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March 12, 2018

VIA ELECTRONIC SUBMISSION **Docket Number:** FDA-2017-N-6502

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

Re: Docket No. FDA-2017-N-6502, Comments for *Opioid Policy Steering Committee: Prescribing Intervention – Exploring a Strategy for Implementation*

On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to provide the comments below to the Opioid Policy Steering Committee regarding both improving the safe use and limiting the misuse of opioid analgesics and decreasing the occurrence of patients becoming addicted, and potential suicides due to overdose.

The ACOFP is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes, and ensuring that patients receive high-quality care.

Overall, as an organization our osteopathic family medicine physicians practice in a variety of settings, including solo, small, rural, group, Native American Indian and Alaska Native healthcare systems, and Alternative Payment Model (APM) systems. Our members treat many of the patients suffering from chronic pain and those who suffer from opioid addiction. We recognize the importance of addressing the ongoing opioid crisis that faces the nation.

Primary care physicians (PCPs) are at the frontlines of care and are often the first to uncover the presentation of behavioral health symptoms, including opioid addiction. PCPs are also in the unique position of diagnosing, treating and prescribing opioids, when medically necessary and clinically indicated. For these reasons, we believe PCPs are in a vital position to provide input on improving safe opioid use and how to limit abuse.

Our full comments are detailed on the following pages. Thank you for the opportunity to share these with you. Should you need any additional information or if you have any questions, please feel free to contact Debbie Sarason, Manager, Practice Enhancement and Quality Reporting at (847) 952-5523 or debbies@acofp.org.

Sincerely,

Rodney M. Wiseman DO, FACOFP, dist.

Patient Access to Clinically Appropriate Items and Services

ACOFP recognizes and supports efforts to combat the opioid crisis. As family physicians, our primary concern is to ensure that clinically appropriate items and services are efficiently delivered to patients. This includes balancing pain management with the appropriate prescribing and use of opioids, as well as the necessary follow-up to monitor for misuse.

Recently, there has been a heightened focus on prescribing practices as a potential contributor to the opioid epidemic. We believe, however, that this misrepresents the reality that most opioid overdoses are a result of illegally obtained opioids, such as heroin and fentanyl. [1] We are concerned that this misplaced focus will result in unintended consequences. Specifically, we are concerned that patient access to clinically appropriate medications will be restricted, resulting in under-treatment of pain, causing reduced quality of life, undue suffering, and other adverse outcomes.

ACOFP strongly supports patient access to clinically appropriate medications. We agree that there should be additional guidance and clarification on clinical appropriateness regarding opioid prescribing, as well as education on monitoring for misuse, but we do not believe imposing broad and overly burdensome requirements is appropriate.

We also believe that protections and safeguards should exist for physicians who prescribe (or choose not to prescribe) in manners consistent with best medical practices and clinical guidelines. Clinically appropriate services should be reimbursed at an appropriate rate to ensure they are provided when needed. We believe additional clarity on these protections will ensure patients continue to have access to needed treatment.

A sizable subset of ACOFP members treat patients in rural health care settings and the underserved. We have witnessed firsthand the correlation between limited patient access to critical health care treatment and services, and the avoidable cost this places on the health care system.

With regards to opioids, if patients have limited access, they will also have untreated pain. Consequently, it is possible that patients will seek alternative medications or alternative sources for pain management. We have significant concerns because of the prevalence of deadly, illegal opioid alternatives and that restricting patient access to clinically appropriate services will drive patients out of doctors' offices.

Instead of placing limitations on prescribing practices, we urge the FDA to work with other agencies, states, and key stakeholders to approach this issue more holistically. State regulations should be more user-friendly and the process of data collection not add an additional burden to the practice of medicine.

ACOFP stands ready to work with the agencies to develop appropriate guidelines and take meaningful steps to address the opioid epidemic.

[1] See, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates.

