHE, physicians may provide direct supervision of pharmacists using real-time interactive audio and video technology. APhA urges Congress to make this flexibility permanent regardless of whether there is a declared PHE. Real-time "virtual" supervision of pharmacist services, where direct supervision is required, will help meet the growing demand for telehealth services and expand access to care.

Conclusion

APhA would like to thank the Committee for issuing this RFI and for continuing to work with us by including S. 1362 and S. 445 and other APhA recommendations in your legislative package to increase access to pharmacist-provided patient care services for patients with mental health conditions, substance use disorder, and opioid use disorder. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone at (202) 429-7507 as a resource as you consider this legislative package.

[38] Bingham J., Axon D.R., Scovis N., Taylor A.M. Evaluating the Effectiveness of Clinical Pharmacy Consultations on Nutrition, Physical Activity, and Sleep in Improving Patient-Reported Psychiatric Outcomes for Individuals with Mental Illnesses. Pharmacy (Basel). 2018 Dec 22;7(1):2. doi: 10.3390/pharmacy7010002. PMID: 30583547; PMCID: PMC6473796. Available at: https://pubmed.ncbi.nlm.nih.gov/30583547/

39 Id.

[40] 85 Fed. Reg. 19230

APhA
American Pharmacists Association

Thank you again for the opportunity to provide comments on this important issue.

Sincerely,

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Senior Vice President, Pharmacy Practice and Government Affairs

Appendix 1: Services and Activities Performed by Mental Health Clinical Pharmacists[41]

Mental health clinical pharmacists provide a wide variety of patient care services as a part of the interprofessional team. These services together allow the mental health clinical pharmacist to provide safe and effective comprehensive medication management and increase patient access to care. This appendix, while not all-inclusive, describes many common types of patient care services performed by this critical team member.

A. **Patient Assessment:** Mental health clinical pharmacists perform assessments to determine appropriate treatment modalities and to monitor efficacy and toxicity. The typical diagnoses of patients evaluated by mental health clinical pharmacists include schizophrenia, depressive disorders, bipolar disorder, ADHD, anxiety disorders, migraine and headache, dementia, sleep-wake disorders, and substance use disorders. They use the same assessment tools as do other mental health professionals, including:
    1. Mental status exams
    2. Suicide risk assessment (e.g., Columbia Rating Scale)
    3. Psychiatric rating scales (e.g., Patient Health Questionnaire-9, PTSD Checklist-17, Generalized Anxiety Disorder-7, Brief Psychiatric Rating Scale, CAGE)
    4. Physical assessments (e.g., weight, blood pressure)
    5. Ordering and interpretation of laboratory tests (e.g., lithium level, complete blood count, basic metabolic panel, hemoglobin A1C)

B. **Medication Prescribing and Monitoring:** Mental health clinical pharmacists provide medication prescribing (e.g. initiation, continuation, change in therapy, discontinuation) and monitoring for medications often utilized in the treatment of mental health disorders as allowed through scope of practice or collaborative practice agreements. These medications include:

    1. Antipsychotics (e.g., Risk Evaluation and Mitigation Strategies [REMS] with clozapine, metabolic adverse effects, abnormal involuntary movement scale)
    2. Antidepressants (e.g., REMS with esketamine, QTc prolongation with citalopram, drug–drug/food interactions with monoamine oxidase inhibitors)
    3. Mood Stabilizers (e.g., levels with lithium, valproic acid/divalproex sodium, carbamazepine, drug–drug interactions)

[41] Board of pharmacy specialties psychiatric pharmacy specialist certification content outline/classification system. 2017. https://www.bpsweb.org/wp-content/uploads/PSYContentOutline2017.pdf. Accessed October 26, 2021.

4. Stimulants (e.g., verifying the prescription drug monitoring program [PDMP] and managing potential adverse effects)
5. Antiepileptics (e.g., managing therapeutic levels and drug–drug interactions)
6. Benzodiazepines (e.g., initiations and tapers, appropriate use evaluations)
7. Triptans and Anti-Calcitonin Gene-related Peptide (CGRP) Monoclonal Antibodies (e.g., obtainment of medications and efficacy and toxicity of medications)
8. Cholinesterase Inhibitors and N-Methyl-D-Aspartate (NMDA) Receptor Antagonist (e.g., efficacy and toxicity of agents)
9. Non-Benzodiazepine Agents (e.g., verifying the PDMP and managing efficacy and toxicity)
10. Medications Used in Substance Use Disorders

C. **Utilization of Long-Acting Injectable Antipsychotics:** Mental health clinical pharmacists are instrumental in the utilization of long-acting injectable antipsychotics. In addition to the prescribing and monitoring of the injection, they assist in the planning of utilization of the injection, and administration in select states under state law.

D. **Utilization of Pharmacogenomics:** Mental health clinical pharmacists are involved in the utilization of pharmacogenomics to help guide treatment decisions. This includes recommending testing when indicated, interpreting and explaining the results to the patient and other members of the healthcare team, and using the results to make recommendations and optimize medication therapy.

E. **Patient and Caregiver Education:** Mental health clinical pharmacists are heavily involved in medication and treatment adherence education, through techniques such as motivational interviewing. Additionally, they provide medication and disease state education to patients and caregivers. Using the shared decision-making process, mental health clinical pharmacists provide information about various treatment options to patients and their caregivers. This allows for making an informed, collaborative decision that takes into account the patient's preferences, values, and beliefs.

F. **Trainee Education:** Mental health clinical pharmacists provide education to health care trainees (e.g., student pharmacists, pharmacy practice residents, medical residents, fellows) through both didactic education and experiential learning experiences.

G. **Management of Transitions of Care:** Mental health clinical pharmacists are involved in medication reconciliation during the transitions of care that patients with mental health disorders may experience over the course of their lifetime.

H. **Pharmacy-Specific Activities:** Mental health clinical pharmacists are involved in many activities in operating and directing pharmacies, including:
   1. Management of formulary in health care facilities in addition to those for insurance and state Medicaid
   2. Medication utilization review, drug utilization review, and policy standards. Mental health clinical pharmacists perform cost-effectiveness analyses, evaluate National Quality Standards, and fulfill National Accreditation and Regulatory requirements.
   3. Drug information and literature review

I. **Substance Use Disorder Treatment:** Mental health clinical pharmacists have developed many practices in the treatment of those with substance use disorders, including:

   1. Initiation and continuation of buprenorphine, in collaboration with DEA "X"-waivered provider
   2. Monitoring patients on buprenorphine
   3. Naltrexone initiation, monitoring, and continuation
   4. Naltrexone administration in select states
   5. Naloxone prescribing, education, and recommendation
   6. Methadone maintenance therapy

J. **Treatment of Mental Health Disorders in Special and/or Vulnerable Populations:** These populations include:
   1. Pediatrics
   2. Geriatrics
   3. Pregnancy/lactation
   4. Ethnically diverse populations, including refugees
   5. Low-income and homeless
   6. Rural, underserved areas
   7. LGBTQ+ (lesbian, gay, bisexual, transgender, transsexual, 2/two-spirit, queer, questioning, intersex, asexual, ally)
   8. Patients with hepatic/renal impairment and/or absorption issues

K. **Health Promotion Strategies:** Mental health clinical pharmacists are involved in the planning and implementation of a diverse range of health promotion strategies.
    1. Wellness screening (e.g., depression screenings)
    2. Tobacco cessation
    3. Suicide prevention

L. **Development and implementation of models of care:** Mental health clinical pharmacists are leading the way in the utilization of varying models of care, including telepsychiatry, assertive community treatment (ACT) teams, and embedment in primary care clinics.

M. **Research:** Mental health clinical pharmacists are involved in all levels of research, including clinical and laboratory research, with some serving as lead investigators on many types of research, including federal studies.