California Medical Association
Physicians dedicated to the health of Californians

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

March 5, 2017

Submitted electronically to www.regulations.gov

RE: CMS-2017-0163 for "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter

Dear Administrator Verma:

On behalf of our more than 43,000 physician and medical student members, the California Medical Association (CMA) would like to thank you for accepting comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare Part D Draft CY 2019 Call Letter.

Like the nation, California has been faced with a serious health care dilemma: how to prescribe controlled substances safely and effectively to relieve pain, while simultaneously reducing the risk of prescription medication misuse, addiction and overdose. CMA has been supportive of efforts to address the complicated issues related to prescription opioid misuse and overdose, and has advocated for a well-balanced approach to opioid prescribing and treatment that considers the unique needs of individual patients. However, CMA is opposed to regulations that would arbitrarily restrict a patient's ability to receive effective, patient-specific, evidence-based, comprehensive pain care. CMA is concerned that the effectiveness of several of the policies proposed by the draft call letter in reducing opioid overdoses have yet to be determined, and legitimate concerns exist regarding unintended consequences that result from restrictive policies.

Successful California Efforts on Opioid Crisis

The CMA and California as a whole has proactively addressed these issues in our state. In 2014, the Medical Board of California (MBC) adopted guidelines entitled, "Guidelines for Prescribing Controlled Substances for Pain," which were largely based upon CMA's white paper on safe prescribing of opioids. CMA suggests that CMS look towards and reference the MBC guidelines as a model document for the prescribing of controlled substances:
http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

CMA Guidelines on Prescribing Controlled Substances: http://www.cmanet.org/resource-library/detail/?item=prescribing-opioids-care-amid-controversy

Although much work remains to be done, California is seeing positive results without implementing restrictive duration and dosage limitations in law – a testament to the comprehensive statewide and local strategy, emphasis upon prevention and treatment, and role of the medical and public health community. Some key takeaways include the following:

- From 2013-2016, California had the second lowest per capita rate of filled opioid prescriptions, and that rate dropped even more in 2016 – California now has the lowest per capita opioid prescribing rate in the country.[1]

- Unlike other states, California has seen its prescription opioid overdose rate decrease over the last two years – and in 2015, the age-adjusted drug overdose death rate was 11.3 per 100,000, which is one of the lower rates in the country.[2]

While California has achieved promising outcomes with a multi-faceted approach to addressing opioid misuse, CMA thinks more emphasis should be placed upon demand-side policies such as increasing access and availability of medication-assisted treatment (MAT), and reducing stigma associated with drug use and addiction. Helping patients obtain adequate treatment for opioid use disorder can immediately save lives, and stresses the concept that addiction is a brain disease and should be treated as such. Many of the proposed policies in the draft call letter instead focus upon supply-side interventions aimed at reducing opioid prescriptions – despite that from 2013 to 2016, opioid prescriptions in the United States decreased by 43 million, a nearly 17 percent decrease. This is complicated by the fact that the drugs responsible for these overdose death rates are changing. In 2016, national estimates indicate that among the more than 64,000 drug overdose deaths, the sharpest increase occurred among deaths related to illicit opioids, with fentanyl and fentanyl analogs (synthetic opioids) producing over 20,000 overdose deaths alone. Further, when combined with heroin overdose deaths, both classes of illicit drugs account for approximately two-thirds of drug overdose deaths in the United States.[3]

CMA Recommendation: Adopt the Medical Board of California Guidelines to voluntarily guide physicians in prescribing controlled substances for pain for Medicare patients. (http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf)

[1] IMS Health, National Prescription Audit (NPATM). Preliminary Update on Opioid Pain Reliever (OPR) Prescription Rates Nationally and by State: 2013-2016.

[2] CDC. Drug Overdose Death Rates by State. 2015. https://www.cdc.gov/drugoverdose/data/statedeaths.html

[3] NIDA. Overdose Death Rates/ https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

Comments and Recommendation Regarding Proposed Strategies of CMS Draft Call Letter:

1) **Identification of high risk beneficiaries who use "potentiator" drugs (such as gabapentin and pregabalin in combination with prescription opioids to ensure that plans provide appropriate case management**. The Food and Drug Administration (FDA) has approved gabapentinoids for the treatment of postherpetic neuralgia (gabapentin and pregabalin), fibromyalgia (pregabalin), and neuropathic pain associated with diabetes or spinal cord injuries (pregabalin). CMA does not support restricting the use of gabapentin and pregabalin as agents in conjunction with a pain control program as they may lower the need for opioids. A meta-analysis that examined the use of gabapentin in post-operative settings found that the drug improves the analgesic efficacy of opioids both at rest and with movement, reduces analgesic consumption and opioid-related adverse effects.[4]

CMA Recommendation: Eliminate the "potentiator" drug prohibition as these medications may lower the need for opioids.

2) **Tracking the percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.** The California MBC Guidelines make reference to the potential risk involved in concurrently prescribing benzodiazepines and opioids, however, they abstain from recommending avoidance of these two medications together. While co-prescribing of benzodiazepines and opioids may increase risk of overdose, there are instances in which it is appropriate to prescribe both concurrently. In cases where benzodiazepines are being considered for treatment of people taking opioids, a consultation and potential co-management with a mental health professional and a specialist in pain medicine is recommended. This reflects the situation of patients with comorbid conditions causing both pain and anxiety. In the case of chronic pain, using combinations of medications may be necessary to treat the patient, but clinicians should exercise caution and due diligence with managing these patients.

CMA Recommendation: Eliminate the recommendation to always avoid concurrent use of opioids and benzodiazepines, and advise cautious, case-specific use of combined therapy.

[4] Peng PW, Wijeysundera DN, Li CC. Use of gabapentin for perioperative pain control – A meta-analysis. Pain Research & Management : The Journal of the Canadian Pain Society. 2007;12(2):85-92.

3) **Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at 90 morphine milligram equivalent (MME), with a 7 days' supply allowance. Implementing a supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME).** Instituting hard caps on duration and dosage limits of prescription opioids fails to appropriately recognize the complexities involved in treating pain and imposes a "one-size-fits-all" solution for pain management that is short-sighted and could have direct consequences on patient care. CMA agrees that opioid therapy (as with ALL pharmacological therapy) should be initiated at the lowest possible effective dose. A variety of prescriber behaviors, patient/user behaviors and characteristics, and environmental and systemic determinants exist that contribute to opioid overdose mortality. These factors may operate independently but interact in complex ways according to geography and population. Accordingly, preventing additional opioid-related mortality will require interventions that address multiple determinants that are tailored to specific locations and populations. For example, in California, local opioid safety coalitions have been funded to bring together a broad group of community stakeholders committed to decreasing overdose deaths - more than 35 of California's 58 counties have active coalitions. These coalitions have developed local leadership and a comprehensive strategy on reducing opioid-related morbidity and mortality that is specific to the culture of the community.[5]

   The crux of the issue is that safe and effective opioid therapy requires a clinician and patient who are working together to closely monitor both the positive and negative effects of opioid therapy. This should happen beginning at a dose of 1 MME/day, and the dose should be allowed to continue increasing based on patient-centered goals of care. While the MED concept originated as a guideline to prompt primary care practitioners to refer a patient to a pain specialist, it has inappropriately morphed into a treatment maximum allowable dosage, severely impacting the ability of clinicians to administer appropriate treatment based on information obtained from a close physician-patient relationship and the patient's observed response to treatment. The draft CMS guidance that plans must have a specific formulary limit of morphine milligram equivalents is problematic, and there is no consensus about the appropriate MME for some drugs, such as fentanyl and methadone. Even if these policies may be appealed if considered medically necessary, doing such poses an administrative burden on the physician practice and disrupts patient care.

[5] Public Health Institute. "Tackling an Epidemic: An Assessment of the California Opioid Safety Coalitions Network." September 2017. Accessed at: http://www.phi.org/resources/?resource=tackling-an-epidemic-an-assessment-of-the-california-opioid-safety-coalitions-network

Opioid prescribing guidelines differ in the specifics of acute care prescribing, but generally recommend starting with the lowest effective dose for the shortest possible duration for pain severe enough to require opioids. However, each patient is unique and may respond differently than the average patient to pain tolerance and treatment options that may include opioid therapy. The MBC Guidelines do not set minimum or maximum duration limit, but rather allow that determination to be made by the clinician in their professional expertise given the particular instance.

CMA Recommendation: Eliminate dosage and duration limits in the Draft Call letter. As an alternative to establishing inappropriate opioid dosage and duration limits in Medicare regulation, CMA urges CMS to adopt the following comprehensive reforms to provide access to the widest possible set of treatment options for Medicare patients:

a) **Adopt the Medical Board of California guidelines, "Guidelines for Prescribing Controlled Substances for Pain."** **http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf**. The Medical Board of California (MBC) conducted a year-long, fully transparent public process that produced well-balanced opioid prescribing guidelines (see enclosure). Health care practitioners who treat pain in diverse settings were extensively engaged and given ample opportunity to provide feedback. The detailed guidelines reflect the realities of patient care and underscore the extraordinary complexity in treating pain. These guidelines have likely played a role in California's lower opioid prescribing rates.

b) **Expand Medicare coverage for multidisciplinary pain management programs.** The multidisciplinary model of chronic pain treatment is based on the biopsychosocial model, which emphasizes the complex and dynamic interaction between physiological, psychological, and social factors that serve to perpetuate and potentially worsen the pain experience. Multidisciplinary pain treatment includes medical treatment, behavioral therapy, physical reconditioning, and education tailored to the needs of the individual patient. Research has demonstrated effectiveness of these programs, however, multidisciplinary pain programs have experienced challenges that stem from a lack of insurance reimbursement for non-pharmacologic options, limited access to a specialist in pain medicine and a fragmented system of care for chronic pain. There should be a renewed focus on comprehensive, multidisciplinary pain programs that are physician led and recognize the interdependency of treatment methods in addressing chronic pain.

c) **Expand Medicare coverage to allow all doctors to use screening tests for "risk stratification."** Given the potential risks of opioid analgesics, careful and thorough patient assessment and risk stratification is essential. According to the MBC Guidelines "risk stratification is one of the most important things a physician can do to mitigate potentially adverse consequences of opioid prescribing." A formal psychological evaluation and assessment of a patient's risk of substance misuse can be made using a number of screening tools, and in some cases, treating physician should seek a consultation with, or refer a patient to, a pain, psychiatry, or an addiction or mental health specialist as needed. CMS should consider funding and incentivizing physician use of such tools and consultations prior to and during opioid therapy.

d) **Expand Medicare coverage and payment for alternative non-opioid medications, therapies, and treatments, such as mental health services, physical therapy, cognitive behavioral therapy, and rehabilitative approaches.** While recommendations have suggested that non-pharmacologic therapy and non-opioid pharmacologic therapy are options that may reduce reliance upon opioids to treat pain, very few third-party payors adequately cover these services and provide them without undue prior authorization needs and restrictions. CMA's white paper on prescribing opioids recognizes that all modalities of pain management tools should be considered every time a health care provider decides to treat a patient with pain, but that access to these services can be hampered by barriers like unsupportive coverage and reimbursement policies. This also includes expanded payments for mental health providers in general so more providers would be willing to accept Medicare patients who have chronic pain problems.

e) **Expand Medicare coverage and payment for medication-assisted treatment for opioid use disorder and reduce drug utilization management barriers.** In 2016, more than 2.1 million people aged 12 or older last year met the diagnostic criteria for an opioid use disorder. Treatment of opioid use disorder with medication-assisted treatment (MAT) has been shown to be cost effective, safe and successful when used appropriately. Further, opioid maintenance therapies have not only been shown to increase abstinence from illicit opioids but also have been shown to reduce mortality from overdose, with buprenorphine having comparable mortality reductions compared to methadone when pharmacotherapy is randomized and not self-selected by the patient. Despite this evidence, only 10 percent of Americans seeking MAT are able to access it with insurance utilization management policies posing as a significant obstacle.[6] Currently, methadone is

[6] H. K. Knudsen, A. J. Abraham, and C. B. Oser, "Barriers to the Implementation of Medication-Assisted Treatment for Substance Use Disorders: The Importance of Funding Policies and Medical Infrastructure," Evaluation and Program Planning 34, no. 4 (November 2011): 375-81, doi:10.1016/j.evalprogplan.2011.02.004.

covered under Medicare Part D only when prescribed for pain, but not when prescribed for opioid use disorder in a treatment program. Not covering an FDA-approved medication that is proven to be effective in treating opioid use disorder is problematic given the incidence of Medicare beneficiaries who may need such services. In addition, newer medications and applications are expanding the effectiveness and reliability of MAT such as injectable sustained release buprenorphine and implantable sustained release naltrexone (i.e., Vivitrol).

Furthermore, many health plans use prior authorization, reauthorization, "fail first" and step-therapy criteria and place annual or lifetime medication limits as a means of reducing expenditures but which thereby restrict access to these treatment services. While these policies have the intention of reducing inappropriate care, they also interrupt patient care during a time in which one day or less can make all the difference – not to mention diverting physician resources away from direct patient care. A 2017 California Society of Addiction Medicine survey of its physician membership indicated that 56 percent of respondents found it difficult to access MAT for patients new to treatment due to insurance barriers, with 41 percent experiencing situations where patients went without treatment.

f) Enhance and incentivize educational opportunities. While California requires that physicians take CME on "pain management" and "the appropriate care and treatment of the terminally ill," there are additional suggestions to incentivize opportunities for physicians to voluntarily increase their knowledge related to opioid analgesics in particular. CMA has taken a leadership role in educating physicians throughout the state by providing onsite lectures, webinars, newsletters and ongoing collaboration with stakeholders. Grants could be provided to support the development and use of voluntary CME related to opioid prescribing. Relevant state licensing boards could be directed to provide voluntary opioid related-education opportunities on a recurring basis. Another strategy is to have all or a portion of the fees that the Drug Enforcement Administration charges for controlled substance registration waived for prescribers who take relevant CME. While nearly all physicians have DEA numbers and the ability to prescribe controlled substances, only a subset of DEA-registered practitioners prescribe opioid analgesics. CMA strongly encourages the availability of physician education, and believes that providing a diverse set of opportunities and materials is an important strategy for reaching physician prescribers.

g) Strengthen and fund state Prescription Drug Monitoring Programs (PDMPs). PDMPs are an important clinical tool that promote legitimate medical practice and

quality patient care, while preventing pharmaceuticals from falling into the wrong hands. If prescribers and dispensers have access to accurate and timely controlled substance history information at the point of care, it can help them identify and assist patients who may be misusing controlled substances and can help guide prescribing decisions.

In particular, integration or interoperability of PDMPs with health information technology is a new and developing practice with the potential to improve physician workflow. Such integration would automatically query PDMPs by electronic health record (EHR) systems and link patients' controlled substance prescription history data in PDMP reports with other patient information in the EHR. The goal of integrating PDMP data with EHRs is to provide a more complete medical record through a single source to support clinical decision-making at the point of care. CMA recommends that CMS work with Congress and the U.S. Department of Health and Human Services to provide grants to states to incentivize integration of PDMPs into existing clinical electronic health records.

CMA also supports a comprehensive PDMP database to ensure prescribers have access to a thorough patient prescription history to assist in their treatment determinations. CMA urges CMS to work with Congress to ensure state PDMPs include dispensing information from federal pharmacies, such as the U.S. Department of Veterans Affairs, U.S. Department of Defense, Indian Health Services and Opioid Treatment Programs (i.e., methadone clinics).

CMA is committed to a broadened and balanced discussion of the efforts to reduce opioid misuse, abuse and overdose. We look forward to working with CMS and appreciate your acceptance of these comments.

Sincerely,

Theodore M. Mazer, MD

President