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Managed Care
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**Food and Drug Administration Meeting: Opioid Policy Steering Committee - Prescribing Intervention -
Exploring a Strategy for Implementation
Docket No. FDA-2017-N-6502
January 30, 2018**

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The Academy of Managed Care Pharmacy (AMCP) thanks the FDA for the opportunity to provide comments before the Opioid Policy Steering Committee. My name is Soumi Saha, and I am the Director of Pharmacy & Regulatory Affairs for AMCP.

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.

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 recently provided detailed comments to the FDA on areas on focus for the OPSC, but for the purposes of today's discussion I will focus on the following three areas: 1) REMS; 2) Labeling, Packaging, Storage, and Disposal; and 3) Additional Focus Areas where AMCP feels that the FDA can be actively involved in combating the opioid epidemic.

Before I begin answering the questions posed by the FDA specific to today's hearing, I wanted to share a guiding principle that AMCP believes is critical in helping to address the opioid epidemic, and that is focusing on evidence-based strategies before implementing any regulatory or policy changes. AMCP encourages the FDA to use evidence in furthering policy and regulatory changes that can help manufacturers, health plans, and patient advocacy groups combat the abuse of opioids:

- **Manufacturers**
 - 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 clinical trial design and post-marketing surveillance requirements.
 - FDA should carefully consider the unintended consequences of designating any novel opioids as a "breakthrough" therapy designation or other accelerated approval pathway. Products with such a designation often come to market with limited clinical data to truly understand their public health effects and long-term impact on addiction and behavioral health.

- Health Plans
 - FDA should 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.
- Patient Advocacy Groups
 - The FDA should 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.

In regards to REMS programs, it is crucial that REMS are integrated into physician and pharmacist workflow and allow for meaningful data extraction. 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. Consideration should be given to the development of a categorization system similar to drug recalls to clearly define what actions must be taken for a Class I vs. Class II recall. Finally, managed care organizations should be allowed to have comprehensive information on prescription drug records and REMS protocol information to conduct research on effectiveness and health outcomes of opioid-related REMS.

In regards to labeling, packaging, storage, and disposal, 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 the current packaging for azithromycin, for opioids that limit maximum dosage, such as a seven-day supply or a dose based on morphine-equivalent doses. Another benefit of this type of packaging is that black box warnings could be affixed on each unit dose 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 medication.

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. The FDA should also consider adding minimum effective dose while considering the impact of patient size, weight, metabolic factors, and other variables on dosing. Finally, the FDA should ensure labels are updated regularly as real-world evidence becomes available.

AMCP encourages the 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. 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.

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 and friends. These resources and

materials should be aligned with the Agency for Healthcare Research and Quality's Health Literacy Universal Precautions.

In regards to additional focus areas, AMCP believes that the FDA should collaborate with Congress and other federal agencies to address the opioid epidemic:

- Work with Congress to align confidentiality of drug and alcohol treatment and prevention records with HIPAA to allow access to information essential for providing comprehensive patient care. This access would allow health care providers and managed care organizations to appropriately 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.
- FDA should also work with states to provide access to state Prescription Drug Monitoring Programs for managed care organizations. While AMCP has no position on a national database, we do support interoperability of PDMPs that are integrated into EHRs and dispensing systems. This interoperability would address workflow issues that can act as a barrier to proper use of PDMPs.
- The FDA can work with the DEA to promote widespread adoption of electronic prescribing of controlled substances, which is now legal in all states, but grossly underutilized. The Office of the National Coordinator can work to enable access to prescribing guidelines within prescriber workflow, as well as promote error reduction, order-entry errors, and alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy. Finally, SAMHSA can expand the definition of "qualified practitioner" under the Controlled Substances Act to include nurse practitioners, physician assistants, and pharmacists.

In summary, AMCP suggests that the OPSC consider the following issues:

- Incorporate evidence-based policy and regulatory changes for manufacturers, managed care organizations, and patient advocacy groups;
- Consider updates to packaging and labels to meet the needs of patients;
- Develop and distribute educational resources for providers and patients; and
- Collaborate with other federal and state agencies and Congress to address gaps in current policies.

Again, I thank you for the opportunity to provide these comments and I am happy to take any questions.

Comments Before the FDA Opioid Policy Steering Committee

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January 30, 2018

Academy of Managed Care Pharmacy



Vision

Managed care pharmacy - improving health care for all



Mission

To empower its members to serve society by using sound medication management principles and strategies to improve health care for all



AMCP

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

Agenda

- REMS
- Labeling, Packaging, Storage, and Disposal
- Additional Focus Areas

Policy and Regulatory Changes Should be Evidence-Based

Manufacturers

- During drug development phase, work with manufacturers to ensure expectations for robust clinical data are met and data generation on public health effects are incorporated into clinical trial design and post-marketing surveillance
- “Breakthrough” designation should be used with caution because an accelerated approval pathway oftentimes means products come to market with limited clinical data available to truly understand long-term effects on addiction and behavioral health

Health Plans

- Engage health plans to understand evidence-based benefit designs and best practices for addressing the opioid epidemic, including cost-effective methods to increase patient access to therapy

Patient Advocacy Groups

- Work with patient-focused drug development framework to better understand the clinical outcomes that patients suffering from acute and chronic pain experience

Any REMS Program Must Include Pharmacists

Any REMS process for opioids should include a standard electronic process that can be integrated into EHRs and workflow and allows for meaningful data extraction. These programs should be flexible enough so that they may be adapted to best meet the needs of new therapies entering the marketplace.

Pharmacists should be consulted on the design and assessment of REMS due to their important role in the administration of REMS programs.

Consideration should be given to the development of a categorization system similar to drug recalls to clearly define what actions must be taken for a Class I vs. Class V recall.

Allow managed care organizations that have comprehensive information on prescription drug records and REMS protocol information to conduct research on effectiveness and health outcomes of opioid-related REMS.

Packaging and Label Updates Could Encourage Appropriate Use

Short-Course Unit Dose Packaging

Limit maximum dosage based on days' supply or morphine-equivalent dosage (similar to azithromycin)

This packaging would also provide opportunity to educate consumers on proper storage and disposal of opioids

Black Box Warnings could be attached to modified packaging

Label Updates for Acute vs. Chronic Use

Distinguish between appropriate doses and duration for acute use and long-term use

Consider adding minimum effective dose while considering the impact of patient size, weight, metabolic factors, and other variables on dosing

Ensure labels are updated regularly as real-world evidence becomes available

Create Educational Resource Center for Health Care Providers & Patients



Work with CDC to promote Guidelines for *Prescribing Opioids for Chronic Pain*



Collaborate with managed care organizations to provide appropriate provider education and quality incentives to prescribers



Develop training for patients and providers on the safe storage and disposal of opioids



Make sure materials for patients are aligned with AHRQ's Health Literacy Universal Precautions

Collaborate with Other Federal & State Agencies

Congress

- Align confidentiality of drug and alcohol treatment and prevention records with HIPAA to allow access to information essential for providing comprehensive patient care
- Access would allow health care providers and managed care organizations to appropriately care for patients and avoid prescribing, administering, dispensing or otherwise providing opioids to an individual being treated for addiction
- Pharmacist access to medical records permit review at point-of-sale

States

- Provide access to state Prescription Drug Monitoring Programs (PDMPs) for managed care organizations
- AMCP has no position on a national database, but does support interoperability of PDMPs that relieves burden and is integrated into EHRs and dispensing systems

Collaborate with Other Federal & State Agencies

Drug Enforcement Agency

- Promote widespread adoption of electronic prescribing of controlled substances (EPCS) which is now legal in all states, but grossly underutilized.

Office of the National Coordinator

- Enable access to prescribing guidelines within prescriber workflow.
- Promote error reduction, order-entry errors, and alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy.

SAMHSA

- Expand the definition of “qualified practitioner” under the Controlled Substances Act to include nurse practitioners, physician assistants, and pharmacists.

Key Takeaways

Incorporate evidence-based policy and regulatory changes

Consider updates to packaging and labels to meet the needs of patients

Develop and distribute educational resources for providers and patients

Collaborate with other federal and state agencies to address gaps in current policies

Thank You!

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