

December 28, 2017

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

***Re: Opioid Policy Steering Committee; Establishment of a Public Docket; Request for Comments
[Docket No. FDA-2017-N-5608]***

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 the request for suggestions, recommendations and comments relevant to the FDA's newly established Opioid Policy Steering Committee (OPSC) as published in the *Federal Register* on September 29, 2017. AMCP commends the FDA for establishing the OPSC and for seeking public input to help identify key areas of focus that the FDA can address. AMCP supports a holistic, comprehensive, and multi-stakeholder approach among health care providers, managed care organizations, and patients to more effectively address the opioid epidemic. AMCP is committed to resolving issues associated with the opioid epidemic and has established an Addiction Treatment Advisory Group which evaluates current gaps and barriers to addiction treatment services and recently developed initial recommendations to improve access to addiction treatment.^{1,2} AMCP's comments include recommendations for areas of focus that FDA can address on its own, as well as areas where FDA should collaborate with other entities to help address the opioid epidemic.

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

¹ The Role of Managed Care Pharmacy in Improving Access to Naloxone: A Viewpoint Article and Findings from the Addiction Treatment Advisory Group. *Journal of Managed Care & Specialty Pharmacy*. December 2016. Available at: <http://www.jmcp.org/pb-assets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf>

² Findings and Considerations for the Evidence-Based Use of Medications Used in the Treatment of Substance Use Disorder: A Viewpoint Article and Findings from the Addiction Treatment Advisory Group. *Journal of Managed Care & Specialty Pharmacy*. December 2016. Available at: <http://www.jmcp.org/pb-assets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf>

practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

FDA Should Ensure a Robust Body of Evidence Is Available Prior to Proposing Policy and Regulatory Changes for Opioids

As the FDA considers regulatory decision making for novel opioids, it is imperative that the FDA consider a robust body of evidence to ensure safety and effectiveness of the medications, while minimizing the impact to the opioid epidemic. To do so, the FDA should work closely with biopharmaceutical manufacturers during the drug development phase to ensure that FDA's expectations for robust clinical data, including data on public health effects, are incorporated into the clinical trial design and post-marketing surveillance. FDA should also work closely with managed care organizations to understand current evidence-based benefit designs and best practices for addressing the opioid epidemic, including cost-effective methods to increase patient access to therapy. FDA should also engage with patient advocacy groups via the patient focused drug development framework to better understand the clinical outcomes that patients suffering from both acute and chronic pain are seeking. Finally, FDA should also carefully consider the unintended consequences of designating any novel opioids as a breakthrough therapy designation or other accelerated approval pathway, as oftentimes products granted these designations come to market with limited clinical data available to truly understand their public health effects and long-term impact on addiction and behavioral health. Overall, AMCP recommends that FDA engage in a multifaceted approach that includes working collaboratively with health care providers, managed care organizations, and patients to gather the necessary level of evidence prior to proposing policy and regulatory changes for opioids.

FDA Should Consider Updates to the Labeling and Packaging of Opioids

AMCP encourages the FDA to consider updates to the label and packaging of opioids to minimize the risk of abuse and diversion, and to better convey the potential harms associated with opioid therapy. For example, the FDA should consider short course unit dose packaging (similar to current packaging for azithromycin, triazolam, and oral contraceptives) for opioids that limits maximum dosage, such as a seven day supply or a dose based upon morphine equivalent doses. Short course unit dose packaging could allow the FDA to affix a black box warning on each unit of use that would be clearly visible to a patient as traditional package inserts are often not included with a dispensed prescription. A short course unit dose package would also allow the FDA to include information pertaining to the proper storage and disposal of opioids, information on how to identify and seek help for addiction treatment, as well as other pertinent warnings and relevant information regarding the safe use of the medication. If FDA chooses this course of action, AMCP encourages it to conduct post-marketing surveillance to analyze the impact on opioid use and cost-effectiveness.

AMCP also encourages the FDA to consider updates to the label for opioids to distinguish between appropriate dose and duration for acute versus long-term use of these medications. AMCP also encourages the FDA to work collaboratively with the Centers for Disease Control and Prevention (CDC) to continually update the *CDC*

*Guideline for Prescribing Opioids for Chronic Pain*³ and consider adding the minimum effective dose to the label for opioids, and also consider the impact of patient size, weight, metabolic factors, and other patient variables on dosage. Finally, AMCP encourages the FDA to find a mechanism to ensure labels are updated regularly as real world evidence on opioids becomes available and as best practices for addressing the opioid epidemic continue to be identified.

FDA Should Develop a Robust Education Strategy for Health Care Providers and Patients Related to Opioids

AMCP encourages FDA to work collaboratively with the CDC to develop a robust education strategy for prescribers on the *CDC Guideline for Prescribing Opioids for Chronic Pain*.⁴ 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 use disorders. Engaging in a collaborative process to raise awareness and educate physicians, pharmacists, behavioral health professionals, employers, and other managed care clients about the value and appropriate use of these medications can result in improved patient outcomes and decreased total cost of care.⁵ Finally, FDA should develop training on how to safely store and dispose of opioid medications to minimize the risk of theft, accidental ingestion by children, or abuse by family members/friends.

To provide this training in a manner that is convenient for health care providers, AMCP recommends creating a FDA educational resource center that incorporates continuing education courses, webinars, podcasts, presentations and other learning media as the FDA recently did for biosimilars.⁶ AMCP also recommends that FDA create resources and educational materials that are specifically intended for patients and present information in a manner that aligns with the Agency for Healthcare Research and Quality (AHRQ) Health Literacy Universal Precautions.⁷

³ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

⁴ *Id.*

⁵ Findings and Considerations for the Evidence-Based Use of Medications Used in the Treatment of Substance Use Disorder: A Viewpoint Article and Findings from the Addiction Treatment Advisory Group. *Journal of Managed Care & Specialty Pharmacy*. December 2016. Available at: <http://www.jmcp.org/pb-assets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf>

⁶ FDA Educational Resource Center for Biosimilars. Available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>.

⁷ Agency for Healthcare Research and Quality Healthy (AHRQ) Health Literacy Universal Precaution Toolkit, 2nd Edition. Last updated. May 2017. Available at: <https://www.ahrq.gov/professionals/quality-patient-safety/qualityresources/tools/literacy-toolkit/index.html>.

FDA Should Work Collaboratively With Other Federal Agencies to Address the Opioid Epidemic

AMCP encourages FDA to work collaboratively with other federal agencies, such as the Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Diseases Control and Prevention (CDC), Drug Enforcement Administration (DEA), and the Centers for Medicare and Medicaid Services (CMS), providers, pharmacists, and patients to develop a holistic, comprehensive, and multi-stakeholder approach to address the opioid epidemic. In the spirit of collaboration, AMCP also encourages FDA to work collaboratively and communicate effectively with the patient's care team, including pharmacists and other health care providers who provide patient care and psychosocial services, to ensure a holistic and comprehensive approach to the patient's individualized treatment. Finally, AMCP encourages FDA, in collaboration with HHS and SAMHSA, to work with Congress to find a mechanism for expanding the definition of a qualified practitioner under section 303(g)(2) of the Controlled Substances Act to include additional providers, such as qualified nurse practitioners, physician assistants, and pharmacists. Enabling non-physician practitioners to prescribe buprenorphine, with the appropriate training and state licensure, is critical to expanding opioid abuse disorder treatment to a greater number of individuals throughout the nation.

FDA Should Advocate for the Modification of Federal Regulations Governing the Confidentiality of Drug and Alcohol Treatment and Prevention Records

The modification of federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), is a priority for AMCP. AMCP is committed to aligning Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) to allow appropriate access to patient information that is essential for providing comprehensive patient care. Part 2 reform is particularly important as we work to address the nation's opioid crisis. The regulations are outdated and are not compatible with the way health care is delivered currently in a team based approach. Without access to a patient's complete medical record, including addiction records, health care providers and managed care organizations are limited in their ability to care for those patients and may, for example, unknowingly prescribe, administer, dispense, or recommend an opioid to an individual being treated for addiction.

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. Access to a patient's complete medical record is critical to patient treatment, safety, and recovery. Of equal concern for patient treatment, safety and recovery, is the multitude of unintended consequences of drug to drug interactions, adverse drug reactions, and even death. Opioids also interact negatively with other controlled substances or those not scheduled by the DEA. 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.

Therefore, AMCP urges FDA to advocate for the modification of federal regulations governing the confidentiality of drug and alcohol treatment and prevention records.

FDA Should Advocate for Legislative Changes to Allow Managed Care Organizations Access to Prescription Drug Monitoring Program Data

While forty-nine states and the District of Columbia have Prescription Drug Monitoring Programs (PDMPs) that collect dispensing data for all opioid medications, including prescriptions paid for by insurance and cash, only five states provide PDMP access to Medicare plan sponsors and three states to commercial third-party payers.⁸ With limited exceptions, the current legislative infrastructure at the state-level is generally a barrier to the ability of managed care organizations to properly assess the true opioid overutilization of their members and provide the necessary care for at-risk members. Therefore, AMCP urges FDA to consider how the inability of managed care organizations to access PDMP information impacts patient care. Furthermore, AMCP urges FDA to address how opioids that are administered directly to patients should be accounted for as most states only require that controlled substances that are dispensed to a patient be reported to a PDMP and do not mandate that opioids administered in a health care setting be reported. To fully assess the risk potential for a patient, it is important to understand the full opioid use profile for a patient, including opioids that are administered in a physician's office, emergency department, or other health care setting.

FDA Should Advocate for the Adoption of Electronic Prescribing for Opioids

Electronic transmission of prescription information offers benefits over written prescriptions in terms of accuracy, storage capacity, accessibility, security and productivity. Benefits of electronic prescriptions include the reduction of errors because of misinterpretation of handwritten prescriptions, confusion between similar-sounding drug names during transmission of prescription orders, and order-entry errors. Electronic prescribing systems alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy, enabling the prescriber to adjust the prescription before the pharmacy dispenses the drug. Electronic prescribing systems also allow prescribers to access the formulary for a patient's prescription drug benefit, aiding a prescriber in selecting a therapy for which the patient has coverage, in addition to any clinical edits that may be present.

Specifically important for opioids, electronic prescribing allows prescription information to be securely transmitted directly to the dispensing pharmacy, reducing the possibility of fraudulent prescribing. Electronic prescribing prevents patients from photocopying, altering, or otherwise tampering with written prescriptions prior to presentation to the pharmacy. Therefore, AMCP encourages FDA to advocate for the adoption of electronic prescribing as the preferred mechanism of prescribing opioid medications to substantially reduce the prevalence of fraudulent or tampered prescriptions.

⁸ Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer