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Lauren K. Roth
Associate Commissioner for Policy
Office of the Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave
Silver Spring, MD 20993

Docket No. FDA-2021-N-0275

Submitted via regulations.gov

Dear Ms. Roth,

Every American deserves affordable, comprehensive coverage that allows them to access equitable and high-quality care. Americans should also have the personalized health care information they need, when they need it to make better, more informed decisions before seeking and receiving care. With this shared commitment in mind, AHIP[1] appreciates the opportunity to provide comments for the Administration's workshop, "Morphine Milligram Equivalents (MME): Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions."

Overview

The opioid crisis is devastating its victims, their families, and their communities across the country. Unfortunately, over the past year, opioid overdose deaths have increased.[2] The opioid crisis must be addressed in a comprehensive way, with everyone working together. This includes local governments, law enforcement and the justice system, social services agencies, community housing programs, Medicaid programs, physicians and other health care providers, pharmacists, health insurance providers, and pharmaceutical companies. Health insurance providers have been part of the solution by working closely with all stakeholders and embracing a comprehensive approach encompassing prevention, early intervention, and substance use disorder treatment and recovery.

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.
[2] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Prescribed and Illicit Opioids Can Lead to Ongoing Challenges

Despite appropriate attention paid to treatment and recovery from addiction, the crisis is not fueled solely by illicit opioid use or exposure to dangerous synthetic opioids. Many factors have caused and contributed to the crisis. One of the triggers for opioid use disorders may begin with opioids prescribed by a clinician to help patients manage their pain that may lead to overuse, dependence and addiction.

Patient-Centered, Evidence-Based Care

Care must be individualized and patient-centered, as the same MME dosages can impact people differently. Our member health insurance providers have reported that opioid overdoses have occurred with patients who have been prescribed opioid prescriptions that are lower than 50 MME per day. Clearly there is no specific MME level that is always safe. There is no simple formula or one-size-fits-all approach to differentiate safe or unsafe opioid prescriptions. While clinical and prescribing guidelines can be helpful, care should be managed by clinicians with specifically relevant expertise, tailored to each patient's individual needs and pain treatment goals, and should ensure appropriate patient monitoring on an ongoing basis while prescribed opioids.

More Research Needed

Further research is needed to close knowledge gaps associated with opioid prescribing, dosages, and risk factors of various populations to better inform clinicians, patients and policymakers. FDA has an important role to play, as do other stakeholders such as the National Institutes of Health, to lead research efforts such as comparative effectiveness studies of prescription opioids including dosages, various formulations for different types of pain (e.g., acute versus chronic pain, pain associated with cancer) and how these approaches to treatment and dosing compare to non-opioid and non-pharmacological treatment modalities to manage various types of pain.

This research could be used to enhance existing risk assessment tools (e.g., the Opioid Risk Tool, Drug Misuse Index) that prescribers use when evaluating patients for treatment with opioids. It would be helpful for providers who treat patients with pain to have clear, evidence-based clinical guidelines that may include a single pain relief potency index for medications that compare and contrast the pain relief properties for available pain relief options, both pharmacological and non-pharmacological.

Guidance for Clinicians

If research and scientific evidence supports the issuance of clinical guidance, FDA and other stakeholders should consider a more nuanced and coordinated approach to evaluating opioid

dosages, accounting for factors beyond MME. There are numerous other patient risk factors for overdose that are not specific to the dosages. Socioeconomic factors, demographics, comorbidities, family and individual history of substance abuse, and co-prescribed medications can contribute to patient risks associated with taking opioids. For example, an elderly patient with chronic obstructive pulmonary disease (COPD) with an opioid prescription for a relatively low MME may be at higher risk of an overdose than a young individual without any comorbidities who is taking a higher MME of opioids.

Before initiating opioid treatment, clinicians need tools available to appropriately ascertain a patient's benefit and risk tradeoff from the use of these medications and alternative treatments that may be effective. Health insurance providers have some tools that can help clinicians including analysis of payer claims, pharmacy benefit manager (PBM) data, and information from electronic health records to help identify patients' comorbidities, and patients' social and economic risk factors that may impact their outcomes. If guidance is developed, it is important that FDA coordinates with health insurance providers, the Centers for Disease Control and Prevention, and other authorities to ensure consistent clinical guidance.

Increased Coordination and Collaboration

The SUPPORT Act calls on the FDA to work with the National Academies of Science, Engineering, and Medicine (NASEM) to develop a prescribing framework that would develop evidence-based guidelines on opioid prescribing to help prescribers identify medical and surgical conditions for which opioids are prescribed. As research is conducted and tools developed, it is important for government agencies involved with addressing the opioid crisis to align and coordinate initiatives to help ensure successful implementation of the opioid framework. While FDA is tasked with this specific provision, such guidelines will impact other entities within the Department of Health and Human Services, the Drug Enforcement Agency, state agencies, and other public health organizations. Coordination and collaboration across the public and private sector will be needed in order to make progress in addressing the crisis.

Conclusion

Health insurance providers will continue to work to combat the opioid crisis among their members and will collaborate with other stakeholders to protect patient safety while maximizing outcomes. The strategies and challenges outlined can assist in the development of future research and clinical guidance, and we appreciate the work that the FDA has done to address this crisis.

Thank you for the opportunity to provide these comments. We look forward to further efforts that recognize this broad engagement, and we stand ready to assist FDA in its efforts to promote appropriate access to pain care and prevent opioid addiction.

Sincerely,

Kate Berry
Senior Vice President