Controlling Opioid Prescribing

ACOFP recognizes that prescribing practices should be assessed and evaluated. However, we believe that efforts like the recently proposed electronic Clinical Quality Measure (eCQM) to assess physician performance based on opioid prescriptions, will exacerbate patient access issues and ignores the other elements involved in the opioid crisis.

ACOFP shared with the Centers for Medicare & Medicaid Services (CMS) our concerns with the proposed eCQM. We believe a likely unintended consequence of restricting opioid prescriptions or tying prescribing to physician performance scores is a lack of physicians willing to prescribe any opioids. Subsequently, we believe this will result in the following adverse impacts, which are out of the PCP's control:

1. Patients will seek alternative pain management solutions. As described above, if patients recognize that they cannot obtain opioids for their pain, they will seek alternative solutions, exacerbating the opioid crisis, which is significantly impacted by the illegal importation and use of heroin and fentanyl.[2]

2. Patients will forego regular PCP visits because they will feel that they cannot obtain needed treatment. If patients do not believe they will receive effective pain management solutions from their PCPs, they will be more inclined to forego regular PCP visits. Consequently, PCPs who could identify behavioral health issues, such as an opioid addiction, will miss this opportunity to follow-up on patients who they have cared for over time. Also, patients, who no longer are treated for their chronic pain by one doctor, may "doctor shop" until they find one who will treat their pain by prescribing opioids.

3. Physicians will be penalized through various satisfaction surveys and other quality measures for following clinically appropriate prescribing standards. Patient satisfaction surveys already have and will continue to skew negatively against physicians who limit or do not prescribe opioids. Efforts to limit opioid prescribing will result in physicians practicing against a prescribing threshold to avoid poor quality scores, instead of working with patients on an individualized treatment plan.

ACOFP is also concerned with efforts to limit opioid prescribing based on duration or dosage. Specifically, a limited duration of opioid prescribing runs in opposition to the CDC definition of chronic pain. In the March 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, chronic pain is defined as, "pain that typically lasts >3 months or past the time of normal tissue healing. What is needed is evidence based guidelines for both acute and chronic pain.

[2] See, Testimony of Daniel D. Baldwin, Section Chief, Office of Global Enforcement, Drug Enforcement Administration, U.S. Department of Justice. Delivered to the Senate Homeland Security & Governmental Affairs Permanent Subcommittee on Investigations. Available here: https://www.hsgac.senate.gov/subcommittees/investigations/hearings/combatting-the-opioid-crisis-exploiting-vulnerabilities-in-international-mail.

Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause."[3] We are concerned that a rigid directive based on duration takes away the physicians' ability to utilize best medical judgement in treating chronic pain patients.

In terms of dosage, we urge that if the FDA pursues dose limits, the agency ensures limits are not quantified by milligram morphine equivalents (MME). MME dosages would put family physicians in a situation where they must dose-convert. According to Webster and Fine, "Recent evidence suggests that the use of dose conversion ratios published in equianalgesic tables may lead to fatal or near-fatal opioid overdoses."[4] Further, they found that the use of dose conversion ratios found in equianalgesic tables may be an important contributor to the increasing incidence of opioid-related fatalities. Therefore, we are concerned that setting a MME dose limit and subsequent dose conversion may exacerbate the opioid crisis.

It is important for physicians to be specific about how they write an opioid script. For example, it may be common for a physician to write a script for Vicodin which states, "take 1-2 pills every 4-6 hours." Patients may interpret this to mean, take 2 pills every 4 hours. When returning to the physician early because they have run out, the physician thinks they are abusing the medication. A better solution may be to write the most conservative dosing on the script – "take 1 pill every 6 hours."

Certain states and payers are now starting to require physicians to put diagnosis codes on opioid scripts. Telling physicians what diagnosis is approved for opioid use does not allow the physician to look at the entire patient's medical history to determine what medication is appropriate.

Addressing the Opioid Epidemic

ACOFP believes the opioid crisis must be treated broadly and from a variety of angles. We believe each stakeholder and industry component has a role to play in combatting the opioid crisis, beginning with insurers. Currently, insurance coverage remains the most significant barrier to transitioning patients from addictive medications to medications with less abuse potential. For example, some insurers will only cover the less expensive (and highly addictive) short-acting opioids, but will not cover long-acting hydrocodone with abuse deterrent, or more expensive but less addictive alternatives like a Butrans patch.

In the past, non-steroidal anti-inflammatory drugs were used broadly to manage acute and chronic pain. They were linked with gastrointestinal problems such as bleeding ulcers, and perforations, as well as dangerous to deadly cardiovascular events including thrombolytic events, and stroke. As a result, many were removed from the market. Celecoxib is still available by prescription. It has a black box warning for gastric and cardiovascular events. NSAIDs may not be appropriate for the elderly population who may be pre-disposed to gastric, cardiovascular, kidney and/or liver disease. (Celecoxib Package Insert).

[3] Available here: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[4] Webster L., Fine P. Review and Critique of Opioid Rotation. Pain Medicine 2012; 13:562-570.

Aspirin, Motrin, Aleve, and other over-the-counter NSAIDs, or NSAID combinations are available to patients who may resort to these drugs if unable to obtain an appropriate opioid prescription from a physician. Dangerous and deadly side-effects include: ulcers, perforations, internal bleeding, kidney damage or failure, and liver damage/failure. Unfortunately, patients may not associate these effects with an over-the-counter medicine and take more than what is listed in the prescribing information.

Forty-six states have chosen to legalize cannabinoids for medicinal purposes, although it is still against Federal Law. It is unclear what role cannabis has in treating pain. With no guidelines, it would be impossible for family physicians to confidently treat pain with this drug. The use of cannabinoids could lead to the increased use of illicit drugs like heroin, cocaine, ecstasy, and methamphetamine as opioid availability declines. This will only exacerbate the crisis.

Opioids have an important role in treating patients suffering from cancer pain. But once the patient has passed, there is the issue of what happens to the remaining medication. What assurance do we have that it is disposed of properly? This is true of other situations where an acute episode of pain resolves and there are remaining pills to be disposed of.

ACOFP physicians stress the importance and need for the development of new medications that are non-addictive, have favorable safety profiles, and are cost-effective. Currently, deterrent medications only prevent intravenous use. An alternative is needed to treat patients' pain.

ACOFP is also committed to ensuring its members obtain training and certification in medication-assisted treatment (MAT) for substance use disorders to bolster their osteopathic training and holistic treatment of patients. We recognize the distinct need for MAT and the benefits the certification provides in terms of recognizing potential problems and how to address them.

While not within FDA's authority, we also believe that CMS reimbursement for non-opioid pain management therapies needs to be revisited and updated. We believe there are opportunities to change routine practices so that we are no longer a "prescribe-first" health care system. Non-pharmacological interventions, such as osteopathic manipulative treatment (OMT) is an area to be explored, either alone or in conjunction with analgesics. OMT is hands-on care that involves using the hands to diagnose, treat, and prevent illness or injury.[5] OMT can help to alleviate and prevent certain types of pain, thereby reducing the need for additional medications.

Conclusion

[5] American College of Osteopathic Family Physicians. Website. Accessed March 1, 2018

ACOFP urges the FDA to consider the on-the-ground experience of PCPs and the reality of the opioid crisis. Our members will continue to work with our patients to provide clinically appropriate medications and services to ensure patients are not unnecessarily suffering from chronic pain. Further, we commit to working to address over-prescribing, but do not believe prescribing practices are the sole issue. Additional efforts must be made by industry to: (1) curb access to illegal drugs; (2) ensure non-addictive and non-opioid therapies are covered by insurance companies; (3) develop new, non-addictive analgesics; and (4) ensure alternative therapies and treatments are appropriately reimbursed.

We ask that the FDA consider these comments and the stark reality that faces many patients and their PCPs. Further, we offer our continued support to work together on addressing the opioid epidemic.