AMCP Academy of Managed Care Pharmacy®

September 10, 2018

Food and Drug Administration
Division of Dockets Management Staff (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments [Docket No. FDA-2018-N-1621]

Dear Sir or Madam,

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to "*Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments"* as published in the *Federal Register* on July 11, 2018. The improper use of opioids incurs enormous costs to our society that go beyond those of traditional health care. AMCP supports the proper management of patients suffering from uncontrolled pain and limiting the abuse and diversion of opioids. As such, policies that seek to mitigate the opioid epidemic must also strike a balance that to ensure the appropriate use of opioids for legitimate medical needs.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Recognizing the widespread and devastating nature of the opioid crisis, AMCP created the Addiction Treatment Advisory Group (ATAG) in 2015. Led by recognized experts across a diverse array of disciplines, the ATAG was charged with reviewing current processes and systems, providing recommendations for managed care organizations (MCOs) to increase access to medications used in the treatment of substance use disorders, and highlighting best practices that improve patient outcomes. In 2016, ATAG published their findings in two articles published in the *Journal of Managed Care & Specialty Pharmacy*. ATAG's article *Findings and Considerations for the Evidence-Based Use of Medications in the Treatment of Substance Use Disorder* provided guidance for MCOs to consider when designing benefits for patients to increase access to medications for substance abuse disorder and manage the use of opioids in a clinically appropriate manner.[1] Their second article, *The Role of Managed Care Pharmacy in*

[1] http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=21700

Improving Access to Naloxone, offered additional guidance for MCOs on increasing the accessibility of naloxone for patients at high risk of opioid overdose.[2]

In 2018, AMCP created the Addiction Advisory Group (AAG) to build on and continue the work of ATAG. The current AAG is comprised of more than 20 national leaders from organizations such as behavioral health organizations, outpatient treatment centers, non-profit advocacy groups, health plans, pharmacy benefit management companies, specialty pharmacies, employers, hospitals, and pharmaceutical manufacturers. The mission of the AAG is to provide health plans, pharmacy benefit managers and other payers can evidence they can use to design benefits that ensure appropriate patient access to opioids and medication assisted treatment for addiction. The group advocates for team-based care and adoption of drug management programs in all payment systems that limit access to pharmacies and prescribers for individuals at risk for opioid addiction or misuse. The AAG also promotes guidelines on appropriate opioid prescribing and provides recommendations on ways to ensure appropriate utilization of opioids and access to medication-assisted treatment.

Based on guidance from ATAG and the AAG, AMCP and its stakeholders offer several recommendations to increase patient access to safe and effective medical treatments for chronic pain. AMCP recognizes that, although opioids are an important tool for chronic pain management, continued focus is needed regarding ways to ensure these medications are used in a safe and effective way.

AMCP's Recommendations

Barriers restricting patient access to adequate treatment for chronic pain are complex, and there are no simple solutions to these issues. One major barrier is the lack of access to important patient information. This hinders providers from making informed decisions regarding patients' treatment plans, properly preventing, diagnosing and treating addiction, and preventing fatal overdoses. Other barriers include the exclusion of MCOs from states' Prescription Drug Monitoring Programs (PDMP) entry, a lack of patient access to naloxone and other rescue drugs, under-utilization of e-prescribing, out-of-date REMS processes, inadequate prescriber and patient education and training regarding opioid addiction and the use of naloxone, and dated packaging and labels for opioid drugs.

1. **The FDA should collaborate with Congress to align the confidentiality of drug and alcohol treatment and prevention records with HIPAA and allow stakeholder access to information essential for providing comprehensive patient care.**

AMCP encourages the FDA to work collaboratively with Congress to modify federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), should be made to align with HIPAA. AMP is also currently working with Congress to codify these provisions. Access to a patient's complete medical record is crucial to patient treatment, safety, and recovery. Yet, without alignment of 42 CFR Part 2 and HIPAA, providers

[2] https://www.jmcp.org/pb-assets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf

and payers will continue to be constrained, limited in the knowledge of a patient's complete medical record that includes the patient's history of substance use disorder and overdose. This confusion can often confound care of patients, increasing risk drug-drug interactions, adverse drug reactions, and even death.

Pharmacists, as medication experts, are integral members of health care provider teams who evaluate whether a patient is at risk or who is currently misusing or abusing opioids and whether a patient could be an appropriate candidate for medication assisted therapy. Pharmacists, working in collaboration with other members of the health care team, help to identify and resolve these issues potentially reducing overdose and death in many patients. However, medical interventions by pharmacists and other health care professionals cannot occur without access to full medical records.

2. **The FDA should work with states to provide access to state Prescription Drug Monitoring Programs (PDMPs) for MCOs.**

Access to patient drug prevention records would provide MCOs, providers, and pharmacists with key information needed to determine when to initiate or continue use of opioids for chronic pain and how to assess and mitigate patient risk of addiction and overdose. Access to PDMPs would allow MCOs and providers to better care for patients and avoid prescribing, administering, dispensing or otherwise providing opioids to an individual being treated for addiction. Pharmacist access to such records at the point-of-sale would provide an additional opportunity for review.

Allowing access by MCOs could help to prevent diversion, "doctor shopping", and improve utilziation management initiatives to ensure that MCOs may review comprehensive information about patients controlled substance prescriptions and other medications, not just those paid through the claims process. AMCP also encourages that state grants for PDMPs permitted under 42 USC 280g-3 to be extended to MCOs.

3. **Patients should have robust access to FDA‐approved medications for opioid addiction, and overdose reversal agents such as naloxone, through all private and public insurance. Furthermore, the FDA should conduct further research on the clinical risk factors and situations where the co-prescribing of naloxone with opioid prescriptions may be appropriate.**

AMCP supports increased accessibility to, and affordability of, naloxone and other rescue drugs for patients. Increased access to naloxone is shown to effectively decrease the morbidity and mortality of opioid overdoses.

Managed care organizations can continue to provide leadership by increasing access to naloxone, evaluating benefit designs in an effort to decrease potential barriers, and providing education and support to increase awareness about naloxone for patients, families, friends, and physicians. Although increasing access to naloxone will not resolve the opioid epidemic, it is an effective way to reduce opioid-related overdose and death while long-term solutions to the issue are developed and implemented.

Regarding co-prescribing of naloxone with opioid prescriptions, AMCP refers FDA to the ATAG recommendation to determine appropriate situations where co-prescribing may be appropriate. Specifically, the ATAG recommends developing quality improvement or management strategies that mitigate the risk of overdose through co-prescribing of naloxone when factors that could increase the risk of overdose are present (e.g., history of substance use disorder, opioid dosages over 50 MME/day and/or current benzodiazepine use)[2]. We encourage the FDA to work with other stakeholders to establish evidence-based criteria for co-prescribing of naloxone.

4. **FDA should develop and endorse national standards for e-prescribing.**

AMCP supports federal and state legislative and regulatory provisions that provide for the electronic transmission of prescription information between prescriber and pharmacist and supports allowing managed health care systems to have access to that electronic transmission for appropriate purposes. We believe that the electronic exchange of prescription, drug benefit, and drug information improves patient drug therapy, enhances the collection and analysis of patient data, increases operational efficiencies, and optimizes health care outcomes. However, use of this technology will require national standards ensuring patient privacy and system interoperability that are developed in concert with the federal government and patient, provider and payer groups.

5. **The FDA should update Risk Evaluation and Mitigation Strategies (REMS) Processes**

REMS are important tools that the FDA can use to reduce new opioid addiction. REMS should be integrated into prescriber and pharmacist workflow to allow for meaningful data extraction. Furthermore, because pharmacists play an important role in the administration of REMS programs, their expertise should be consulted on the design and assessment of the programs. Finally, MCOs should be allowed access to comprehensive information on prescription drug records and REMS protocol information to conduct research on effectiveness and health outcomes of opioid-related REMS.

6. **The FDA should collaborate with other government entities to develop continuing education and training strategies for prescribers and students in medical, pharmacy, dental and nursing schools about opioids.**

AMCP encourages the FDA to work collaboratively with the Centers for Disease Control and Prevention (CDC) to develop a robust education strategy for prescribers and students on the CDC Guideline for Prescribing Opioids for Chronic Pain. In addition, AMCP encourages FDA to work collaboratively with managed care organizations, who are in a unique position to provide appropriate provider education and quality incentives to health care professionals to ensure compliance with evidence-based guidelines and facilitate the use of medications used in the treatment of substance abuse disorders.

7. **Labeling and Packaging of Opioids**

AMCP encourages the FDA to consider updates to the labeling and packaging of opioids to minimize the risk of abuse and diversion and to better convey the potential harms associated with opioid therapy.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with the FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer