



October 11, 2019

[Submitted electronically to PainandSUDTreatment@cms.hhs.gov]

Re: Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the efforts of the Center for Medicare & Medicaid Services (CMS) to implement Section 6032 of the Substance Use-Disorder Prevention the Promotes Opioid Recovery and Treatment for patients and Communities Act (“SUPPORT Act”) by hosting the September 20, 2019 Public Meeting and issuing the “Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment” (RFI). Section 6032 of the SUPPORT Act directs the Department of Health and Human Services (HHS) Secretary to work with the HHS Pain Management Best Practices Inter-Agency Task Force (“Task Force”) to develop an Action Plan to prevent opioid addiction and enhance access to medication-assisted treatment (MAT). While pharmacists already play a vital role in both preventing opioid addiction and enhancing access to MAT, many opportunities exist to better utilize pharmacists’ medication expertise and accessibility to improve patient care and public health.

Founded in 1852 as the American Pharmaceutical Association, APhA represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. Despite patient care demands and needs to optimize medication use and safety, lack of coverage of pharmacists’ services by Medicare, particularly Part B, Medicaid and other payers is a significant barrier for health care teams and patients who need pharmacist-provided patient care. Therefore, as CMS collaborates with the Task Force to develop an Action Plan and future report to Congress, APhA encourages CMS to consider both recommendations and implementation options to help advance the goals of improving treatment of acute and chronic pain and opioid use disorder.

I. Key Recommendations

- 1. Support expansion of care models that currently face expansion barriers due to restrictive coverage and payment policies.*

In the RFI, CMS seeks feedback on different care models and services that address the needs of patients with acute and chronic pain and those with substance use disorder (SUD). APhA appreciates CMS’ efforts to learn more about different approaches to care. Often, APhA is

made aware of specific, effective care models that reimburse and/or provide coverage for pharmacist provided services while improving patient outcomes, but the ability to expand care models to reach Medicare beneficiaries is stunted because pharmacist-provided services are not recognized under the Social Security Act. These specific models often “cobble together” the resources to support pharmacists using a mixture of administrative overhead and other mechanisms. As a result, expanding these models in Medicare is not financially feasible because the services pharmacists provide would not be directly reimbursed. Since Medicare coverage decisions are often mirrored by other payers, this issue is exacerbated as many other payers also do not cover pharmacist-provided services. APhA also understands and supports value-based models and the changes in payment that accompany them, but in the current environment, fee-for-service payment is still an important component of most models, and therefore a barrier to pharmacist participation. APhA views the efforts of the Task Force and CMS as an opportunity to correct this pervasive issue.

In the past, APhA has advocated for legislative solutions (e.g., H.R. 592/ S.109 *Pharmacy and Medically Underserved Areas Enhancement Act*)¹ which were specifically intended to help pharmacists fill care needs in underserved communities. APhA urges CMS to include in its Action Plan a goal to expand patient access to pharmacist-provided care. To the extent that CMS finds a legislative solution is necessary to achieve this goal, APhA suggests CMS recommend, in the report provided to Congress under the SUPPORT Act, that Congress pass legislation with components like the *Pharmacy and Medically Underserved Areas Enhancement Act*. APhA also welcomes the opportunity to work with HHS, CMS and Congress to develop alternative legislative solutions that utilize pharmacists to meet patients’ care needs, including those who need pain management and substance use disorder services.

2. *Clarify the types of health care practitioners CMS encourages including on care teams by providing examples at the beginning of the Action Plan and including pharmacists in those examples.*

As CMS develops the Action Plan, APhA urges CMS to include recommendations consistent with the Task Force’s report which recognizes “insufficient access to... pharmacists... has hindered the development of efficient, cost-effective health care delivery models to treat chronic pain”². Since pharmacists are not consistently included in different definitions of “provider”, “health care professional”, “eligible clinician”, and “health care practitioner”, among other terms, it may not be apparent that a recommendation includes pharmacists. As a result, those reading the Action Plan may not accurately interpret or implement its findings or recommendations.

