May 14, 2018

The Honorable Eric Greitens
Governor, State of Missouri
Capitol Building, Room 216
Jefferson City, MO 65101

Randall Williams, MD, FACOG, Director
Missouri Department of Health and
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Dear Governor Greitens, et. al.:

The Missouri Chapter of the American College of Physicians (MO-ACP) would like to express our concerns for the new Missouri Medicaid Opioid Prescribing Intervention (OPI) Program. The MO-ACP represents a broad range of physicians in the state with a membership of nearly 2,300 internal medicine physicians, residents and students. We also represent many physicians who are primary care providers who may be affected by this program. As a practicing internal medicine physician who has treated patients with chronic pain for 25 years, the CDC guidelines for prescribing opioids were a step forward.[1] However efforts to enforce them may have serious unexpected consequences.

Much has changed over the last twenty years on how chronic pain is managed. Unfortunately, chronic opioids were recommended by many organizations and experts.[2] It is now clear that chronic opioids have great risk. Fortunately overall opioid prescribing appears to have peaked in 2010.[3] Yet with the continued high rates of opioid overdose and opioid misuse/addiction, more needs to be done.

While the CDC guidelines provide extensive details on how best to initiate opioids and how to monitor patients as the dose is increased (see recommendations #1- 5), the guidelines provide little guidance for how best to manage patients who are receiving chronic stable opioid medications. Recommendations #7 and 8 apply to these patients. Nowhere in these recommendations does it state that there is a cut-off for patients already on opioids. Moreover, the recommendation specifically states, to consider tapering only if harms outweigh the benefits. The recommendation does state that if patients are taking high-risk regimens (e.g., dosages ≥50 MME/day or opioids combined with benzodiazepines) AND there is no evidence of benefit, then the physician should work to reduce or discontinue the opioid. Nowhere in the CDC guidelines does it state that all patients on higher doses of opioids should be tapered to 90 MME or less.

The CDC guidelines made a clear distinction in how to manage patients when starting opioids and how to treat those who have been on stable opioids. This is due to the absence of clinical data on how best to manage patients who have been on chronic opioids for long term. While recent trials do show patients had some improvement when tapered off opioids, these studies only looked at patients who

voluntarily agreed to dose reduction.[4] Also these trials of opioid tapers usually included extensive support for the patients. No prospective trials of forced reductions have been published.

It is important to emphasize that the CDC guidelines were never meant to be prescriptive:

Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.[3]

It is my clinical experience that tapering opioids for patients who have been on them for years is extremely challenging. The CDC guidelines acknowledge this by stating that "Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages." (Recommendation 5) Opioid tapers should be slow enough to minimize symptoms and signs of opioid withdrawal. The guideline also state tapers "should be individualized based on the patients goals and concerns." Also it states that tapers may need to be stopped and restarted and may need to be slowed as the patient reaches lower doses. The MO OPI proposes to taper in a "step-wise" fashion patients on chronic table opioids of 300 MMEs or more. However In the absence of a clear risk e.g. recent evidence for overdose, patients on these high doses should have their tapers started and managed by either the prescribing physician or one expert in pain management. For most patients on these high doses it is very likely that their tapers will need to be slow and likely need some breaks.

There is also increasing evidence that using a binary cut-off like the proposed 90 MME will likely introduce incentives to push patients to below this level quickly. There have been increasing reports of patients being forced to decrease their prescription opioids to a set lower level resulting which resulted in suicides, overdoses, and clinical deterioration.[5,6]

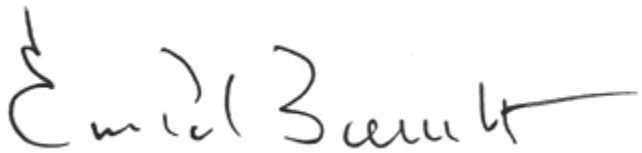
Another area of great concern, is the overall lack of alternatives to opioids for chronic pain treatment for Missouri Medicaid patients. The information sheet included in the OPI letter to physicians addressing the "Use of opioids for 60 or more days in absence of a diagnosis supporting chronic use" specifically recommends "non-pharmacologic options (such as cognitive behavioral therapy, exercise, physical therapy, relaxation)." However none of these are either routinely covered by Missouri Medicaid or are readily accessible. Also non-opioid medications which may be used in place of opioids or assist in the taper, are either denied, non-formulary, or require cumbersome prior authorizations, e.g. topical diclofenac, lidocaine patch, pregabalin, duloxetine.

The push to treat pain aggressively when pain was added as the fifth vital sign was part of the storm that we are navigating today. While well-intentioned, the use of high dose chronic opioids occurred when there was little scientific evidence for this practice. I worry that practices to rapidly taper and the use of binary set limits e.g. 90 MMEs, also lack good scientific evidence. More physicians now feel that chronic high dose opioids are a bad idea but rapid tapers without the patient's buy-in is a worse idea.

The opioid overdose and addiction problem in Missouri continues to worsen. We physicians see the devastation that has resulted from these problems. The MO-ACP wishes to work with the state and support the goals to limit opioid prescribing, increase access for alternate non-opioid treatments for pain, increase access for treatment of substance use disorder, and establish a state prescription drug

monitoring program. We appreciate the opportunity to express our thoughts and make ourselves available for any questions. Please feel free to contact me at (314) 454-8225.

Sincerely,



Ernie-Paul Barrette, MD, FACP
Chair, Health and Public Policy Committee
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Endnotes:

1. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR 2016;65:1-49
2. Ballantyne JC, Mao J. Opioid therapy for chronic pain. New Eng J Med 2003;349:1943-53.
3. Vital Signs: Changes in opioid prescribing in the United States, 2006-2015. MMWR 2017;66:697-704
4. Frank JW, Lovejoy TI, Becker WC, Morasco BJ, Koenig CJ, Hoffecker L, et al. Patient Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy: A Systematic Review. Ann Intern Med. 2017;167(3):181–91.
5. Weeks WB**.** Hailey. JAMA. 2016;316(19):1975–76.
6. Szalavitz M. Cracking Down on Opioids Hurts People With Chronic Pain2017 November 7, 2017. https://tonic.vice.com/en_us/article/8x5m7g/opioid-crackdown-chronic-pain-patients-suicide Accessed May 4, 2018.