January 17, 2020

[Submitted electronically via PatientsOverPaperwork@cms.hhs.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (HHS)
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Request for Feedback on Scope of Practice

Dear Administrator Verma:

Our organizations are pleased to submit these comments regarding the Centers for Medicare & Medicaid Services' ("CMS") request for additional input and recommendations, under Executive Order ("EO") #13890 – "Protecting and Improving Medicare for Our Nation's Seniors," regarding elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. Collectively, we represent over 300,000 pharmacists,[1] student pharmacists, residents, and pharmacy technicians in all settings.

[1] HRSA. Allied Health Workforce Projections, 2016-2030. Last Accessed, January 16, 2020, available at: https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/projections/pharmacists-2016-2030.pdf

We believe there are a number of opportunities where CMS could provide regulatory relief to alleviate regulatory burdens under Medicare that are more stringent than applicable state scope of practice laws. A growing number of states[2] and private payers are providing enrollees beneficial pharmacist-provided patient-care services in a variety of practice settings. However, current federal regulations severely limit the ability of pharmacists to practice at the top of their license and training.

As discussed below, our organizations request CMS include the following changes in agency regulations, programs, and policies to implement the charges outlined in the EO:

I. General Recommendations
   a. Use inclusive provider language in rulemakings, programs, and policies to ensure pharmacist inclusion to support medication optimization and improve patient outcomes.
   b. Issue a Center for Medicaid & CHIP Services ("CMCS") Information Bulletin where payers could utilize pharmacists to better address needs for patients.
   c. Attribute and promote significant contributions of pharmacists to health outcomes of Medicare beneficiaries.
   d. Expand service models utilizing pharmacist-provided patient care services using CMS Center for Medicare and Medicaid Innovation ("CMMI") data, including in value-based payment models by employing CCMI's waiver authority.
   e. Incorporate and/or test an alternative model at CMMI in rural and medically underserved areas/populations focusing on optimizing medication use and health outcomes as part of coordinated care delivery including pharmacists.
   f. Ensure pharmacists can engage in remote patient monitoring and other telehealth services.

II. Specific Recommendations
   a. Implement a general supervision requirement vs. direct supervision for services delivered by highly trained pharmacists.
   b. Align Medicare service requirements with the most robust pharmacist state scopes of practice.
   c. Clarify physicians and other qualified practitioners can bill for "incident to" services provided to Medicare beneficiaries by pharmacists at levels higher than Evaluation and Management ("E/M") code 99211.
   d. Address challenges for pharmacists and pharmacies to deliver diabetes self-management services ("DSMT") and continuous glucose monitoring ("CGM") services.
   e. Allow pharmacist initiated electronic prior authorization.

[2] CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017, available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

f. Allow pharmacists to be Drug Addiction Treatment Act of 2000 ("DATA")-waived providers by including as qualified practitioners.

BACKGROUND

Pharmacists are the most accessible health care provider and provide care and services in a wide variety of practice settings in communities across our nation – making them uniquely qualified to reduce clinical burdens and improve patient health. In fact, 90% of all Americans live within five miles of a community pharmacy.[3] In addition to being medication experts, pharmacists also provide a broad array of services beyond dispensing medications, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventive services, and immunizations.[4]

Pharmacists are uniquely qualified to provide the type of medication and disease management (including behavioral health conditions) services needed to not only stem adverse drug events and medication nonadherence, but also to enhance patient outcomes through improved medication use. Pharmacists offer an in-depth knowledge of medications that is unmatched in the health care arena. Pharmacists today receive clinically based doctor of pharmacy degrees (Pharm.D.), and many also complete postgraduate residencies and become board certified in a variety of specialties. Pharmacists work with physicians, nurses, and other providers to manage patients' medications and ensure appropriate care transitions, often as part of interprofessional teams. Patient care discussions with other providers often revolve around the pathophysiology of disease or chronic conditions, but far too often patients receive little information regarding perhaps the most essential part and primary mode of treatment — the medication prescribed to cure or manage the condition. In many cases, the prescribing clinician does not have the same medication expertise as a pharmacist. Thus, if the goal is to avoid overspending on drugs and to maximize the value of the drugs patients purchase, pharmacists must play a more prominent role in medication selection and modification, patient education, follow-up and monitoring of medication, and overall medication and chronic disease management.[5]

However, due to statutory and regulatory barriers such as references to "provider," "eligible professional," or similar terms that do not include pharmacists in their definition, pharmacists are often an underutilized health care resource. Meeting CMS' goal of adding value and access through coordinated, team-based care delivery will require CMS to eliminate barriers that exclude/ prohibit pharmacists and other nonphysician practitioners from providing patient care services. These services are well within pharmacists' legal state scope of practice and pharmacy licenses.

We share CMS' goals of reducing unnecessary barriers to patient care and access. To meet these goals for patients across the nation, we urge the agency consider how to better incorporate

[3] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.
[4] Avalere. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 21, 2014, available at: https://avalere.com/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment
[5] Studies indicate that the inclusion of pharmacists on the health care team demonstrates a significant return on investment in both patient outcomes and real dollars. See, e.g., [5] C.A. Bond and C.L. Raehl, *Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates,* 27 Pharmacotherapy 482-93 (2007); See also, M.E. Arnold, et al., *Impact of Pharmacist Intervention in Conjunction with Outpatient Physician Follow-up Visits after Hospital Discharge on Readmission Rate*, 72 Am. J. Health-Sys. Pharm., Supp. 1 (2015).

highly qualified providers like pharmacists beyond those listed in 1848(k)(3)(B) of the social security act ("SSA"). To ensure better inclusion and engagement of pharmacists in agency programs, services, and benefits, we urge CMS to implement the following recommendations:

I. GENERAL RECOMMENDATIONS: CMS should leverage pharmacists' expertise broadly under Medicare.

a. Use Inclusive Provider Language in Rulemakings, Programs, and Policies to Ensure Pharmacist Inclusion to Support Medication Optimization and Improve Patient Outcomes: The pharmacy profession continues to advocate for pharmacist provider status in all aspects of practice and payment. We urge CMS to examine and articulate the roles of highly qualified pharmacists in regulatory changes for specific Medicare services. Certain Medicare Part B services and care frameworks currently leverage pharmacists and pharmacist-provided patient care services, including: incident to physician services in a physician-based practice; incident to physician services in a hospital outpatient clinic; transitional care management ("TCM") as part of a team-based bundled payment; chronic care management ("CCM") as part of team-based bundled payment; annual wellness visits ("AWV"); DSMT and other services, including in various advanced alternative payment models ("APMs"). Rather than defaulting to the list of providers in section 1848(k)(3)(B) when delineating the clinicians that can provide Medicare services, we urge CMS to use more inclusive language. We recognize section 1848(k)(3)(B) can be "helpful shorthand" for the agency, but its use can and does result in the unintentional exclusion of pharmacists and other nonphysician practitioners from patient-care teams. For example, CMS recently used such discretion when the agency recognized use of the term "eligible professional" (as defined in section 1848(k)(3)(B) of the SSA in the Calendar Year ("CY") 2020 physician fee schedule ("PFS") proposed rule. The proposed rule unintentionally excluded pharmacists from the list of prescribing, ordering, or dispensing physicians and other eligible professionals for Opioid Treatment Programs ("OTPs"). CMS revised § 424.67(b)(1)(i) in the final PFS rule[6] to clearly include pharmacists on this list and recognized pharmacists' legal authority under their state scope of practice to help address our nation's opioid treatment crisis. However, this regulatory change came about as a result of the comment process. To avoid the regulatory headaches and confusion caused when section 1848(k)(3)(B) is used in situations when pharmacists can provide Medicare services, we urge CMS to use more inclusive language, expressly identifying pharmacists, during the initial drafting and promulgation of rules.

b. Issue a CMCS Information Bulletin Where Payers (e.g., Medicaid) Could Utilize Pharmacists to Better Address Needs for Patients: Our organizations greatly appreciate CMS' CMCS Services Information Bulletin released in January 2019 that addressed state flexibility to facilitate timely access to drug therapy (e.g.,

[6] CMS. Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Final Rule. 84 FR 62568. November 15, 2019, available at: https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other

naloxone for opioid overdose) by expanding the scope of pharmacy practice using collaborative practice agreements ("CPAs"), standing orders and other predetermined protocols.[7] While our members applauded the release of the informational bulletin, we encourage CMS to issue a similar informational bulletin highlighting opportunities where payers (e.g., Medicaid) could and should utilize pharmacists to better address needs for patients with other pharmacist-patient care services.

c. Attribute and Promote the Significant Contributions of Pharmacists to the Health Outcomes of Medicare Beneficiaries: We urge CMS to implement mechanisms to better monitor, measure and attribute the impact different providers, including pharmacists, have on the health outcomes of Medicare beneficiaries. Currently, pharmacists cannot bill for their Part B services nor is there a mechanism to assess how they are contributing to quality metrics in value-based payment models (e.g., Merit-based Incentive Payment System ("MIPS"), APMs). Pharmacists are not fully utilized by CMS under Part B, and while there have been well-intentioned efforts from CMS to allow providers to use pharmacists in team-based care and bundled payment models, CMS has few, if any, mechanisms to evaluate pharmacists' contributions under the current system. We suggest that CMS either require the inclusion of the pharmacist National Provider Identifier ("NPI") on all claims or add a pharmacist modifier to provide greater visibility into the scope and outcomes of the Medicare services pharmacists currently provide. CMS could also test such system in an CMMI model or pilot to better understand the contributions of pharmacists to team-based care and better health outcomes in Medicare beneficiaries.

   As previously mentioned, there are over 300,000 pharmacists in the U.S., many of whom are underutilized in their capacity to mitigate these unmet health care needs. As medications are becoming more complex and the population ages, optimizing patients' medications will be crucial under MIPS, Advanced APMs, and other Medicare programs. Therefore, recognizing the unique and essential contributions that pharmacists make on patient care teams is fundamental to sustaining new payment systems and models.

d. Expand Service Models Utilizing Pharmacist-Provided Patient Care Services Using CMS CMMI Data, Including in Value-Based Payment Models by Employing CCMI's Waiver Authority: We urge CMS to utilize data garnered from CMMI models in which pharmacists manage chronic diseases and medications and play an important role in comprehensive medication management and transitions of care, and use regulatory authority to provide coverage for pharmacists' services. We recommend that CMS expand tried and tested models such as the Comprehensive Primary Care Plus (CPC+) primary care model that integrates pharmacists with the care team to provide medication management services, that include evaluating medication regimens, providing

[7] CMS. CMCS Informational Bulletin. January 17, 2017, available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf,

medication self-management support for patients to help them adhere to their prescribed therapies, and promoting clinically-sound, cost-effective medication therapies. CMS previously utilized this authority to expand the Medicare Diabetes Prevention Program ("MDDP") model on the basis of evidence from 5,969 Medicare beneficiaries who participated in a CMMI model test of the program.[8]

e. Incorporate and/or Test an Alternative Model at CMMI in Rural and MUAs/Ps Focused on Optimizing Medication Use and Health Outcomes as Part of Coordinated Care Delivery Including Pharmacists: Currently, payment models that preclude participation from health care practitioners qualified to provide care have the unintended consequence of limiting access to care, including care in rural settings. Physicians and other health care practitioners are challenged to meet the growing demand for patient care services. According to the Association of American Medical Colleges ("AAMC"), the estimated shortage of physicians due to workforce aging, population growth and increased demand for health care services will range from 40,000 to 90,000 by 2025.[9] The effects of shortages will be exacerbated in rural communities which already struggle to meet patient needs.[10] 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 practitioners.[11] The American Medical Association ("AMA") has already developed modules for its members on embedding pharmacists into their practice and collaborating with pharmacists to improve patient outcomes.[12]

Leveraging pharmacists in rural health settings to provide patient-care services that are covered by Medicare Part B could also help prevent rural clinics and pharmacies from closing while providing care in underserved areas. Rural clinic and pharmacy closures also impact hospitals and other care settings, medication adherence, patient safety and leave significant gaps in care to important services such as administering vaccines.[13,14,15,16] Therefore, our organizations urge CMS to

[8] CDC. Medicare Diabetes Prevention Program (MDPP) Expanded Model. Last modified June 6, 2018, available at: https://nationaldppcsc.cdc.gov/s/article/Medicare-Diabetes-Prevention-Program-MDPP-Expanded-Model-Home-Page
[9] Association of American Medical Colleges, Physician Supply and Demand Through 2025: Key Findings. 2015, available at: https://www.aamc.org/download/450420/data/physiciansupplyanddemandthrough2025.pdf
[10] 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.
[11] 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, available at: https://www.ncbi.nlm.nih.gov/pubmed/24191075
[12] AMA. Embedding Pharmacists Into the Practice - Collaborate with pharmacists to improve patient outcomes. AMA Steps Forward. June 17, 2019, available at: https://edhub.ama-assn.org/steps-forward/module/2702554?resultClick=1&bypassSolrId=J_2702554
[13] Qato, D.M., Alexander, G.C., & Chakraborty, A. (2019). Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults, *Journal of the American Medical Association,* 2(4):e192606, available at: https://www.ncbi.nlm.nih.gov/pubmed/31002324
[14] Traynor, A.P., Sorenson, T.D. & Larson, T. (2011). The Main Street Pharmacy: Becoming an Endangered Species, *Rural Minnesota Journal,* 2(1), available at: https://www.ruralmn.org/wp-content/uploads/2011/03/The-Main-Street-Pharmacy.pdf
[15] Bartch, S.M., Taitel, M.S., DePasse, J.V., Cox, S.N., Smith-Ray, R.L., Wedlock, P., Singh, T.G., Carr, S., Siegmund, S.S. & Lee, B.Y. (2018). Epidemiologic and economic impact of pharmacies as vaccination location during an influenza epidemic, *Vaccine,* 34(46), 7054-7063, available at: https://www.ncbi.nlm.nih.gov/pubmed/30340884
[16] Rural Policy Research Institute & Rural Health Research & Policy Centers, (2017). Issues Confronting Rural Pharmacies after a Decade of Medicare Part D, available at: https://rupri.public-health.uiowa.edu/publications/policybriefs/2017/Issues%20confronting%20rural%20pharmacies.pdf

carefully consider how pharmacists across all practice settings can be included in different aspects of Medicare in the interest of patient care and sustainability of the program. We recommend that the agency test this model as well as any proven pharmacist-provided patient care services based on evidence (cost savings, improved health outcomes) to beneficiaries residing in all Medically Underserved Areas/ Populations ("MUAs/Ps").

f. Ensure Pharmacists Can Engage in Remote Patient Monitoring and Other Telehealth Services: Our organizations support technology developments that will help increase access to care, better connect patients to health care providers, and improve the flow of information 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.

We applaud CMS' recent decision regarding the general supervision requirement for remote physiological monitoring services when provided "incident to" a physician and support use of remote patient monitoring as one mechanism to improve care and expand access.[17] We recommend that CMS identify other telehealth services that could benefit from pharmacists' expertise and provide regulatory authority for them to be delivered by pharmacists under general supervision. For example, we strongly advocate that CMS permit pharmacists and other providers whose scope of practice allows them to provide CGM interpretation services for diabetes patients under general supervision (preferably) or direct supervision.

II. SPECIFIC RECOMMENDATIONS: CMS should implement supervision, service, billing, and coding requirements that allow pharmacists to practice at the top of their license.

Supervision

a. Implement a General Supervision Requirement vs. Direct Supervision for Services Delivered by Highly Trained Pharmacists: Currently, the only mechanism for pharmacists' patient care services to be financially covered in the Medicare program is for physicians and other qualified practitioners to bill for them and for supervisory relationships to be in place. We urge CMS to implement a general supervision requirement for services delivered by highly trained pharmacists that would provide increased flexibility and expand beneficiary access to coordinated care. Similar to the change CMS implemented in the CY 2020 Hospital Outpatient Prospective Payment final rule,[18] we request CMS include language in the 2021 final PFS rule to add a provision at 42 CFR

[17] CMS. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; etc.; Correction. March 15, 2019, available at: https://www.regulations.gov/document?D=CMS-2018-0076-15377

[18] CMS amendeded § 410.27(a)(1)(iv) to provide that the default minimum level of supervision for each hospital outpatient therapeutic service is "general." CMS. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. Final Rule. 84 FR 61142. November 12, 2019, available at: https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center

410.32(b)(3) expressly clarifying and identifying the specific services to be provided by pharmacists under general supervision.

- E/M services under "incident to" arrangements between pharmacists and physicians, and AWVs could be delivered using general supervision.[19] Pharmacists working in collaborative arrangements with physicians could expand access to care by providing E/M services under general supervision as they are currently doing for CCM and TCM services.

  For AWVs, non-physicians must legally be authorized and qualified to provide them in the state in which the services are furnished. In 2014, only 15.6% of eligible patients across the nation took advantage of their covered AWV.[20] In medical practices in which few physicians have the time to reach most of their Medicare Part B–eligible patients, a pharmacist will not only help in this task but can also add value through this collaborative effort between the two health care professions. Patients receiving an AWV from a pharmacist have the added benefit of receiving a comprehensive medication review. An AWV with a pharmacist can have a significant impact on patient outcomes. Recent studies have found the composite of interventions and screenings was significantly higher in a pharmacist managed AWV group than a physician managed AWV group and that pharmacist-provided AWVs are at least comparable to those provided by physicians and offer an additional access point for valuable services for Medicare beneficiaries.[21]

- Tobacco cessation counseling by pharmacists could be delivered under general supervision. Medicare Part B covers two levels of tobacco cessation counseling for symptomatic and asymptomatic patients: intermediate (greater than 3 minutes but no more than 10 minutes) and intensive (greater than 10 minutes). To qualify for Medicare payment, the following criteria must be met at the time of service: patients must be competent and alert at the time of the counseling is provided and counseling must be provided by a physician or other Medicare-recognized health care professional. In the CMS Decision Memo for Smoking & Tobacco Use Cessation Counseling (CAG-00241N), CMS states "[l]ocal Medicare contractors currently have discretion to cover these services when they determine them to be medically necessary for the individual patient. The benefit categories for smoking cessation counseling are the following… Section 1861(s)(2)(A) Service furnished as an incident to a

[19] Alhossan A, Kennedy A, Leal S. Outcomes of annual wellness visits provided by pharmacists in an accountable care organization associated with a federally qualified health center. Am J Health Syst Pharm. 2016:73(4):225-228. doi: 10.2146/ajhp150343, available at: https://www.ncbi.nlm.nih.gov/pubmed/26843499 (Finding during a 3-month study evaluating 300 patient records, clinical pharmacists completed an average of 5.4 interventions, made 272 referrals, ordered 183 diabetes and lipid screenings, offered 370 vaccinations, and made 24 medication and dosage changes during the AWV).

[20] Ganguli, Ishani. Et. al. Trends in Use of the US Medicare Annual Wellness Visit, 2011-2014. AMA. 2017;317(21):2233-2235. doi:10.1001/jama.2017.4342, available at: https://jamanetwork.com/journals/jama/fullarticle/2622010

[21] Sewell, Mary Jean. Et. al. Comparison of Pharmacist and Physician Managed Annual Medicare Wellness Services. J Manag Care Spec Pharm. 2016;22(12):1412-16, available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.12.1412

physician's professional service."[22] Accordingly, pharmacists offering tobacco cessation counseling to Medicare beneficiaries must currently do so under a direct supervision requirement. A systematic review of tobacco interventions by pharmacists demonstrated that pharmacists can deliver smoking-cessation services and suggested they are effective in helping patients successfully quit.[23] Pharmacists who provide smoking-cessation services have cessation rates similar to those of other health care professionals.[24] Thus, we recommend CMS permit pharmacists to provide tobacco cessation services to Medicare beneficiaries under general supervision.

- We request that CMS consider additional Medicare services where a general supervision requirement could be utilized for pharmacist services to expand access to care.

Service Requirements Under State Scope of Practice

b. Align Medicare Service Requirements with the Most Robust Pharmacist State Scopes of Practice: CMS should ensure that pharmacists can fully engage in the provision of other Medicare services where pharmacists' scope of practice and increased uptake in the state and private sector are increasing access to care and helping to address public health needs (e.g., opioid risk assessment, opioid antagonist training, telehealth services, tobacco cessation services, oral contraceptive services, pre-exposure prophylaxis for risk of HIV, etc.). CMS recently granted increased flexibility to physician supervision for other non-physician practitioners—physician assistants ("PAs") and PA services in the CY 2020 final PFS rule.[25] In many states, pharmacists as part of health care teams function very similarly to practitioners ("NPs") and PAs, resulting in robust state scopes of practice that may include initiating, modifying, and discontinuing certain medications and ordering laboratory tests under the parameters of a CPA and as delegated by the physician.[26]

When pharmacists partner with physicians and other health care professionals they streamline and improve outcomes, but regulations and policies that lag-behind state scope of practice laws add extra barriers that limit patient access to care. When state laws and regulations expand, it is important that federal regulations adapt to allow health care practitioners to contribute fully to patient

[22] CMS. Decision Memo for Smoking & Tobacco Use Cessation Counseling (CAG-00241N). March 22, 2005, available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=130&NcaName=Smoking+&+Tobacco+Use+Cessation+Counseling&DocID=CAG-00241N&fromdb=true
[23] Dent LA, Harris KJ, Noonan CW. Tobacco interventions delivered by pharmacists: a summary and systematic review. Pharmacotherapy. 2007;27:1040-105, available at: https://www.ncbi.nlm.nih.gov/pubmed/17594210
[24] Shen X, Bachyrycz A, Anderson JR, et al. Quitting patterns and predictors of success among participants in a tobacco cessation program provided by pharmacists in New Mexico. J Manag Care Spec Pharm. 2014;20:579-587, available at: https://www.ncbi.nlm.nih.gov/pubmed/24856596
[25] CMS. Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Final Rule. 84 FR 62568. November 15, 2019, available at: https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other
[26] NASPA. Scope of Practice Resources. 2019, available at: https://naspa.us/restopic/scope/

care. Lack of CMS coverage of pharmacist-provided care services, rigid supervision requirements and unclear coverage policies for incident to services create unnecessary layers of complexity for health care providers and patients. As explained below, pharmacists have prescribing authority in most states, and are trained to perform assessments and monitor and manage medications and diseases.

- *CPAs*: Currently, forty-nine (49) states and the District of Columbia grant pharmacists the ability to practice collaboratively in some capacity with other prescribers to perform functions such as assessments, initiate, adjust, or discontinue medications, and order and interpret laboratory tests.[27] It is important to note that CPAs provide an expanded scope of practice for pharmacists and are not tied to supervision requirements.

- *Pharmacist Prescribing*: Forty-three (43) states now permit pharmacist prescribing as part of CPAs. In addition, pharmacist scope of practice has expanded by states authorizing pharmacists to prescribe medications via statewide protocols and other mechanisms. Pharmacists are addressing unmet patient needs by performing assessments and prescribing medications(s) for minor ailments or public health needs. Our organizations believe the ability to perform an assessment and initiate a medication in an outpatient setting is a prerequisite to leveraging pharmacist prescriptive authority to meet health care needs in a scalable manner. Depending on the state, patients can access medications commonly authorized under statewide protocols or other mechanisms, such as naloxone for opioid overdose reversal, oral contraceptives, tobacco cessation medications, and travel medications.

- *Pharmacist Prescribing Based on the Results of a Rapid Diagnostic Test*: There has been a growing interest in pharmacist prescribing based on an assessment, including the results of a rapid diagnostic test, such as for strep throat or influenza. For example, Idaho pharmacists are allowed to independently prescribe products to treat strep/flu pursuant to a rapid diagnostic test and using an evidence-based protocol. Beyond statewide authority, many other states have CPA authority broad enough to allow pharmacists to prescribe pursuant to a rapid diagnostic test. Overall, 17 states would be able to implement a test-and-treat program in some capacity.[28]

  Under Medicare, a pharmacy may possess a Clinical Laboratory Improvement Amendments ("CLIA") Certificate of Waiver so that they may expand patient access to CLIA-waived tests and improve public health. For example, patients may come to a pharmacy that has a

[27] *See* Centers for Disease Control and Prevention (2017), *Advancing Team-Based Care Through Collaborative Practice Agreements*, available at: https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf

[28] NASPA. Pharmacist Prescribing: "Test and Treat," February 8, 2019, available at: https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/

Certificate of Waiver and ask to obtain a CLIA-waived point-of-care ("POC") test for an infectious disease. One recent study involved pharmacists in three states, where pharmacists in waivered pharmacies worked with a physician under a CPA to help identify patients for an influenza POC test and subsequent identification and management of patients who tested positive for influenza.[29] This model improves identification of patients with infectious conditions earlier, particularly for patients without a primary care provider or who are screened outside of regular clinic office hours. However, the ability to recoup both the costs associated with the CLIA-waived test and the pharmacist's time is a significant barrier to uptake of this model.[30]

- *Naloxone*: In regard to opioids, to help ensure that naloxone is on hand for life-threatening emergencies, all 50 states authorize pharmacists furnish naloxone under statewide protocols and other mechanisms.[31] The Centers for Disease Control ("CDC") has acknowledged the ability for pharmacists to initiate or prescribe naloxone has contributed to significant reductions[32] in fatal overdoses (deaths) and also lives saved in emergency department visits.[33]

- *Tobacco Cessation Medications*: We recommend that Medicare recognize and reimburse tobacco cessation services provided by pharmacists at a level commensurate with innovative state models. Further, as noted above, CMS should allow these services to be provided under general, rather than direct supervision. Currently, there are 12 states with statutes or regulations for pharmacist prescribing of smoking cessation medications, including Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Maine, Missouri, New Mexico, Oregon, and West Virginia.[34]

- *Hormonal Contraception:* While we recognize that there is likely to be limited utilization of hormonal contraception by Medicare beneficiaries (other than dual-eligibles), we recommend that Medicare regulations align with state laws that allow pharmacist prescribing of these drugs. Currently, there are 10 U.S. jurisdictions with statutes or regulations that allow pharmacists to prescribe contraceptives under statewide protocols or other mechanisms (without a CPA): California, Colorado, District of Columbia,

[29] ME Klepser, et al. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. J Am Pharm Assoc. 2016; 56:14-21, available at: https://www.ncbi.nlm.nih.gov/pubmed/26802915
[30] *See,* Burley, E., Klepser, S. & Klepser, M. (2014). Opportunities for Pharmacists to Improve Access to Primary Care Through the Use of CLIA-waived tests. *Michigan Pharmacists Association,* 52(2), available at: https://www.michiganpharmacists.org/Portals/0/resources/poctesting/poctesting0414.pdf, last accessed, December 27, 2019.
[31] NASPA. Pharmacist Prescribing: Naloxone. Updated January 17, 2019, available at: https://naspa.us/resource/naloxone-access-community-pharmacies/
[32] CDC. Life-Saving Naloxone from Pharmacies. More dispensing needed despite progress. Last reviewed: August 6, 2019, available at: https://www.cdc.gov/vitalsigns/naloxone/index.html
[33] Abouk, Rahi. Et. al. Association Between State Laws Facilitating Pharmacy Distribution of Naloxone and Risk of Fatal Overdose. JAMA Intern Med. 2019;179(6):805-811. May 6, 2019, available at: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2732118
[34] NASPA. Pharmacist Prescribing: Tobacco Cessation Aids. November 22, 2019, available at: https://naspa.us/resource/tobacco-cessation/

Hawaii, Idaho, Maryland, New Mexico, Oregon, Utah, and West Virginia.[35]

- *Pharmacogenomics*: As pharmacogenomics becomes increasingly integral to patient care,[36] CMS must ensure that Medicare regulation of the practice recognizes and integrates pharmacists. Similar to rapid diagnostic testing, allowing pharmacists to manage medication therapy, including pharmacogenomics elements, frees up physicians to spend additional time with patients and reducing burden on overtaxed providers.

In order to avoid barriers to access or hindrances to innovative care delivery models, we urge the agency to align its pharmacist supervision and services requirements with the most robust state scopes of practice. When considering eligibility and coverage for patient care services, CMS should proactively consider how its regulations and subregulatory guidance match up to state scope of practice laws for pharmacists and other practitioners.

Billing & Coding: E/M Clarification Needed

c. Clarify Physicians and Other Qualified Practitioners Can Bill for "Incident to" Services Provided to Medicare Beneficiaries by Pharmacists at Levels Higher than E/M Code 99211: We recommend CMS clarify that physicians and other practitioners can bill for "incident to" services provided to Medicare beneficiaries by pharmacists at levels higher than E/M code 99211. There are several barriers to billing and coding for pharmacists' incident to services that CMS can help overcome. First, there are competing interpretations of whether pharmacists can bill for services using 99212-15. In 2014, the American Academy of Family Physicians ("AAFP") petitioned CMS for clarification on whether a physician may bill for services provided by a pharmacist as "incident to" services.[37] CMS responded stating that, "if all the requirements of the "incident to" statute and regulations are met, a physician may bill for services provided by a pharmacist as "incident to" services."[38] Subsequent communication from CMS later in 2014 confirmed this interpretation of "incident to" billing provisions. The matter is further confused in states that consider pharmacists providers. In Washington, for example, pharmacists are recognized as providers by those commercial health plans under the State's purview and they bill under the full range of CPT codes (99211-99215).[39] Nevertheless, at the national level, they may encounter barriers to physicians billing the same codes for the same services under incident to arrangements. Despite the aforementioned CMS statements on this issue, we

[35] NASPA. Pharmacist Prescribing: Hormonal Contraceptives. May 24, 2019, available at: https://naspa.us/resource/contraceptives/
[36] Sandler, Sierra. Et. al. The importance of preventative medicine in conjunction with modern day genetic studies. Genes Dis. 2018 Jun; 5(2): 107–111, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6146230/#bib15
[37] American Academy of Family Physicians letter to Centers for Medicare & Medicaid Services, (Jan 2014), available at: https://www.accp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf
[38] Centers for Medicare & Medicaid Services response to American Academy of Family Physicians, (March 2014), available at: https://www.accp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf
[39] Roshon, Jeff. Credentialing and Privileging 101: Essential Steps to Bill for Patient Care Services. Slide 61. Presentation at APhA2018. March 28, 2018, available at: http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf

continue to receive reports of difficulties associated with "incident to" billing of E/M services when provided by pharmacists.

Our organizations are concerned these issues stem from a lack of awareness of the clarification CMS provided in 2014. Despite CMS' statements on pharmacist "incident to" billing, Medicare Administrative Contractors ("MACs") have provided differing interpretations of permissible billing practices. Thus, at the institutional leadership level, there is reluctance from billing and coding departments and legal counsel to permit billing for these services. Despite the fact that the complexity of most services delivered by pharmacists meets the requirements for physicians to bill at higher levels (E/M codes 99212-215), physicians are often discouraged from billing for pharmacists' services at a level above E/M code 99211 due to concerns of a CMS audit. Absent CMS clarification, this issue is unlikely to change. We have also received reports of reluctance to use higher level E/M billing codes from pharmacists working in value-based models that have a fee-for-service component. This continued uncertainty is a detriment to team-based care. Given pharmacists' ability to reduce the $528 billion spent annually on medication-related issues,[40] it is critical that pharmacists are fully and effectively engaged as part of patient care teams.

Second, the CY 2020 final PFS rule included the intent to adopt in 2021 the AMA's revisions to the E/M office visit CPT® codes (99201-99215) code descriptors and documentation standards.[41] While our organizations support CMS' intent to streamline documentation and billing for E/M services, we have significant concerns that the terminology in the AMA revision could restrict physician incident to billing for pharmacists' complex E/M services to CPT code 99211. AMA's Current Procedural Terminology ("CPT") definitions, do not expressly state/ confirm that pharmacists are "other qualified health care professionals," as used for coding purposes. AMA's CPT codebook's definition states:

> "A "physician or other qualified health care professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service."[42]

[40] 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

[41] AMA. CPT® Evaluation and Management (E/M) Office or Other Outpatient (99202-99215) and Prolonged Services (99354, 99355, 99356, 99XXX) Code and Guideline Changes. 2019, available at: https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf

[42] AMA. Instructions for Use of the CPT Codebook. November 18, 2019, available at: https://bioportal.bioontology.org/ontologies/CPT?p=classes&conceptid=1022195

Other policies may also affect who may report specific services. AMA's CPT codebook also states "[t]hroughout the CPT code set the use of terms "physician," "qualified health care professional, or "individual" is not intended to indicate that other entities may not report the service.[43]

We request that CMS expressly clarify in the EO regulation that "incident to" services provided by a pharmacist currently can be billed at E/M codes 92212-15 commensurate with the services delivered. Related to the upcoming E/M changes in 2021, pharmacists cannot currently individually report services in Medicare, and therefore are considered clinical staff. CMS could use regulatory authority to implement an individual reporting mechanism for pharmacist services such as those described in section I.c. of this letter to clarify that pharmacists' services can be billed at levels higher than 99211 in 2021 and beyond. We recommend that the clarification be discussed in the regulation CMS prepares pursuant to the EO. CMS could also further communicate this in other public vehicles (e.g., MLN Matters) or in a prominent location on the CMS website. Our organizations can facilitate distribution of the clarification to our members and provide technical assistance on this issue. Clarifying this issue will help reduce the burden on health care practitioners who are unable to utilize pharmacists for more complex patient care needs.

Our organizations urge CMS to look at Washington state in clarifying billing for E/M levels. Under Washington State law, pharmacists are recognized as providers by those commercial health plans under the State's purview. As previously mentioned, Washington pharmacists have billed and been paid for E/M services using the full range of applicable CPT codes (99211-99215) appropriate for the type of service provided.[44]

DSMT and CGM Clarification Needed

d. Address Challenges for Pharmacists and Pharmacies to Deliver DSMT and CGM Services: Our organizations appreciated CMS' recognition of pharmacists as instructors "who actually furnish DSMT services…," in the CY 2017 PFS proposed rule.[45] However, as CMS then stated, pharmacists "do not qualify to enroll in Medicare as certified providers, as that term is defined at section 1861(qq)(2)(A) of the [Social Security] Act, and codified in our regulations at §410.140 as approved entit(ies)." Yet, §1861(qq)(2)(A) states that DSMT services can be provided by "certified providers," which include "individual[s]" who meets "quality standards established by the Secretary…" "...for furnishing these services." While pharmacists and their services are not listed under §1861 and

[43] AMA. Instructions for Use of the CPT Codebook. November 18, 2019, available at: https://bioportal.bioontology.org/ontologies/CPT?p=classes&conceptid=1022195
[44] Roshan, Jeff. Credentialing and Privileging 101: Essential Steps to Bill for Patient Care Services. Slide 61. Presentation at APhA2018. March 28, 2018, available at: http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf
[45] CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. 82 FR 33950. July 15, 2016, available at: https://www.federalregister.gov/documents/2016/07/15/2016-16097/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

therefore, are not eligible to directly bill for DSMT services, accredited pharmacies are able to provide such services upon meeting certain requirements.

Our members continue to experience barriers to providing DSMT services due to lack of awareness that accredited pharmacies can bill for DSMT services and that pharmacists are recognized DSMT instructors. For example, it took one community pharmacy 9 months to receive an NPI to bill for DSMT services primarily because of MAC assertions that a pharmacy should only be requesting an NPI for Part D services. In addition, our members have had claims rejected when submitting bills from a DSMT accredited pharmacy because a pharmacist signed the billing paperwork and not a Part B DSMT certified provider.[46] Policies that allow a pharmacist to be an instructor for an accredited DSMT pharmacy, but not sign the bills for DSMT services is illogical and inconsistent with CMS' policies and aim to make such services more accessible to patients. In many cases, the pharmacist is the most accessible health care provider in a community and may be the sole instructor for DSMT. Furthermore, when pharmacists inquire about DSMT billing problems to CMS or MACs, staff are not often aware of pharmacists' and pharmacies' roles in DSMT. This was not clarified in the CY 2017 final PFS rule or subsequent rules. Accordingly, our organizations request that CMS clarify that pharmacists and pharmacies can provide DSMT services. We also ask CMS provide education and training materials for staff and in information for patients and other stakeholders about the program and its benefits. This acknowledgement and awareness will address concerns expressed in the CY 2017 PFS proposed rule, that "claims have been rejected or denied because of confusion about the credentials of the individuals who furnish DSMT services," and will help address the "issues that may contribute to the low utilization of these services." We also ask CMS to clarify that a DSMT accredited pharmacy can bill for services without sign-off from a Part B DSMT accredited provider—a position reinforced by the fact that CMS and national accreditation organizations ("NAOs") allow pharmacists to be DSMT certified instructors.

Similarly, we also strongly recommend that CMS clarify in the Medicare Benefit Policy Manual, Chapter 15, Section 300[47] that DSMT services are already permitted at pharmacies that meet CMS' and NAOs' requirements.[48] Moreover, to truly maintain the viability of DSMT programs, we urge CMS to update the outdated terminology and design of the benefit. Our organizations also recommend CMS adopt the updated terminology defined in the 2016 Standards of Medical Care in Diabetes, "diabetes self-management education and support" or "DSME/S." This terminology reflects the continuous support that diabetes patients need in managing their chronic condition as patients may require

[46] *See* §1848(k)(3)(B) and 1842(b)(18)(C). Available at: https://www.ssa.gov/OP_Home/ssact/title18/1848.htm
[47] *See* CMS. Medicare Policy Benefit Manual. Section 300. May 13, 2016, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
[48] In accordance with § 410.144, a CMS-approved NAO may accredit an individual, physician or entity to meet one of three sets of DSMT quality standards: CMS quality standards; the National Standards for Diabetes Self-Management Education Programs (National Standards); or the standards of an NAO that represents individuals with diabetes that meet or exceed our quality standards. Currently, CMS recognizes the American Diabetes Association and the American Association of Diabetes Educators as approved NAOs, both of whom follow National Standards. Medicare payment for outpatient DSMT services is made in accordance with §414.63.

intensified re-education and self-management planning and support that often go beyond the current DSMT benefit. In addition, CMS should also consider allowing additional hours of DSMT for beneficiaries, similar to the Medical Nutrition Therapy ("MNT") benefit, during the four critical times[49] identified in the Joint Position Statement of the American Association of Diabetes Educators ("AADE"), the American Diabetes Association ("ADA") and the Academy of Nutrition and Dietetics ("AND").[50] Investing in a more robust service for certain high-risk diabetes patients can help improve their quality of life and health outcomes, and prevent high-cost services and procedures.

As stated in Section I.f. of this letter, we urge CMS to expand access to needed diabetes services, specifically by covering CGM that is delivered by pharmacists and other qualified practitioners under direct or general (preferable) supervision.

Prior Authorization Relief

e. Allow Pharmacist Initiated Electronic Prior Authorization: In an effort to properly update e-prescribing standards to reduce provider burden and expedite access to needed medications, we strongly urge CMS modify its proposed rule to allow pharmacists to submit prior authorization requests. As National Council for Prescription Drug Programs ("NCPDP") SCRIPT has already established precedence for including pharmacist initiated prior authorizations, we specifically request CMS recognize pharmacists as eligible individuals who may request an initial determination for Part D enrollees. CMS can take this action by expanding section 40.6 to include the pharmacist under the "Medicare Program; Secure Electronic Prior Authorization for Medicare Part D," a proposed rule that would adopt the NCPDP SCRIPT Standard for electronic Prior Authorization ("ePA") Transactions.[51]

Our organizations support the agency's proposal to select the NCPDP SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017, as the ePA standard for the Medicare Part D program beginning January 1, 2021. NCPDP Script standards support pharmacists initiating/requesting ePAs, due to the requirements for prescriber, provider, and pharmacy information to be included on an initial determination request.

Despite our organizations' support, section 40.6 (Who May Request an Initial Determination) of that same guidance defines who may make a Part D standard or expedited initial determination request, which unintentionally excludes

[49] The Joint Statement identified for critical times for allowing additional hours of DSMT: 1. New diagnosis of type 2 diabetes; 2. Annually for health maintenance and prevention of complications; 3. When new complicating factors influence self-management; and 4. When transitions in care occur.

[50] Powers, Margaret. Et. al. A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Self-management Education and Support in Type 2 Diabetes. 2015, available at: https://www.diabeteseducator.org/docs/default-source/practice/practice-resources/position-statements/dsme_joint_position_statement_2015.pdf?sfvrsn=0

[51] CMS. Medicare Program; Secure Electronic Prior Authorization for Medicare Part D. Proposed Rule. 84 FR 2845. June 19, 2019, available at: https://www.federalregister.gov/documents/2019/06/19/2019-13028/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d

pharmacists due to certain terminology, such as the "enrollee's prescribing physician or other prescriber," or the "Staff of said prescriber's office acting on said prescriber's behalf (e.g., request is on said prescriber's letterhead or comes from the prescriber office fax machine)."

CMS should work with other HHS operating divisions to ensure that pharmacists are fully and effectively engaged in combatting the opioid crisis[52]

f. Allow Pharmacists to be DATA-Waived Providers: To further expand access to treatment, we urge the HHS 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 be able to provide medication-assisted treatment ("MAT") services, in addition to physicians, nurse practitioners, physician assistants, and others. The law states "[t]he Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause."[53] We believe that utilizing pharmacists' expertise in the provision of MAT is an important step toward the Administration's goal of "tackl[ing] the scourge of the opioid epidemic that is destroying so many individuals, families, and communities." Our organizations view MAT as an important component of a multipronged approach to addressing substance use disorder and improving treatment. We support efforts to expand access to MAT, such as increasing DATA-waivered physician's prescribing caps and allowing additional practitioners to obtain a DATA waiver. Allowing pharmacists to be data-waived providers for buprenorphine is also consistent with intent of the Administration's deregulatory efforts due to the hindrance that federal, as opposed to state, regulations have on pharmacists' ability to improve care by preventing them from increasing patient access to needed treatment in each state.

At present, the exclusion of pharmacists from DATA waiver eligibility has robbed patients of care access at a time when demand for care far outstrips capacity. Furthermore, failure to utilize pharmacists' medication knowledge and training has led to significant results. For instance, as noted above, despite the fact that all 50 states authorize pharmacists to dispense naloxone under statewide protocols, resulting in a significant reduction[54]of fatal overdoses (deaths) and a corresponding increase in nonfatal overdoses (lives saved),[55] pharmacists cannot fully and effectively engage in MAT treatment.

Pharmacists, as the medication expert on the care team, have more medication-related training than any other clinician. Pharmacist involvement in MAT for

[52] See, Appendix I. (below) which our organizations provide as an example of how CMS could implement regulations that incorporate pharmacist-provided patient care services (opioid risk assessment; opioid antagonist counseling and opioid risk factor reduction intervention) under an equivalent process to all other health care providers under Medicare Part B.
[53] P.L. 114-198, available at: https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf. Sec. 303.
[54] CDC. Life-Saving Naloxone from Pharmacies. More dispensing needed despite progress. Last reviewed: August 6, 2019, available at: https://www.cdc.gov/vitalsigns/naloxone/index.html
[55] Abouk, Rahi. Et. al. Association Between State Laws Facilitating Pharmacy Distribution of Naloxone and Risk of Fatal Overdose. JAMA Intern Med. 2019;179(6):805-811. May 6, 2019, available at: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2732118

opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.[56,57] As mentioned above, there are currently 49 states along with the District of Columbia that allow pharmacists to enter into CPAs,[58] with physicians and other prescribers to provide advanced care to patients, which may include components of MAT. In addition, according to the Drug Enforcement Agency ("DEA"), pharmacists are mid-level practitioners like PAs and NPs, and states[59] may allow pharmacists to prescribe Schedule II-V controlled substances under a CPA.[60] Consequently, 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 federal laws and regulations do not allow their eligibility for a DATA waiver.

When pharmacists partner with physicians and other health care professionals to provide MAT, they streamline and improve care. For example, due to innovations like the expanded use of psychiatric pharmacists, Alameda county in California saw the following improvements over two years (2015-2017): 44% decrease in mortality rate; 16% increase in MAT, 16% decrease in inappropriate opioid prescribing.[61] Pharmacists' responsibilities for MAT and substance use disorder ("SUD") treatment may include treatment plan development, patient communication, care coordination, adherence monitoring and improvement activities, among others. A DATA-waived pharmacist working under a CPA in a state that permits prescribing of controlled substances would also be able to initiate buprenorphine and make dosage adjustments, which would greatly increase access to MAT and address treatment gaps.

CONCLUSION

Thank you for the opportunity to provide feedback to CMS regarding barriers to allow pharmacists to practice at the top of their license/ profession. If you have any questions or require additional information, each organization's contact person is below. We look forward to working with CMS to reduce regulatory burdens that inhibit patient access and limit care quality.

Sincerely,

Michael Baxter, Director, Regulatory Affairs
mbaxter@aphanet.org (202) 429-7538
American Pharmacists Association (APhA)

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[56] DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, Journal of the American Pharmacists Association, 55(2), 187-192, available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

[57] Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy,* 36(2), 312-321.

[58] *See* Centers for Disease Control and Prevention (2017), *Advancing Team-Based Care Through Collaborative Practice Agreements,* available at: https://www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf

[59] States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, North Carolina, Ohio, and Washington.

[60] *See* Drug Enforcement Agency, Mid-Level Practitioners Authorization by State, available at: https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

[61] CPNP. Psychiatric Pharmacists: combating the opioid crisis through medication-assisted treatment. Last accessed: January 15, 2020, available at: https://cpnp.org/psychpharm/profile?view=link-0-1471880668&.pdf

Jillanne Schulte Wall, J.D., Senior Director, Health and Regulatory Policy
jschulte@ashp.org (301) 664-8696
American Society of Health-System Pharmacists (ASHP)

Allie Jo Shipman, Pharm.D., MBA, Director, State Policy
ajshipman@naspa.us (803) 257-1818
National Alliance of State Pharmacy Association (NASPA)

Veronica Charles, MPA, Manager, Government Affairs
vcharles@ascp.com (703) 739-1318
American Society of Consultant Pharmacists (ASCP)

Ronna Hauser, Pharm.D. Vice President, Policy and Regulatory Affairs
ronna.hauser@ncpanet.org (703) 838-2691
National Community Pharmacists Association (NCPA)

Jasey Cárdenas, Associate Director of Strategic Engagement
jcardenas@aacp.org (703) 739-2330 x1037
American Association of Colleges of Pharmacy (AACP)

Brenda Schimenti, Executive Director
bschimenti@cpnp.org (402) 476-1677
College of Psychiatric and Neurologic Pharmacists (CPNP)

Phil Bongiorno, Vice President, Policy and Government Relations
pbongiorno@amcp.org (703) 684-2603
Academy of Managed Care Pharmacy (AMCP)

Don L. Bell, II, J.D., Senior Vice President, Health Policy & General Counsel
dbell@nacds.org (703) 837-4231
National Association of Chain Drug Stores (NACDS)

State Associations and Affiliates:

Louise Jones
ljones@aparx.org
Alabama Pharmacy Association

Thomas H. Cobb
Thomas.Cobb@jackson.org
Alabama Society of Health System Pharmacists

Molly Gray
akphrmcy@alaska.net
Alaska Pharmacists Association

Kelly Fine
kelly@azpharmacy.org
Arizona Pharmacy Association

John Vinson, PharmD
john@arrx.org
Arkansas Pharmacists Association

Erin Beth Hays
ebhays@wrmc.com
Arkansas Association of Health-System Pharmacists

Michelle Rivas
mrivas@cpha.com
California Pharmacists Association

Loriann De Martini
ldemartini@cshp.org
California Society of Health System Pharmacists

Emily Zadvorny
emily.zadvorny@cuanschutz.edu
Colorado Pharmacist Society

Nathan Tinker
ntinker@ctpharmacists.org
Connecticut Pharmacists Association

Sherri Oken
office@cshponline.org
Connecticut Society of Health System Pharmacists

Kim Robbins
rxistkim@gmail.com
Delaware Pharmacists Society

Michael Jackson
jackson@pharmview.com
Florida Pharmacy Association

Tamekia Bennett
Tamekia@fshp.org
Florida Society of Health-System Pharmacists

Bob Coleman
bcoleman@gpha.org
Georgia Pharmacy Association

Steve Glass
sglass@gshp.org
Georgia Society of Health-System Pharmacists

Marcella Chock
msetochock@gmail.com
Hawaii Pharmacists Association

Pam Eaton
ispa@idahopharmacists.com
Idaho State Pharmacy Association

Chris Oswald
pharmeroswald@gmail.com
Idaho Society of Health-System Pharmacists

Garth K. Reynolds
greynolds@ipha.org
Illinois Pharmacists Association

Scott A. Meyers
scottm@ichpnet.org
Illinois Council of Health-System Pharmacists

Randy Hitchens
randy@indianapharmacists.org
Indiana Pharmacists Alliance

Kate Gainer
kgainer@iarx.org
Iowa Pharmacy Association

Aaron Dunkel
aaron@ksrx.org
Kansas Pharmacists Association

Joe D. Slechta
joe.slechta@hcahealthcare.com
Kansas Council of Health-System Pharmacy

Mark Glasper
mglasper@kphanet.org
Kentucky Pharmacists Association

Josh Elder
president@kshp.org
Kentucky Society of Health-System Pharmacists

Kisha Gant
Kisha.Gant@gmail.com
Louisiana Society of Health-System Pharmacists

Amy Downing
amy@mainepharmacy.org
Maine Pharmacy Association

Aliyah Horton
Aliyah.horton@mdpha.com
Maryland Pharmacists Association

Stacy Elder Dalpoas
selder5@jhmi.edu
Maryland Society of Health-System Pharmacy

Lindsay DeSantis
ldesantis@masspharmacists.org
Massachusetts Pharmacists Association

Nicole Clark
nclark@melrosewakefield.org
Massachusetts Society of Health System Pharmacists

Larry Wagenknecht
larry@michiganpharmacists.org
Michigan Pharmacists Association
Curtis Smith
CurtisSmith@ferris.edu
Michigan Society of Health-system Pharmacists

Sarah Derr
sarahd@mpha.org
Minnesota Pharmacists Association

Brandon Ordway
bordway1@fairview.org
Minnesota Society of Health-System Pharmacists

Brynna Clark
brynna@mspharm.org
Mississippi Pharmacists Association

Anees Kanorwala
aneeskanor@gmail.com
Mississippi Society of Health-System Pharmacists

Ron Fitzwater
ron@morx.com
Missouri Pharmacy Association

Stuart Doggett
stuart@montana.com
Montana Pharmacy Association

Joni Cover
joni@npharm.org
Nebraska Pharmacists Association

Bob Stout
rjstoutrph@comcast.net
New Hampshire Pharmacists Association

Elise M. Barry
ebarry@njpharma.org
New Jersey Pharmacists Association

R. Dale Tinker
dtinker@nmpharmacy.org
New Mexico Pharmacists Association

Christopher Gallegos
Executivedirector@nmshp.org
New Mexico Society of Health-System Pharmacists

Shaun Flynn
sflynn@nyschp.org
New York State Council of Health-system Pharmacists

Penny Shelton
penny@ncpharmacists.org
North Carolina Association of Pharmacists

Michael Schwab
mschwab@nodakpharmacy.net
North Dakota Pharmacists Association

Ernest Boyd
eboyd@ohiopharmacists.org
Ohio Pharmacists Association

Robert M. Parsons
bobparsons@aol.com
Ohio Society of Health-System Pharmacists

Debra Billingsley
dbillingsley@opha.com
Oklahoma Pharmacists Association

Adrian Irwin
info@oregonpharmacy.org
Oregon State Pharmacy Association

Patricia Epple
pepple@papharmacists.com
Pennsylvania Pharmacists Association

Deanna Ennello-Butler
ed@pssny.org
Pharmacists Society of the State of New York

Sarah Sorum
sarahs@pswi.org
Pharmacy Society of Wisconsin

Ken Correia
info@ripharmacists.org
Rhode Island Pharmacists Association

Mark E. Rogers
Mark.Rogers@LMHOSP.ORG
Rhode Island Society of Health-System Pharmacists

Craig Burridge
craig@scrx.org
South Carolina Pharmacy Association

Amanda Bacon
amanda@sdpha.org
South Dakota Pharmacists Association

Micah Cost
micah@tnpharm.org
Tennessee Pharmacists Association

Debbie Garza
Dgarza@texaspharmacy.org
Texas Pharmacy Association

Stacey Mather
Stacey.mather@tshp.org
Texas Society of Health-System Pharmacists

Adam Jones
ajones@associationsutah.com
Utah Pharmacists Association

Jordan McPherson
ushp@ushp.org
Utah Society of Health-System Pharmacists

James Marmar
vtpa@sover.net
Vermont Pharmacists Association

Selma Zjakic
Selmazjakic@gmail.com
Vermont Society of Health System Pharmacists

Christina Barrille
christina@virginiapharmacists.org
Virginia Pharmacists Association

Steve Glass
contact@vshp.org
Virginia Society of Health-System Pharmacists

Jeff Rochon
jeff@wsparx.org
Washington State Pharmacy Association

Craig Frederick
director@wpha.net
Wyoming Pharmacy Association

cc:
The Honorable Alex Azar II, Secretary, HHS
The Honorable Elinore F. McCance-Katz, M.D., Ph.D., Assistant Secretary for Mental Health and Substance Use, SAMHSA

Appendix I.

Communities throughout the country continue to face devastation due to prescription and illicit opioid abuse, misuse, addiction, and overdose. As the most accessible member of the health care team, pharmacists are medication experts who are often underutilized in pain management and treatment of substance use disorders.

Opioid Risk Assessment

Pharmacists' training enables them to deliver evidence-based care that fits into existing workflows and leverages the specialized training they receive in medication safety to meet the needs of patients who use opioids. Pharmacists screen and assess patients' risk for misuse and abuse, provide interventions and care coordination, and furnish naloxone where authorized. Research has demonstrated the value of pharmacists in positively impacting patients with chronic pain.

An excellent example is North Dakota's funding for ONE Rx[62] (Opioid and Naloxone Education), a program to make the training available to all pharmacists in North Dakota. More than 900 patients have been screened so far using the Opioid Risk Tool ("ORT"),[63] while 28 percent were identified as being at risk of accidental overdose based on medication interactions, patient profile or disease states.

Opioid Antagonist Counseling

As an illustrative example, our organizations are providing the following walk-through of how opioid risk assessment and opioid antagonist counseling would function if permitted under the forthcoming regulation to implement the EO to allow practitioners, such as pharmacists, to practice at the top of their profession.

How does a patient get to a pharmacy/pharmacist for services and what would happen when they arrive at a pharmacy?

A physician initiates a referral for a Medicare beneficiary who is on high doses of opioids (90 MME and above) and is at risk for opioid misuse and/or abuse and would benefit from 1) opioid antagonist counseling and/or 2) risk factor reduction if:

- The physician or physician group practice does not or is not able to provide these services.
- The physician has an established and trusted relationship with the pharmacist either informally or through a formal CPA to provide opioid antagonist counseling and risk factor reduction services.
- Patient is eligible; the patient must be prescribed a high dosage of opioids with a dosage of greater than 90 morphine milligram equivalents ("MME") per day. We have compiled

[62] *See*, https://www.nodakpharmacy.com/onerx/define.asp

[63] The Opioid Risk Tool (ORT) from the National Institute on Drug Abuse is a brief, self-reported screening tool validated for assessing risk of opioid misuse in patients prescribed opioids for chronic pain. The researchers combined the ORT with a patient intake form that provides crucial information about a patient's disease state(s) and complete medications list, information a pharmacist is often missing. This patient information provides a picture of the risks facing a patient who may, as Strand noted, be unknowingly starting down a dangerous path to opioid use disorder.

additional information on opioid prescribing and can provide this information upon request. We estimate currently that about 1.4 million Medicare beneficiaries met or exceeded the 90 MME for at least one day.

- The pharmacy/pharmacist enrolls as a Medicare provider and provides these services under the CPA.
    - Not every pharmacy/pharmacist will provide these services; not every pharmacist would have a business model to support the provision of these services, especially for a small patient population.
    - The pharmacy/pharmacist receiving the referral from the physician (including through a CPA) could be in a variety of practice settings (e.g. community pharmacy, physician office, outpatient clinic, etc).
- Patient wants and takes advantage of the service(s).

If all the above factors are met, a pharmacist would provide:

- **Opioid antagonist counseling** such as overdose reversal antidote evaluation and use.
    - An opioid antagonist refers to a medication (e.g., naloxone) that acts on one or more receptors—effectively blocking them—to counteract against an opioid drug overdose.
    - Through this service (separate from the dispensing of naloxone or other product), a pharmacist would evaluate a patient's risk for overdose—using a structured screening and/or professional judgement—and develop a mitigation strategy that would likely include dispensing of naloxone, which also may result from a prescription from the referring physician and the pharmacists subsequent counseling on its use.
        - Possible codes that CMS could authorize physicians utilizing pharmacists to provide this service include 99401-99404, "Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual" (note these codes are not currently used for Part B billing).
        - Each code increases by 15-minute intervals up to 60 minutes.

- **Opioid risk factor reduction intervention** such as for the purpose of promoting health and preventing substance abuse.
    - The purpose of this intervention is to allow the pharmacist to provide feedback to the patient, face-to-face, and tailored to the information collected (prior to or during the visit) to promote health and to reduce the risk of opioid abuse/misuse.
    - The goal is to identify opioid treatment related behavior that has the potential to exacerbate the patient's condition, preventing potential misuse and/or abuse.
        - Screen and assess for risk of misuse and abuse; using a standardized approach:
            - Assess patient and medication profile;
            - Given the indication, assess appropriateness of the dosage; and
            - Identify co-risk factors (e.g. alcohol, tobacco, other or prior drug use).
        - Intervention
            - Educate Patient (e.g. risk associated with opioid misuse, appropriate/secure storage and disposal);

        - Care coordination – If needed, pharmacist makes recommendations (e.g. other risk mitigation services, therapy changes, etc.) to referring physician based on results of the risk assessment.
    - Possible codes CMS could authorize to bill for this service or the physician bills for the service performed under general supervision include G0396 and G0397 – "Alcohol and/or substance abuse structured screening and brief intervention services;" 15-30 minutes and 30+ minutes, respectively.

Information on precisely what would happen between pharmacist/physician and caregiver being given naloxone

- Physician identifies patient (Medicare beneficiary[64]) at risk for opioid misuse whose opioid dosage exceeds 90 MME/day and who needs an opioid antagonist for potential overdose and death.
    - Physician provides patient with prescription for naloxone OR instructs patient to obtain naloxone directly from pharmacy (via statewide protocol, standing order, etc.).
    - Physician refers patient to pharmacist for opioid antagonist counseling.
- Physician refers patient; patient requests for the pharmacist to provide opioid antagonist counseling/education.
- Pharmacist provides intensive opioid antagonist counseling to educate the patient about the need for the medication, importance of contacting emergency medical services, how to use the product and verify patient understanding, and the care after administration of naloxone.
- Pharmacist documents the education and communicates pertinent information to the referring physician.
- This service would be separate from dispensing or provision of the product.

As articulated in our comments, our organizations ask CMS continue to examine, through notice and comment rulemaking, pharmacist-provided opioid treatments/ patient care services that could be delivered under general supervision in "incident to" arrangements.

[64] Note that while a caregiver may be educated on behalf of a beneficiary in many situations, this is intended to be exclusively for a beneficiary.