To help avoid this issue and provide clarity, APhA recommends CMS’s Action Plan include an introductory paragraph to clarify that when a term like “provider” or “health care practitioner” is used readers should interpret the term to include a range of providers and provide examples of the types of providers ((e.g., pharmacists, physicians, nurse practitioners, behavioral

¹ See H.R. 592 – Pharmacy and Medically Underserved Areas Enhancement Act, available at: <https://www.congress.gov/bill/115th-congress/house-bill/592/text>

² Department of Health and Human Services, (May 2019). Pain Management Best Practices Inter-Agency Task Force Report, at 65, available at: <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>, last accessed, October 10, 2019.

health specialists etc.) that should be included. APhA believes this clarity will encourage practitioner diversity on collaborative care teams.

II. Responses to Questions on Acute and Chronic Pain

1. *What actions can CMS take to enhance access to appropriate care for acute and/or chronic pain in Medicare and Medicaid, including (a) For special populations (for example, individuals with sickle cell anemia or individuals living in health professional shortage areas) and/or (b) Through remote patient monitoring, telehealth, and other telecommunications technologies?*

Medicare Part B

As stated above and in APhA's comments to the Task Force in April 2019³, pharmacists can provide a variety of different services to support patients with acute and chronic pain, but current Part B payment policies do not directly include pharmacists. Notably, under Medicare Part B, there is a lack of reimbursement for pharmacist-provided services related to pain management (e.g., medication management; provision of naloxone; patient monitoring; screening and referrals; patient counseling and education; opioid tapering; ordering and interpreting laboratory tests to monitor medications, pharmacogenomic test interpretation; and treatment planning in coordination with other care team members). Limited reimbursement options prevent patients from receiving care and disincentivizes care teams from integrating pharmacists because it may not be financially sustainable to employ a pharmacist unlike other health care practitioners. **APhA urges CMS to advance payment policies in Medicare Part B that directly cover pharmacist-provided patient care services.**

In the near-term, CMS can help support patient access to different types pharmacist-provided patient care services by clarifying permissible billing of evaluation and management (E/M) codes for pharmacists' services under incident to physician services arrangements. Currently, APhA's members encounter variable interpretations from Medicare administrative contractors (MACs) and billing and coding and legal departments within organizations regarding the appropriateness of physician billing for pharmacists providing E/M services under "incident to arrangements" above the level of CPT code 99211. While CMS, in 2014, indicated physicians can bill for pharmacists' E/M services provided under "incident to" arrangements and consistent with pharmacist's state scope of practice, variable billing practices suggest that this clarity has yet to be accepted and more widely adopted.⁴ APhA encourages CMS to include in the Action Plan its interpretation that physicians can bill for higher levels of E/M services provided by pharmacists and a description of how it will disseminate this message in Medicare Claims Processing Manuals and other guidances relied upon by Medicare Administrative Contractors

³ American Pharmacists Association (April 2019). Department of Health and Human Services Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations (Docket Number: HHS-OS-2018-0027), available at: [pharmacist.com/sites/default/files/audience/APhA%20Comments%20-%20HHS%20Interagency%20Task%20Force%20FINAL.pdf](https://www.pharmacist.com/sites/default/files/audience/APhA%20Comments%20-%20HHS%20Interagency%20Task%20Force%20FINAL.pdf)

⁴ See Department of Health and Human Services letter to American Academy of Family Physicians (2014). Available at: <https://www.aacfp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf>, last accessed October 6, 2019.

and other stakeholders. APhA welcomes the opportunity to help address this issue in collaboration with CMS.

Another option would be for CMS to consider utilizing its authority, including providing discretion, to allow Medicare to accept claims for services provided to Medicare beneficiaries by health care practitioners (e.g., pharmacists) operating consistently with their scope of practice but outside of current Medicare policy. APhA notes current payment options involving pharmacists do not reimburse pharmacists for the full scope of services they can provide, including more complex services, a point HHS recently recognized in their report “Reforming America’s Healthcare System through Choice and Competition.”⁵

Lastly, under general supervision by physicians, pharmacists are eligible as “Clinical Staff” to provide certain other services, including chronic care management (CCM). However, patients with chronic pain may be unable to gain access to these services if they do not have certain conditions for eligibility. APhA encourages CMS to review the eligibility requirements for CCM services and consider broadening eligibility to better include chronic pain patients. Should CMS finalize its proposal to implement principal care management (PCM) services, this could also help patients with chronic pain.

Medicare and Medicaid

APhA greatly appreciated CMS’s Center for Medicaid & CHIP Services Information Bulletin released in January 2019 that addressed state flexibility to facilitate timely access to drug therapy (e.g., naloxone for opioid overdose) by expanding the scope of pharmacy practice using collaborative practice agreements, standing orders and other predetermined protocols.⁶ While APhA applauded the release of the informational bulletin, we encourage CMS to issue a similar informational bulletin highlighting opportunities specific to acute and chronic pain where payers (e.g., Medicaid) could utilize pharmacists to better address needs for patients with acute and chronic pain. Building on this effort, CMS could also issue include in the bulletin complementary reimbursement opportunities within Medicare or Medicaid.

In addition, as payment policies generally shift away from fee-for-service towards value-based models, APhA notes the need for meaningful quality measures related to pain management and substance use disorder. To improve current and future efforts, APhA suggests CMS monitor the application of quality measures to identify unintended consequences. APhA also encourages CMS to work with organizations such as the Pharmacy Quality Alliance (PQA) and the National Academies of Medicine’s Action Collaborative on Countering the U.S. Opioid Epidemic if the agency is considering including quality measurement in future payment and coverage approaches.

(a) Special populations: Individuals Living in Health Professional Shortage Areas

⁵ See Department of Health and Human Services, Reforming America’s Healthcare System through Choice and Competition, available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>, last accessed: October 7, 2019.

⁶ See Centers for Medicare and Medicaid Services, (January 17, 2017) CMCS Informational Bulletin, available at: <https://www.medicare.gov/federal-policy-guidance/downloads/cib011717.pdf>, last accessed, September 30, 2019.

APhA believes pharmacists can be particularly impactful in filling gaps in care for patients living in health professional shortage areas. Pharmacists are the most accessible health care providers with nearly 90% of Americans living within 5 miles of a community pharmacy. As noted above, APhA supports elements in legislative solutions (e.g., H.R. 592/ S.109 *Pharmacy and Medically Underserved Areas Enhancement Act*)⁷ specifically intended to help pharmacists fill care needs in underserved communities. APhA encourages CMS to provide beneficiaries in health professional shortage areas with more options to access care by enabling those patients to receive care from different types of practitioners, including pharmacists.

(b) Remote patient monitoring, telehealth, and other telecommunications technologies

APhA supports technology developments that will help increase access to care, better connect patients to health care providers, and improve the flow of information from patients and among health care providers. Remote patient monitoring and telehealth services, including those provided by pharmacists, have the potential to significantly impact the unmet needs of patients with pain or treatment of substance use disorder. APhA encourages CMS to also consider other services provided remotely, such as telepharmacy, in the Action Plan.⁸

APhA also supports comments submitted by the Pharmacy Health Information Technology Collaborative (PHIT), including the recommendation that CMS review and consider incorporating the [Pharmacist eCare Plan Initiative](#) into the Action Plan.

APhA applauds CMS' recent decision regarding the general supervision requirement for remote physiological monitoring services when provided "incident to" a physician. APhA supports use of remote patient monitoring as one mechanism to improve care and expand access. As policies are developed to facilitate the uptake of such services, APhA encourages CMS to evaluate barriers to adoption of services to help guide future policies.

- 2. What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of acute and/or chronic pain, do you believe, may have contributed to the use of opioids? If answering this question, please provide information on how these policies have contributed.*

APhA believes payment and coverage policies that provide limited access to alternative treatments for pain may have contributed to the use of opioids. Since opioids are often the most affordable treatment option and can help control pain, payment and coverage policies likely helped support broad use. However, the same coverage policies that did not provide coverage for alternative treatments also did not cover services that promote medication safety and adherence, missing an opportunity to prevent misuse and provide more careful monitoring. Better leveraging pharmacists in providing risk management services for opioids, especially given their accessibility could have helped in avoiding some of the current problems and can be utilized now to prevent harm and optimize medication use.

⁷ See H.R. 592 – Pharmacy and Medically Underserved Areas Enhancement Act, available at: <https://www.congress.gov/bill/115th-congress/house-bill/592/text>

⁸ See American Pharmacists Association, Telehealth, available at: <https://www.pharmacist.com/telehealth>, noting the differences between telehealth and telepharmacy

3. *What, if any, payment and coverage policy in Medicare and/or Medicaid have enhanced or impeded access to non-opioid treatment of acute and/or chronic pain?*

APhA believes payment and coverage policies in Medicare and Medicaid, such as those described above and value-based models, have the capacity to enhance access to non-opioid treatment of acute and/or chronic pain since they tend to support a patient-centered, multimodal and multi-disciplinary care models.

5. *What payment and service delivery models, such as those that utilize multimodal and multi-disciplinary approaches to effectively manage acute and chronic pain and minimize the risk of opioid misuse and OUD, could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects? a. What existing models, treatments or strategies to identify and effectively manage the population of individuals misusing prescription opioids or using illicit opioids who then develop new or exacerbating pain?*

APhA is pleased CMS is seeking feedback regarding different models that could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects. To the extent that CMS recommends models not described by APhA, we urge CMS to consider including pharmacists in these models. APhA encourages CMS considering the following:

- Pharmacist integration into primary care teams (e.g., Veterans Health Administration⁹, Indian Health Service¹⁰)
- Development of community-based demonstration projects that include community and other pharmacists as members of the care delivery team.
- Working with stakeholders to develop a coordinated care model that involves providers (including pharmacists) who are not co-located but have the technology infrastructure to collaborate in providing coordinated pain care¹¹
- Utilize frameworks like those provided for CCM and PCM (as noted in II. 1) to deliver pain management services
- Test mechanisms to support academic detailing programs^{12,13}

6. *What can CMS do to better ensure appropriate care management for Medicare beneficiaries with pain who transition across settings, and/or between pain therapies?*

⁹ McFarland, M., Nelson, J., Ourth, H., Groppi, J. & Morreale, A. (2019). Optimizing the Primary Care Clinical Pharmacy Specialist: Increasing Patient Access and Quality of Care within the Veterans Health Administration, available at: <https://accpjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/jac5.1177>, last accessed: October 10, 2019.

¹⁰ Duvivier, H., Gustafson, S., Greutman, M., Jangchup, T., Knapp, A., Harden, A. & Warshany, (2017). Indian Health Service pharmacists engaged in opioid safety initiatives expanding access to naloxone, *Journal of the American Pharmacists Association*, 57(2), S135-S140.

¹¹ See Fay, A.E., Ferreri, S.P., Shepherd, G., Lundeen, K., Tong, G.L. & Pfeifferberger, T. (2017). Care team perspectives on community pharmacy enhanced services, *Journal of the American Pharmacists Association*, 58(4), S83-S88.e3.

¹² Wells, D.L., Popsish, S., Kay, C., Torrise, V., * Christopher, M. (2016). VA Academic Detailing Service: Implementation and Lessons Learned, *Federal Practitioner*, 35(5), 38-42.

¹³ Larson, M. Browne, C., Nikitin, R.V., Wooten, N.R., Ball, S. & Sayko Adams, R. (2017). Physicians report adopting safer opioid prescribing behaviors after academic detailing intervention, *Journal of Substance Abuse*, 39(2), 218-224.

To help patients transition across settings, APhA believes CMS can help improve information sharing as patients move throughout the care continuum. For example, community pharmacists often lack a patient’s diagnosis code and much less frequently have access to critical information from the health record. In addition, where there is a pain management agreement in place between patient and prescriber, it is rare that a pharmacist would receive such information. Providing this information to pharmacists would help in providing coordinated care, improve safety and may help facilitate more collaborative relationships among health care practitioners, as well as with patients. Another important care coordination factor is the need for better mechanisms to facilitate widespread clinical information exchange and improved interoperability of health information systems. APhA encourages CMS to implement policies that support both information sharing among health care providers, including pharmacists, and to encourage physicians and other providers to proactively communicate with pharmacists and patients to improve patient care.

As patients switch between therapies, there is an opportunity to utilize pharmacists’ knowledge, scope of practice and collaborative practice agreements (which vary by state). When pharmacists were added to an interdisciplinary team managing patients prescribed chronic opioid therapy they (in accordance with their scope of practice) initiated nonopioid medications, completed urine drug screens and medication agreement reviews and helped free physician time, ultimately helping reduce morphine equivalent dose, and optimize opioid and nonopioid therapy.¹⁴ APhA encourages CMS to develop payment and coverage policies that support collaborative care models that are scalable, focus on patient outcomes and safety and not administratively burdensome.

7. *How can Medicare and Medicaid data collection for acute and chronic pain better support coverage, payment, treatment, access policies and ongoing monitoring?*

APhA suggests Medicare and Medicaid data collection efforts attempt to identify circumstances where patients pay out-of-pocket for medications or services that are otherwise not covered by Medicare or subject to Medicare safety edits or utilization management. APhA is concerned about the potential unintended consequences of certain coverage policies as it can be difficult to adequately balance an individualized patient-centered approach to care with MME quantity limits that may result in patients being inappropriately tapered from their medications. Collection of this out-of-pocket data will provide a clearer picture of how patients are impacted by recent payment and coverage policies.

Also, APhA encourages CMS to collect data that better indicates practitioner type when providing care such that different care models and practitioners’ roles can be better understood. Currently, pharmacists effectively operate as “ghosts” within health care practices because the work they perform is not captured in medical claims data and therefore, not attributed to them. Should CMS advance such an effort, APhA would recommend the agency also study the financial impacts, particularly the cost-savings that result when pharmacists are included on care teams.

¹⁴ Boren, L.L., Locke, A.M., Friedman, A.S., Blackmore, C.C. & Woolf, R. (2019). Team-Based Medicine: Incorporating a Clinical Pharmacist into Pain and Opioid Practice Management, *Physical Medicine & Rehabilitation*, DOI: [10.1002/pmrj.12127](https://doi.org/10.1002/pmrj.12127)

8. *What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance access to and effective management of beneficiaries with acute and/or chronic pain?*

As CMS aims to improve coverage and payment policies in Medicare and Medicaid for beneficiaries with acute and/or chronic pain, we encourage the agency to advance policies that encourage multimodal and multi-disciplinary care models. APhA also reiterates our recommendations from I.

III. Responses to Questions on Substance Use Disorders, including Opioid Use Disorders

1. *What, if any, payment and coverage policies under Medicare and/or Medicaid for the treatment of SUDs, including MAT, do you believe, may help address the Nation's opioid crisis? If answering this question, please provide information on how these policies may help.*

APhA believes broadening patient choice and supporting collaborative care models for the treatment of SUDs will help the address the Nation's opioid crisis and we encourage CMS to adopt recommendations noted in I and II, as several of those will also have positive implications for patients with SUDs.

To align payment and coverage policies with services currently available but inaccessible to patients, APhA encourages CMS to continue implementing care models that can include pharmacists, and other underutilized health care practitioners. APhA appreciates recent efforts by Congress and CMS to propose bundled payment models in office-based settings and opioid treatment programs. As CMS finalizes these models, APhA encourages CMS to monitor patient outcomes and provider responses to determine how these models can be improved, simplified, and potentially expanded to reach patients with other types of SUDs.

2. *What, if any, payment and coverage policies in Medicare and Medicaid have enhanced or impeded the identification of, and access to the treatment by, beneficiaries with SUDs, including OUD.*

APhA has heard concerns that it can be difficult for pharmacies to serve patients with opioid use disorder due to cost constraints or issues in acquiring the medications, including when the purchase price exceeds the reimbursement rate. Members reported that often the costs of medications to treat OUD significantly exceeded reimbursement rates. For example, in Colorado, the reimbursement rate of naltrexone under Medicaid was reported to be significantly below the cost to acquire the medication. Despite pharmacists and other health care providers' interest in providing naltrexone to patients, the high cost of the medication relative to reimbursement resulted in a loss and therefore, was not financially sustainable. As direct and indirect remuneration fees have forced pharmacies to operate on even tighter margins, community pharmacies already struggle to stay afloat and cannot take on additional losses. APhA urges CMS to review reimbursement of medications to treat OUD to determine whether it would be financially sustainable for a pharmacy or other care setting to dispense these medications.

In addition, pharmacists described issues when purchasing certain medications due to limits in place from wholesale distributors, shortages, or for reasons that are not clear to the pharmacists. When purchases issues are encountered, the pharmacy may have the recommend the patient go to another pharmacy or there can be a delay in filling the prescription. Under both circumstances, patient access and adherence may be jeopardized. Furthermore, barriers pharmacies encounter when attempting to purchase controlled substances, including buprenorphine for MAT, can prevent or limit pharmacies from taking on new patients due to inability to stock enough medication to serve their patients' needs. APhA suggests CMS work with DEA and potentially wholesale distributors and other stakeholders to learn how DEA's policies could be modified to better enable pharmacies to consistently obtain medications, particularly those used in MAT. It may also be appropriate for CMS to work with DEA to ensure that production quotas align with anticipated treatment demands from the Medicare and Medicaid populations.

APhA believes payment and coverage policies related to naloxone (including time spent counseling patients), MAT bundles, and Screening, Brief Intervention, and Referral to Treatment (SBIRT) may help enhance identification of, and access to the treatment by, beneficiaries with SUDs, so long as practitioners are aware of these changes. States' efforts to increase coverage of pharmacist-furnished naloxone and SBIRT have already begun, such as Virginia's Medicaid program.^{15,16} However, APhA notes that creating awareness of payment and coverage policies to foster broad uptake needs to be accounted for when developing and implementing new policies as there may be a lag in provider uptake. APhA strongly recommends CMS provide resources and education to health care providers to encourage their rapid participation in current and future payment models. CMS could also work with health care professionals and their associations to determine factors, such as reimbursement and administrative burden or perceived complexity, to identify changes and messaging strategies to support uptake.

4. *What payment and service delivery models that identify and treat people with pain who are at risk of, or have a past history of OUD could be tested by the Center for Medicare and Medicaid Innovation, or through other federal demonstration projects?*

APhA is pleased CMS is seeking feedback regarding different models that could be tested by the Center for Medicare and Medicaid Innovation or through other federal demonstration projects. To the extent that CMS recommends models not described by APhA, we urge CMS consider including pharmacists in such models. APhA encourages CMS to consider the following:

- Virginia state Medicaid coverage of SBIRT screening by pharmacists¹⁷

¹⁵ See Centers for Medicare and Medicaid Services, (January 17, 2017). CMCS Informational Bulletin, available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf>, last accessed, October 10, 2019.

¹⁶ 12 VAC 300130-5070, Covered Services: Practitioner Services: Early Intervention/Screening Brief Intervention and Referral to Treatment, available at: <https://law.lis.virginia.gov/admincode/title12/agency30/chapter130/section5070/>, stating, "C. Physicians, pharmacists, and other credentialed addiction treatment professionals shall administer the evidence-based screening tool with the individual and provide the counseling and intervention. "

¹⁷ 12 VAC 300130-5070, Covered Services: Practitioner Services: Early Intervention/Screening Brief Intervention and Referral to Treatment, available at: <https://law.lis.virginia.gov/admincode/title12/agency30/chapter130/section5070/>, stating, "C.

- Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients^{18,19}
- Reimbursement of pharmacist-provided naltrexone services in states where pharmacists are permitted to do so based on their scope of practice²⁰

5. *What actions could CMS take to improve access to evidence-based, FDA approved MAT or other therapy in Medicare and Medicaid, including for special populations (for examples individuals living in health professional shortage areas)?*

To improve access to evidence-based, FDA approved MAT or other therapy in Medicare and Medicaid, APhA believes CMS needs to consider patient access to different components of MAT, including services and medications.

For MAT services, APhA encourages CMS to more broadly cover pharmacist-provided care services and treatment models that utilize pharmacists to minimize burdens on patients. For example, in Kentucky, pharmacists may prescribe and administer naltrexone in accordance with a state protocol.²¹ Pharmacists in many states have authority to administer medications which APhA encourages CMS to further leverage.²² Alternatively, pharmacists can play a greater role in caring for patients where a physician, for example, prescribes medications and has a collaborative relationship with a pharmacist who provides in-person care to assist in monitoring (e.g., supervised dosing, treatment planning, dose modification etc.) for the patient. APhA encourages CMS to utilize and promote coverage of care models where providers practice at the top of their license, to expand treatment and access opportunities for patients with OUD.

As stated above (III. 2), APhA has heard concerns from our members that difficulty in obtaining medications to treat OUD is a significant barrier to patient care. APhA encourages CMS to review reimbursement of medications to treat OUD and supply chain issues to ensure it is feasible for a pharmacy or other care setting to dispense or provide such medications to recurring and new patients.

Lastly, as CMS is aware, prior authorization and other formulary-related restrictions can negatively impact patient access to the medication component of MAT. While there have been improvements, APhA encourages CMS to continue to monitor different coverage policies, determine the extent to which patient care is impacted and attempt to learn more about the circumstances that lead to patients pay out-of-pocket for their medications.

Physicians, pharmacists, and other credentialed addiction treatment professionals shall administer the evidence-based screening tool with the individual and provide the counseling and intervention. "

¹⁸ DiPaula, B. & Machery, E. (2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, *Journal of the American Pharmacists Association*, 55(2), 187-192.

¹⁹ Alford, D.P., LaBelle, C.T. & Kretsch, N. (2011). Collaborative Care of Opioid-Addicted Patients in Primary Care Using Buprenorphine, Five Year Experience, *JAMA Internal Medicine*, 171(5): 425-431.

²⁰ Ford, J.H., Gilson, A. & Mott, D.A. (2019) Systematic Analysis of the Service Process and the Legislative and Regulatory Environment for a Pharmacist-Provided Naltrexone Service in Wisconsin, *Pharmacy (Basel)*, 7(2), 59.

²¹ See Kentucky Board of Pharmacy, (2018). Opioid Use Disorder Naltrexone Therapy Protocol v2, available at: <https://pharmacy.ky.gov/Board%20Authorized%20Protocols/Opioid%20Use%20Disorder%20Protocol%20v2%20Approved%20December%2012,%202018.pdf>, last accessed October 10, 2019.

²² National Alliance of State Pharmacy Associations and the College of Psychiatric and Neurologic Pharmacists, (2017). State policy recommendations for pharmacist administration of medications, available at: <https://naspa.us/wp-content/uploads/2017/04/Medication-Administration-Meeting-Report-FINAL.pdf>, last accessed: October 10, 2019.

6. *What can CMS do to expand access to the treatment of SUDs, including OUD, in Medicare and Medicaid through remote patient monitoring, telehealth, telecommunications and other technologies?*

The aspects of care related to remote patient monitoring, telehealth, telecommunications and other technologies APhA raised above (Section II. 2b) in regard to acute and chronic pain also apply to the treatment of SUDs. Also, as stated above, APhA supports comments submitted by the Pharmacy Health Information Technology Collaborative (PHIT), including the recommendation that CMS review and consider incorporating the [Pharmacist eCare Plan Initiative](#) into the Action Plan.

7. *What recommendations do you have for data collection in Medicare and/or Medicaid a. On the treatment of SUDs, including OUD, to better support coverage, payment, treatment, access policies and ongoing monitoring, and/or b. to facilitate research, policy development, and inform coverage and payment policies to prevent OUD.*

APhA reiterates our comments raised in II. 7, and believes those suggestions are also relevant in the context of substance use disorder.

9. *What other issues should CMS consider to improve coverage and payment policies in Medicare and Medicaid to enhance the identification of, treatment access by, and the treatment of beneficiaries with SUDs, including OUD.*

APhA highlights that pharmacists are playing a growing role in providing tobacco cessation services with several states allowing pharmacist prescribing of such treatment. APhA encourages CMS provide coverage for different types of SUDs and we again, direct CMS to consider recommendations in I.

As CMS is aware, beneficiaries with SUDs, including OUD, often suffer from other conditions. APhA believes it is imperative CMS adopt policies that enable health care practitioners to treat patients' concomitant conditions. APhA cautions that policies aiming to only treat a patient's pain or SUD can result in siloed care that misses an opportunity to deliver patient-centered coordinated care.

APhA thanks CMS for the opportunity to provide comments to help inform the Action Plan. We support CMS' and the Task Force's ongoing efforts to continue to fight the opioid epidemic and appreciate the collaborative approach taken to help patients with acute and chronic pain and those with SUDs. If you have any questions or require additional information, please contact Jenna Ventresca by email (jventresca@aphanet.org) or by phone at (202) 558-2727.

Sincerely,



Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO