



April 1, 2019

[Submitted electronically to <http://www.regulations.gov>]

Re: Department of Health and Human Services Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations (Docket Number: HHS-OS-2018-0027)

Dear Pain Management Best Practices Inter-Agency Task Force,

The American Pharmacists Association (APhA) is pleased to provide comments in response to the Department of Health and Human Services (HHS) Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations (hereinafter, "Draft Report"). APhA is the largest national professional pharmacy association representing practicing pharmacists in all practice settings. APhA recognizes and advocates for the importance of balancing patients' pain management needs with efforts to minimize risk and prevent diversion. We are aware of negative, unintended consequences related to efforts to address the opioid epidemic. To the extent possible, the Task Force needs to consider how these unintended consequences can be addressed within the context of the opioid epidemic.

Overall, the Draft Report provides a comprehensive and useful overview of the issues, gaps, and needs to be addressed in order to appropriately provide care to patients with acute and chronic pain. The following comments detail our suggestions for enhancing the Draft Report.

I. Pharmacists Can Fill Gaps in Care

Pharmacists are medication experts who can fill many gaps in care; their expertise goes well-beyond dispensing medications. APhA recommends the Task Force recognize pharmacist-provided services (e.g., medication management; academic detailing; Screening, Brief Intervention and Referral to Treatment (SBIRT)); provision of naloxone; patient monitoring; urine drug screen interpretation; referrals; patient counseling and education; tapering; lab and pharmacogenomic test interpretation; treatment planning) and opportunities to include pharmacists as part of pain care teams, either in clinic settings, community practice, or through virtual means in the following sections: *Sec. 2.1 Gap 1 Rec. 1a; Sec. 2.1 Rec 1b-1c; Sec 2.2 Gap1 Rec. 1d; Sec 2.2 Gap 1 Recs. 2b-2c; Sec. 2.2.1.2 Gap 1 Rec 1a; Sec. 2.2.1.2 Gap 2 Rec. 2a; Sec. 2.2.2, Gap 1, Recs. 1a-1c; Sec. 2.5.2, Gap 1, Rec. 1b; Sec. 2.5.2 Gap 1 Rec. 1c; Sec. 3.3.2; Sec. 3.2.2 Gap 1 Rec. 1a; Sec. 3.3.2 Gap 3 Rec. 4a*

II. Team-based Care

Several sections of the Draft Report rely on pain management teams and other team-based care models. APhA emphasizes these models are often not accessible to patients given practitioner shortages, a lack of trained specialists, and lack of effective coordinated care models. This is especially difficult for many patients who do not have access to integrated pain care delivery models that are often based in large health systems. These patients are often left to navigate a fragmented health care system. The Draft Report could benefit from a section that defines the pain medicine team, including providers to consider including on the team, and provides examples of pain medicine teams both within integrated systems like the VA, and outside of health systems where care is generally not as coordinated. APhA recommends the Task Force carefully consider these care limitations in the following recommendations: *Sec. 2.2 Gap 1 Rec. 1b-c; Sec 2.2 Gap 2 Rec. 2d; Sec 2.2.1.1 Gap 1 Rec. 1d; Sec 2.2.1.2 Gap 2, Rec. 2a; Sec 2.4.1, Gap 1, Rec. 1a; Sec. 2.6; Sec. 2.7.3; Sec. 2.7.3 Gap 2; Sec 2.7.5 Gap 1 Rec. 1a; Sec 3.2.2 Gap 2 Rec. 2a*

III. Coverage of Pharmacist-Provided Care Services

To fully leverage pharmacists' contributions to pain management and as stated in APhA's September 2018 commentsⁱ (Appendix 1), we urge the Task Force to explicitly recommend Congress pass legislation to cover pharmacist-provided patient care services under Medicare Part B. In addition, the Task Force should recommend Medicaid and other payers cover pharmacist-provided care services. This recommendation is particularly applicable to the following sections of the Draft Report: *Sec. 3.2.2 Gap 2 Rec. 2c; Sec. 3.3.2 Gap 1 Rec 1a-1b*

IV. Section-Specific Responses

Sec. 2.1 Gap 1: Significant fragmentation occurs outside of health systems. APhA urges the Task Force to also focus on fragmentation outside of health systems in the following recommendations: *Sec. 2.1.1 Gap 1 Rec. 1c; Sec. 2.2 Gap 2 Rec. 2e; Sec. 2.2 Gap 4 Rec. 4b; Sec. 2.4 Gap 2 Rec. 2b; Sec. 2.5.1*

Gap 1 Rec. 1c; Sec. 2.7.6 Gap 3 Rec. 3c: APhA recommends consolidating coverage and reimbursement recommendations in the Section 3 – Access to Care, to prevent confusing clinical best practices with coverage and reimbursement recommendations.

Sec. 2.1 Gap 1 Rec. 1a: Although APhA supports including the highlighted collaborative care model, it does not represent many settings where limited practitioners/resources are available. APhA recommends providing additional examples of coordinated and collaborative care of different types (*See Appendix 2*).

Sec. 2.1.1 Gap 2 Rec. 2a-2b: The Draft Report should clearly articulate how Recommendation 2a and Recommendation 2b are meant to be applied by different stakeholders (e.g., practitioners and payers) seeking to apply guidelines clinically for individual patients versus payer decisions for populations.

Sec. 2.2 Gap 1: APhA recommends clarifying that guidelines and algorithms, including for specific populations, should reinforce the individualized nature of prescribing and emphasize flexibility in application. Guidelines should help clinical decision-making, not dictate a one-size fits all approach.

Sec. 2.2 Gap 1 Rec. 1a: APhA suggests removing “physicians” and inserting “health care providers” to better account for the array of practitioners using algorithms.

Sec. 2.2 Gap 1 Rec. 1c: APhA notes that collaborative, multimodal treatment plans involving pharmacists often include services as described in Appendix 2. These services should be articulated in the report.

Sec. 2.2 Gap 1 Rec. 1d: APhA recommends modifying this section to better emphasize the need for joint collaborative efforts between pharmacists and prescribers to cultivate patient-centered delivery systems. Community pharmacists have many challenges in meeting their corresponding responsibilityⁱⁱ and health plan requirements. Often pharmacists must overcome significant barriers to obtain critical information to serve their patients. APhA’s members report local physicians and other providers are often not receptive to collaboration requests initiated by the pharmacist. To improve patient care, the onus for collaborating should not only be on the pharmacy/pharmacist, but on all of the patient’s health care providers.

Sec. 2.2 Gap 2: More guidance for other health care provider types, including pharmacists, regarding appropriate pain treatment approaches is needed. APhA recommends broadening this recommendation to address the knowledge gap of a broader spectrum of health care providers.

Sec. 2.2 Gap 2 Rec. 2a-2c: APhA recommends health care providers understand pharmacogenomic aspects of pain treatments.

Sec. 2.2 Gap 5 Rec. 5b: APhA notes that costs can be a barrier for disposal sites and suggests the Task Force recommend additional funds for disposal and that DEA evaluate options to ease disposal requirements.

Sec. 2.2. Gap 5 Rec. 5d: APhA suggests the Task Force recommend DEA update partial fill regulations to create more consistency among states and utilization of partial fill options.

Sec. 2.2.1.1: Like prescribers, many states require pharmacists to use and report to prescription drug monitoring programs (PDMPs). APhA recommends the first line in paragraph 1 on page 16ⁱⁱⁱ also include pharmacists. Also, the last three sentences in paragraph 1 on page 16^{iv} reference PDMP applications by pharmacists, dispensing, and “doctor shopping.” APhA is concerned these sentences do not draw conclusions related to referenced research in the recommendation which focuses on prescribing and PDMP checks before a medication is both prescribed and dispensed. In addition, this section does not adequately describe the different uses of a PDMP. For example, pharmacists use PDMPs to identify “red flags”^{v,vi} (e.g., multiple concurrent prescribers) that may mean the patient is at-risk and then work to resolve them, including outreach to the provider(s). Given the fragmentation in the health care system, pharmacists face significant barriers in obtaining clinical information, including diagnoses; having access to information available to the other health care team members; and receiving time-sensitive responses from prescribers when verifying prescriptions as part of their corresponding responsibility^{viii} and as part of providing patient care services. APhA requests that the Task Force revise this section to provide a more balanced perspective and promote collaborative efforts between pharmacists and prescribers.

Sec. 2.2.1.2 Gap 1 Rec. 1a: APhA strongly agrees with the need to provide adequate compensation for services to implement screening methods. Pharmacists in various settings are involved in screening (e.g., SBIRT, urine drug testing).^{viii} However, pharmacists' time is often not eligible for reimbursement by payers. APhA urges the Task Force to recommend payers reimburse pharmacists for screening measures.

Sec. 2.2.1.2 Gap 3 Recs. 3a-3b: APhA suggests healthcare providers initiating treatment agreements also facilitate sharing the agreement with the patient's health care team, including pharmacists.

Sec. 2.2.2, Gap 1, Recs. 1a-1c: Coverage policies should reimburse providers, including pharmacists, for services associated with furnishing naloxone.

Sec. 2.5.2 Gap 1 Rec. 1c: The Draft Report recommends referring patients to both pain and addiction specialists when OUD is suspected. Pharmacists play roles in screening,^{ix} but barriers to pharmacists' referral exist. APhA suggests the Task Force recommend development of robust referral mechanisms that include pharmacists (*See Appendix 4*).

Sec. 3.2.2 Gap 1 Rec. 1a: APhA supports patient access to educational tools, including clinician visits (e.g., pharmacists) and patient handouts. The need for meaningful counseling and evidence-based, consumer- friendly resources (and payment mechanisms to support them) should be highlighted.

Sec. 3.2.2 Gap 2 Rec. 2c: APhA suggests modifying the recommendation to read: "CMS and other payers should compensate according to provider-patient time spent...".

Sec. 3.2.2 Gap 3 Rec 3b: APhA seeks clarification that pharmacists are included among "clinicians" on the expert panel and "pharmacies" included among the settings disseminating patient education programs and materials.

Sec. 3.2.3 Gap 1 Rec 1a-1c: APhA is concerned other health care providers', including pharmacists', curriculum, graduate education, residency programs and other training opportunities are not adequately addressed in this recommendation and suggests including more healthcare providers in this section.

Sec. 3.3: APhA is concerned this section does not accurately depict "retail" pharmacies and pharmacists. Several of the factors noted in the Draft Report negatively effecting patient care are most apparent at community pharmacies because it is these facilities and pharmacists who must overcome these barriers (e.g., poorly functioning drug supply systems, payer medication coverage limitations/restrictions, prescriber communication requirements and delayed provider responses). As drafted, the Draft Report appears to improperly attribute broader policy shifts to practices within retail pharmacies. To better understand factors impacting patient access, the Task Force should recommend HHS evaluate the degree to which different barriers effect patient access to medications.

Sec. 3.3.1 Gap 1 Rec.1a-1b: See Appendix 3 for APhA's drug shortages recommendations.

Sec. 3.3.2 Gap 1 Rec 1a-1b: APhA urges the Task Force explicitly recommend coverage for medication management services as part of complex management situations and include pharmacists as part of the holistic team.

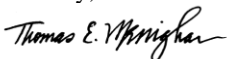
Sec. 3.3.2 Gap 4 Rec. 4a: APhA urges the Task Force recommend payers cover services by all health care practitioners providing pain management services (e.g, pharmacists), using a chronic disease management model.

Sec. 3.3 Gap 1 Rec. 1b: APhA recommends the Task Force recognize pharmacists may be considered pain specialists. While post-graduate year 2 residency (PGY2) programs exist in pain management and palliative care and psychiatric pharmacy, more are needed.^{x,xi} APhA urges the Task Force to recommend expansion of PGY2 pharmacy residency programs in pain management and palliative care.

Sec. 3.3 Gap 1 Rec. 1c: APhA recommends including pharmacists in addition to the other non-physician specialists.

Thank you for the opportunity to provide comments to the Task Force. We support the Task Force's ongoing efforts to continue to fight the opioid epidemic. If you have any questions or require additional information, please contact Jenna Ventresca, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,



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

Appendix 1:

Copy of APhA Comments Re: Second Meeting of the Pain Management Best Practices Inter-Agency Task Force (HHS-OS-2018-0016-0026); submitted September 17, 2018

Re: Second Meeting of the Pain Management Best Practices Inter-Agency Task Force (HHS-OS-2018-0016-0026)

Dear Members of the Pain Management Best Practices Inter-Agency Task Force:

The American Pharmacists Association (APhA) applauds the efforts of the Pain Management Best Practices Inter-Agency Task Force (“Task Force”) to develop a report to Congress with updates on best practices and recommendations on addressing gaps or inconsistencies for pain management, including chronic and acute pain. Founded in 1852 as the American Pharmaceutical Association, APhA represents 62,000 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. Policies that utilize pharmacists and harness their education and training are needed to better address the opioid epidemic while balancing the need to provide care to patients in pain. APhA offers the following recommendation for the Task Force’s consideration which we believe will be most impactful in helping patients in pain and in stemming the opioid epidemic.

Primary Recommendation: To improve pain management and enhance prevention efforts related to opioids, Medicare Part B and other payers should cover pharmacist-provided services

Pharmacists’ services are not broadly covered under Medicare Part B, state Medicaid programs or private payors. Because Medicare often serves as an informal bar for other payers, Medicare coverage of pharmacist-provided services is a crucial first step in helping patients benefit from pharmacist-provided care which fosters safe and effective medication use, among other advantages. However, without such coverage, beneficiaries’ access to the health care practitioner with the most medication-related education and training is limited and restricted mainly to services associated with the dispensing of medications.

As described above, pharmacists provide care in many different care settings and can provide a vast array of services beyond dispensing. For example, over 6,500 pharmacists’ working for the U.S. Department of Veterans Affairs (“VA”) “enjoy a high level of clinical practice that utilizes their training in comprehensive medication management”, and “Clinical Pharmacy Specialists work under a scope of practice with authority to prescribe and monitor medication therapies...”.¹ Unlike the VA, Medicare’s lack of coverage of pharmacists’ services

¹ See U.S. Department of Veterans Affairs, Veterans Health Administration, (2012) *Become a VA Pharmacist*, available at: https://www.pbm.va.gov/PBM/education/residency/generalinfo/Pharmacist_Brochure.pdf, last accessed: September 14, 2018.

fails to optimize pharmacists' education and training and consequently, opportunities to address gaps in care, including increasing beneficiary access, are missed. If Medicare covered pharmacists' services, pharmacists would be better positioned to address the opioid epidemic and patients' pain management needs. Specifically, they could screen for and assess beneficiary risk for misuse and abuse (e.g., assess patient and medication profiles, assess appropriate dosage based on the indication, identify co-risk factors) and provide interventions such as patient education (e.g., opioid misuse, appropriate storage, security and disposal), referral and care coordination (e.g., medication changes, tapering). Additionally, if pharmacists are included among other Part B providers whose services are covered, it would be easier for other members of the health care team and patients to work with pharmacists as a part of a coordinated, team-based approach to care.

Although APhA has many different recommendations related pain management and the opioid epidemic, we believe the most impactful change would be for Medicare to cover pharmacist-provided services. Given 89 percent of Americans live within five miles of a community pharmacy and the treatment and prevention necessities of patients in pain, strategies to better utilize pharmacists are essential in bridging gaps in care, preventing abuse and misuse, and improving outcomes. Therefore, APhA urges the Task Force to support the *Pharmacy and Medically Underserved Areas Enhancement Act (S. 109 / H.R. 592)* to advance this commonsense policy.

Thank you for the opportunity to provide comments to the Task Force. We support the Task Force's ongoing efforts to continue to fight the opioid epidemic. If you have any questions or require additional information, please contact Jenna Ventresca, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,



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

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs

Appendix 2:

Integrating Pharmacists into Pain Management Teams and Services

Pharmacist integration into pain management teams and services would be enhanced by addressing current barriers to their inclusion. There is a need for better healthcare team provider and patient/caregiver education and awareness of the enhanced services and expertise pharmacists can contribute to effective pain management in order to improve collaborations.^{2,3} Promotion of successful models beyond the efforts currently underway in the pharmacy profession would help in raising awareness. In addition, integrating community pharmacies into health information exchanges to better facilitate communications and data-sharing is an essential component of team-based care.^{4,5} Yet, the most significant barrier to widespread adoption of the models noted is that payers, including Medicare, provide little reimbursement opportunities for pharmacist-provided patient care services, including pain management-related services. The lack of payment hinders organizations from financially supporting the work of pharmacists within health care teams or contracting with community pharmacies to provide pain management-related services as part of the team. While value-based payment models are changing to facilitate integration of pharmacists, the predominant fee-for-service model remains a barrier to pharmacist inclusion. Effectively addressing these barriers is crucial to health care teams seeking to better integrate pharmacists into pain management.

When these barriers are overcome, integration of pharmacists into pain management services helps fill gaps in care, enhance treatment capacity and options, increase cost savings, reduce pain, improve functionality, improve adherence, reduce adverse events and enhance patient satisfaction, among other benefits. Coordination and alignment of the various pharmacists interacting with patients, team members and caregivers is critical if we are to optimize pain management for the patients served.

Common Collaborative Structures

Pharmacists can work collaboratively with other members of the patient's health care team in an "embedded" model where the pharmacist sees patients and works at the practice site with other health care team members. Pharmacists practicing in embedded models are usually located in physician office practices, hospital outpatient clinics, and hospitals. Pharmacists in embedded models providing pain management services have defined roles and responsibilities and often work under collaborative practice agreements. These voluntary agreements, permitted in 48 states and the District of Columbia, allow the prescriber to delegate certain functions to the pharmacists beyond the pharmacist's normal practice authority, often prescribing (post-diagnosis), adjusting, or discontinuing medications and ordering laboratory tests. These

² Fay, A.E., Ferreri S. P., Shepherd, G., Lundeen, K., Tong, G.L. & Pfeiffenberger, T. (2018). Care team perspectives on community pharmacy enhanced services, *Journal of the American Pharmacists Association*, 58, S83-S88

³ Doucette, W.R., Rippe, J.J., Gaither, C.A., Kreling, D.H., Mott, D.A. & Schommer, J.C. (2017). Influences on the frequency and type of community pharmacy services, *Journal of the American Pharmacists Association*, 57, 72-76.

⁴ See Community Pharmacy Enhanced Services Network, *Integrating Pharmacists into the Medical Home Team*, available at: <https://www.communitycarenc.org/what-we-do/supporting-primary-care/pharmacy/cpesn>, last accessed: March 13, 2019.

⁵ See also, Pharmacy Health Information Technology Collaborative, (2018). Integrating Pharmacists into Health Information Exchanges – Update Version, available at: <http://www.pharmacyhit.org/pdfs/workshop-documents/WG3-Post-2018-01.pdf>, last accessed March 13, 2019.

agreements allow the pharmacist to manage and make adjustments to pain medications resulting in improved treatment outcomes and expanded access to care. Additional services pharmacists tend to provide include medication history review and reconciliation, medication regimen recommendation, adherence assessments, behavior modification techniques and follow-up for nonadherence, monitoring, patient education, academic detailing, screening, lab result interpretation (e.g., urine drug screen, pharmacogenomic reports), and care coordination.

Pharmacists working on pain management teams bring valued expertise focused on optimizing medication therapies by comprehensively evaluating all of the medications that the patient is taking, not just the pain medications. Since patients with pain often have other conditions, the pharmacist's role in coordinating their medications can help to avoid problems arising from multiple prescribers. These pharmacists are also important conduits and coordinators with community pharmacists and other practitioners caring for patients.

Other activities that pharmacists working on pain management teams are involved in include working with physicians and others on the team to provide education on evidence-based guidelines, monitoring pain medication use, working with the health care team to consider non-opioid medications/treatments to control pain, providing opioid and benzodiazepine tapering services, performing risk assessments for substance use disorder or mental health conditions, and facilitating or furnishing naloxone. Pharmacists meet regularly with team members, document in the electronic health record, share information, and communicate with prescribers and other members of the team. Referral processes are often in place for other team members to refer patients to the pharmacist.

Another team-based delivery model involves community pharmacists working with physician practices in a more "virtual" team-based arrangement for patient care services that go beyond traditional dispensing. While not as common as the embedded model, these virtual arrangements often include data sharing and communications agreements and referrals for patient care services. Medicare's Chronic Care Management (CCM) Service is an example where virtual team-based service delivery is occurring that can include aspects of pain management. In addition, some community pharmacists are also partnering with physician office practices to offer opioid tapering services, an aspect of pain management, often using collaborative practice agreements, exploring how they can assist in monitoring for risk of substance use disorder, and providing naloxone.

Benefits of utilizing pharmacists in pain management teams and services:

- A systematic review published in the *Journal of the American Medical Association* indicated that while up to 92% of patients studied reported they had "unused" opioids after surgery, utilizing pharmacists in the assessment of opioid prescribing can help minimize the risk of drug diversion.⁶
- Pharmacists can perform a complete review of a patient's medication regimen to optimize therapy and minimize side-effects.

⁶ Bicket MC, Long JJ, Pronovost PJ, Alexander GC, Wu CL. Prescription Opioid Analgesics Commonly Unused After Surgery A Systematic Review. *JAMA Surg.* 2017;152(11):1066–1071. doi:10.1001/jamasurg.2017.0831

- As part of this service, they may recommend non-opioid pain alternatives and work with prescribers to provide screening, medication management, monitoring and tapering services.
- A study analyzing the economic impact of opioid-related adverse drug events (e.g. nausea, respiratory complications), estimated over half experiencing an event would have a longer hospital stay resulting in 47% higher cost of care for that patient. Involving pharmacists in the process of counseling, discharge, and clinic follow-up of post-operative patients who are prescribed opioids can help reduce opioid-related adverse drug events and subsequent health care costs.⁷
- Pharmacists are involved in pain management programs that include monitoring and medication tapering services, work in medication assisted treatment programs, and furnish naloxone where authorized. Research has demonstrated the value of pharmacists in positively impacting patients with chronic pain.^{8,9}
- Pharmacists' medication expertise helps inform other care team members about safer and alternative prescribing options, and naloxone.^{10,11} For example, physicians in community practices and the U.S. Department of Veterans Affairs medical settings who received services such as academic detailing from a pharmacist regarding safer opioid prescribing later reported adopting safer prescribing behaviors.^{12,13}
- Pharmacist involvement in MAT for opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.^{14,15,16} Currently, six states explicitly allow pharmacists to prescribe Schedule II-V controlled substances under a collaborative practice agreement. Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are constrained by federal law, specifically the Drug Addiction Treatment Act of 2000, from further expanding patient access to MAT.

⁷ E.R. Kessler, M. Shah, S.K. Gruschkus, A. Raju (2013). Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes *Pharmacotherapy*, 33(4), 383-391

⁸ Cox, N., Tak, C.R., Cochella, S.E., Leishman E., & Gunning, K. (2018). Impact of Pharmacist Previsit Input to Providers on Chronic Opioid Prescribing Safety

⁹ <https://doi.org/10.1016/j.japh.2017.01.016>

¹⁰ See Trotter Davis, M., Bateman, B. & Avorn J. Educational Outreach to Opioid Prescribers: The Care for Academic Detailing, *Pain Physician*, 2017, 20:S147-S:151. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28226336>.

¹¹ Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135-S140

¹² Larson, M.J., Browne, C., Nikitin, R.V., Wooten, N.R., Ball, S., Adams, R.S. & Barth, K. (2018). Physicians report adopting safer opioid prescribing behaviors after academic detailing intervention, *Substance Abuse*, Apr 2:1 to 7. Available at: https://www.researchgate.net/publication/324172121_Physicians_report_adopting_safer_opioid_prescribing_behaviors_after_academic_detailing_intervention.

¹³ Gelland, W.F., Good, C.B. and Shulkin, D.J. (2017). Addressing the Opioid Epidemic in the United States Lessons from the Department of Veterans Affairs, *JAMA Intern Med*. 177(5):611-612.

¹⁴ DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. *J Am Pharm Assoc*. 2015; 55: 187-192.

¹⁵ Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135-S140.

¹⁶ Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, *Mental Health Clinician*, 2013, 3(6), Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association*. 57 (2017), S135-S140 290-291.

Detailed examples of effective team-based care delivery for pain management

1. Cox, N., Tak, C.R., Cochella, S.E., Leishman E., & Gunning, K. (2018). Impact of Pharmacist Previsit Input to Providers on Chronic Opioid Prescribing Safety

- Pharmacist's Role: All adult patients with an appointment for chronic pain who were prescribed >50 morphine milligram equivalents (MMEs)/day had charts reviewed by a pharmacist before each appointment; recommendations were sent electronically to the provider before the appointment.
- Results: When comparing outcomes before and after intervention, the mean MMEs/day decreased by 14% ($P < .001$), with no change in pain scores ($P = .783$). Statistically significant improvements were noted in multiple other secondary opioid safety outcomes.
- Conclusion: Clinical pharmacists providing previsit recommendations was associated with decreased opioid utilization with no corresponding increase in pain scores and increased compliance to guideline recommendations.

2. Genord, C., Frost, T. & Eid, D. (2017). Opioid exit plan: A pharmacist's role in managing acute postoperative pain, *Journal of the American Pharmacists Association*, 57(2), S92-S98.

- Pharmacist's Role: Pharmacist-led opioid exit plan (OEP) for acute postoperative pain management. OEP is a tool and its benefits include medication reconciliation review and prescription drug-monitoring program search before admission, interdisciplinary rounds with the medical team to provide optimal inpatient postoperative pain management, clinical assessment of outpatient prescriptions with opioid discharge counseling, and medication evaluation of prescribed pain regimen and opioid discontinuation status at the post-discharge follow-up appointment. An OEP is a national practice model.
 - This paper summarizes the setup of a new pharmacist-led OEP practice model and the potential role that pharmacists and students can have before admission, during inpatient visits, and during transitions of care for discharge in acute pain management patients.
- Conclusion: A pharmacy pain management team can be key to guiding the appropriate prescribing practices of inpatient opioids and ensure best practices with quantity and quality of opioid prescriptions written on discharge. Future outcomes-based evaluations of the success of this practice model are in progress.

3. Luchen, G.C., Proshaska, E.S., Ruisinger, J.F. & Melton, B.L. (2018). Impact of community pharmacist intervention on concurrent benzodiazepine and opioid prescribing patterns, *Journal of the American Pharmacists Association*, 59(2), 238-242.

- Pharmacist's Role: Community pharmacists sent communications to prescribers when patients were concurrently prescribed opioids and benzodiazepines. In the pharmacist's communication, prescribers were provided with proposed evidence-based prescription changes.
- Results: There was a statistically significant positive correlation between the number of positive prescription changes and the number of prescribers involved in a patient's

- care, indicating that more positive changes occurred when multiple prescribers were involved in a patient's care. The majority of prescription changes (63%) that occurred after pharmacist intervention resulted in tapering or discontinuation of the opioid or benzodiazepine.
- Conclusion: A faxed pharmacist intervention may help to reduce opioid/benzodiazepine coprescribing, especially when multiple providers are involved in a patient's care.
- 4. Michalets, E., Creger, J. & Shillinglaw, W.R. (2015). Outcomes of expanded use of clinical pharmacist practitioners in addition to team-based care in a community health system intensive care unit, *American Journal of Health System Pharmacy*, 72(1), 47-53.**
- Pharmacist's Role: Dedicated clinical pharmacist practitioner (CPP) was made available five days per week in multidisciplinary team (trauma surgeon, bedside nurse, care manager, pharmacist, respiratory therapist, and nutrition support professional) rounds in a neurotrauma ICU. A practice agreement was in place to allow the CPP to initiate, modify, or discontinue medications on the hospital formulary and to order pertinent laboratory tests. In addition, the CPP could provide comprehensive medication management for medications administered in the ICU.
 - The pharmacist was responsible for clinical services, participation in the multidisciplinary team, electronic verification of medication orders, participation in emergency-code responses and provisions of clinical services. The CPP assisted with the development of individualized care plans, daily monitoring of patients and precepting of pharmacy student and residents.
 - Results:
 - Based on the evaluated national benchmarking data, the estimated cost savings or avoidance associated with these patient encounters was \$2,118,426 over the two-year period. The ROI increased after the CPP expansion, from \$9 per \$1 invested in year 1 to \$18 per \$1 invested in year 2. This doubling of the ROI reflected daily consistency in CPP involvement in NTICU care and provision of more meaningful therapeutic interventions.
 - Comparison of the year 1 and year 2 data indicated a significant increase in the frequency of patient encounters for therapeutic optimization ($p < 0.01$) along with a 29% increase in cost savings with the CPP expansion (Table 3). Thus, the addition of two CPPs increased the volume of meaningful interventions. Although not a statistically significant decline, patient deaths decreased by 5.6 per 1000 ICU days during the study.
 - Conclusion: With expanded CPP involvement on the NTICU team, there was a substantial increase in therapeutic optimization interventions and a clinically notable reduction in preventable ADEs, as well as an estimated 30% increase in associated cost savings.
- 5. Mathew, S. Chamberlain, C., Alvarez, K.S. & Shah, M. (2016). Impact of a Pharmacy-Led Pain Management Team on Adults in an Academic Medical Center, *Hospital Pharmacy*, 51(8), 639-645.**

- Pharmacist's role: Pharmacy pain medication management service (pharmacy pain consult) was provided to certain adult patients.
- Results: Eight hundred twenty-one interventions were made by the clinical pharmacists. Patients displayed a significant reduction in their pre- and post-consult pain intensity scores on a 0 to 10 numerical rating scale (6.15 vs 3.25; $p < .001$). Likewise, a significant reduction in pain intensity scores was seen from pre-consult to pre-discharge (6.15 vs 3.6; $p < .001$). Overall functional improvement, specifically sleep, mobility, and appetite, was seen in 86.6% of patients.
- Conclusion: Pain management is an area that provides opportunities for pharmacotherapy interventions. Pharmacists' involvement in pain management on an inpatient consult service had a positive impact on pain scores and improvement in functionality.

6. Hammer, K.J., Segal, E.M., Alwan, L., Li, S., Patel, A.M., Tran, M. & Marshall, H.M. (2016). Collaborative practice model for management of pain in patients with cancer, *American Journal of Health System Pharmacy*, 73(18), 1434-1441.

- Pharmacist's Role: A clinic offering cancer pain management via an interprofessional team including physicians, advanced practice providers, nurses, and pharmacists, expanded the pharmacists' role by allowing them (through an extensive credentialing process and under a collaborative drug therapy agreement) to evaluate patients, develop treatment plans, and prescribe pain medications for oncology patients. For cancer-related pain, the pharmacist, in conjunction with the attending provider, developed a pain medication plan following the principles of the World Health Organization's analgesic ladder. The pharmacists in the pain clinic also emphasize functional goals and improvement in functional status rather than complete relief of pain.
- Results: By having pharmacists provide these services, the pain clinic can improve medication dosing, ensure that medications are managed consistently, improve patients' quality of care, and save providers time by allowing tasks to be completed by appropriately trained ancillary staff.

7. 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, *PM&R*, doi: 10.1002/pmrj.12127.

- Pharmacist's Role: A clinical pharmacist was added to a team-based care model in an outpatient Physical Medicine and Rehabilitation clinic in a tertiary hospital.
- Results: A clinically significant reduction in MED with an average decrease of 207 mg was seen after five or more visits with the pharmacist. The pharmacist initiated non-opioid medications at 209 (19.5%) unique patient visits. The pharmacist completed 1,197 visits during the study time frame, increasing physician access by at least 2 additional visits per patient per year. Completion of urine drug screens and medication agreement reviews improved over time ($p < .001$). There was an increase in MED for patients who did not complete this monitoring, while the MED remained stable in those who did complete the monitoring.

- Conclusion: The addition of a clinical pharmacist to an interdisciplinary team managing COT patients resulted in a MED reduction after five or more visits with the pharmacist, improved adherence to best practice standards, optimization of opioid and non-opioid medication therapy, and increased patient access.
8. **Chen, J., Lu, X., Wang, W., Shen, B., Ye, Y., Jiang, H., Wang, Q. & Chang, B. (2014). Impact of a Clinical Pharmacists-Led Guidance Team on Cancer Pain Therapy in China: A Prospective Multicenter Cohort Study, *Journal of Pain and Symptom Management*, 48(4), 500-509. (Note: Chinese study)**
- Pharmacist's Role: Clinical Pharmacist-Led Guidance Teams provided pre-therapy consultation and drug education to physicians, monitored prescriptions during treatment, and conducted patient follow-up.
 - Results: A total of 542 patients were enrolled, 269 in the CPGT intervention group (CPGT group) and 273 controls. Standardization of opioid administration was improved significantly in the CPGT group, including more frequent pain evaluation ($P < 0.001$), more standardized dosing titration ($P < 0.001$), and less frequent meperidine prescriptions ($P < 0.001$). The pain scores in the CPGT group were significantly improved compared with the control group ($P < 0.05$). The incidences of gastrointestinal adverse events were significantly lower in the CPGT group (constipation: $P = 0.041$; nausea: $P = 0.028$; vomiting: $P = 0.035$), and overall quality of life was improved ($P = 0.032$). No opioid addiction was encountered in the CPGT group. Risk analysis revealed that patient follow-up by pharmacists and the controlled dosing of opioids were the major factors in improving treatment efficacy.
 - Conclusion: The CPGTs significantly improved standardization, efficiency, and efficacy of cancer pain therapy in China. In a country where clinical pharmacy is still developing, this is a valuable service model that may enhance cancer treatment capacity and efficacy while promoting recognition of the clinical pharmacy profession.
9. **Slipp, M. & Burnham, R. (2017). Medication management of chronic pain: A comparison of 2 care delivery models, *Canadian Pharmacists Journal*, <https://doi.org/10.1177/1715163517690540> (Note: Canadian study)**
- Pharmacist's Role: In the pharmacists-physician team model, the physician did the medical assessment, diagnosis, and established a treatment plan in consultation with the patient and pharmacist. The pharmacist then provided the ongoing follow-up including education, dose titration and side effect management and consulted with the physician as needed.
 - Results: Both models of medication management resulted in significant and comparable improvements in pain, disability and patient perception of medication effectiveness. Patients in the physician-only group were seen more frequently and at a greater cost. The pharmacist-physician team approach was markedly more cost-effective, and patients expressed a high level of satisfaction with their medication management.

- **Conclusion:** The pharmacist-physician team model of medication management results in significant reductions of pain and disability for chronic nonmalignant pain sufferers at a reduced cost and is well accepted by patients.

Appendix 3

American Pharmacists Association, House of Delegates policy regarding drug supply shortages available at: https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf

2012

Drug Supply Shortages and Patient Care

1. APhA supports the immediate reporting by manufacturers to the U.S. Food and Drug Administration (FDA) of disruptions that may impact the market supply of medically necessary drug products to prevent, mitigate, or resolve drug shortage issues and supports the authority for FDA to impose penalties for failing to report.
2. APhA supports revising current laws and regulations that restrict the FDA's ability to provide timely communication to pharmacists, other health care providers, health systems, and professional associations regarding potential or real drug shortages.
3. APhA encourages the FDA, the Drug Enforcement Administration (DEA), and other stakeholders to collaborate in order to minimize barriers (e.g., aggregate production quotas, annual assessment of needs, unapproved drug initiatives) that contribute to or exacerbate drug shortages.
4. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
5. APhA encourages pharmacists and other health care providers to assist in maintaining continuity of care during drug shortage situations by:
 - (a) creating a practice site drug shortage plan as well as policies and procedures,
 - (b) using reputable drug shortage management and information resources in decision making,
 - (c) communicating with patients and coordinating with other health care providers,
 - (d) avoiding excessive ordering and stockpiling of drugs,
 - (e) acquiring drugs from reputable distributors, and
 - (f) heightening their awareness of the potential for counterfeit or adulterated drugs entering the drug distribution system.
6. APhA encourages accrediting and regulatory agencies and the pharmaceutical science and manufacturing communities to evaluate policies/procedures related to the establishment and use of drug expiration dates and any impact those policies/procedures may have on drug shortages.
7. APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2017)

Appendix 4:

American Pharmacists Association, House of Delegates policy regarding referrals available at: https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf

2018

Pharmacists Electronic Referral Tracking

1. APhA supports the development of electronic systems that enhance and simplify the ability of pharmacists in all practice settings to receive, send, and track referrals between all members of the health care team, including other pharmacists, irrespective of the health care system, model, or network in which the patient participates.
2. APhA supports the interoperability and integration of referral tracking systems with electronic health records so patients can receive the benefit of optimally coordinated care from all members of the health care team. (JAPhA 58(4):356 July/August 2018)

ⁱ See American Pharmacists Association (September 2018), Comments Re: Second Meeting of the Pain Management Best Practices Inter-Agency Task Force (HHS-OS-2018-0016-0026), available at:

https://www.pharmacist.com/sites/default/files/audience/American%20Pharmacists%20Association%20-%20HHS%20Interagency%20Task%20Force_0.pdf

ⁱⁱ 21 CFR §1306.04(a), *stating* “A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription...”

ⁱⁱⁱ Draft Report, Page 16, paragraph 1, line 1-3 states “Prescribers may be required to use PDMP data at the point of care, allowing them to identify patients with multiple provider episodes or potentially overlapping prescriptions that place them at risk.”

^{iv} Draft Report, Page 16, paragraph 1, lines 11-15 states “Caution is needed when using PDMPs as a tool to aid in the proper dispensing of medications. However, PDMPs are not to be used as tools to stop dispensing medications appropriately to those in need. For example, it is also important for pharmacists to know that doctors often work as teams and to ensure that “doctor shopping” is a conclusion made after the pharmacist has made contact with the provider.”

^v National Association of Boards of Pharmacy (2015). Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, available at: <https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf>.

^{vi} See, Centers for Medicare & Medicaid Services (2018). A Prescriber’s Guide to the New Medicare Part D Opioid Overutilization Policies for 2019, available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE18016.pdf>, *stating*, care coordination safety alerts should trigger for pharmacists, “especially is the patient is receiving prescription opioids from multiple prescribers or pharmacies” and “Potential at-risk beneficiaries are identified by their opioid use which involve multiple doctors and pharmacies.”

^{vii} 21 CFR §1306.04(a)

^{viii} 21 CFR §1306.04(a)

^{ix} Pringle, J., Cochran, J. & Aruru, A. (2019). Role of Pharmacists in the Opioid Use Disorder (OUD) crisis, *Research in Social and Administrative Pharmacy*, 15(2), 228-229.

^x See, American Society of Health-System Pharmacists, *Online Residency Directory*, available at: <https://accred.ashp.org/aps/pages/directory/residencyProgramSearch.aspx>.

^{xi} Atkinson, T.J., Gulum, A.H. & Forkum, W.G. (2016). The future of pain pharmacy: driven by need, *Integr Pharm Res Pract.* 5, 33-42.