Conscientious medical providers face difficult tradeoffs when deciding whether to prescribe opioid medications to treat patients with chronic pain. For patients who have failed other therapies, opioids can offer powerful pain relief and restore quality of life. But these drugs come with substantial and well-documented regulatory and patient-safety risks because of their potential for abuse.

On February 10, 2022, the Centers for Disease Control and Prevention (CDC)
published in draft form a revised version of its Clinical Practice Guideline for Prescribing Opioids, and requested public comments. Once finalized, the 2022 Guideline will replace the CDC’s 2016 Guideline for Prescribing Opioids for Chronic Pain, which many commentators argue is clinical guidance that has been misapplied and misunderstood to be regulatory dictates.

The CDC’s draft guidance moves away from suggested dosage ranges (which regulators have heavily relied on for enforcement purposes) and emphasizes provider discretion when balancing the benefits and risks of opioids. An approach grounded in recognition of the need for provider discretion in medicine will certainly have implications for healthcare enforcement actions that seek to question the reasonableness of medical decisions.

**Criticism of the 2016 Guideline**

The CDC’s draft 2022 Guideline arrived in the wake of widespread confusion regarding the intent and implications of the CDC’s 2016 Guideline. Perhaps the most frequently commented-upon issue was the proper application of the CDC’s maximum recommended dose of 90mg MME (morphine milligram equivalent units) for primary care and general practitioners. Indeed, in the years after the CDC issued the 2016 Guideline, many regulators, prosecutors and courts have insisted that the CDC’s guidance set out limits or caps as to dosage, above which prescriptions were presumed to be improper and even illegal.

The concerns over the role of the practitioner guidelines in enforcement actions are well founded. For example, in June 2018, the Office of Inspector General (OIG), published a report based on the 2016 Guideline in which it identified almost 300 prescribers that OIG believed required further investigation because of their pattern of prescribing opioids. [1] Likewise, on November 19, 2021, the US District Court for the District of Maryland permanently enjoined a physician assistant from prescribing opioids, as well as other controlled substances, because the physician assistant prescribed opioids to patients above the 90 MME dosage recommended by the 2016 Guideline. [2] In a similar case, two doctors from Tennessee pled guilty to unlawful distribution of a controlled substance for prescribing opioids at doses that exceeded the 2016 Guideline. [3] On October 4, 2021, the government reached a civil settlement with Olive Street Pharmacy and its owner in connection with allegations of violating the False Claims Act and the Controlled Substances Act for dispensing prescriptions of opioids in dosage amounts that exceeded the CDC’s recommendations, among other claims. [4]

The American Medical Association (AMA), which generally supported adoption of the 2016 Guideline, later adopted resolutions “that call[ed] for restraint in implementing the CDC guideline—particularly as it applies to the agency’s maximum recommended dose of 90mg MME. . . .” [5] One AMA resolution emphasized that patients can benefit from taking a higher dosage than that recommended by the CDC and that “AMA advocate[s] that no entity should use MME thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds” found in the 2016 Guideline. [6]
Draft 2022 Guideline for Prescribing Opioids Suggests More Deference to Physicians

The draft 2022 Guideline addresses many of the issues raised in criticism of the 2016 Guideline. The 2022 Guideline emphatically rejects any suggestion that its guidance is mandatory. In its request for public comments, the CDC emphasizes that “[t]his voluntary clinical practice guideline provides recommendations and does not require mandatory compliance; and the clinical practice guideline is intended to be flexible so as to support, not supplant, clinical judgment and individualized, patient-centered decision-making.” [7] Likewise, “[t]his clinical practice guideline is not intended to be applied as inflexible standards of care across patient populations by healthcare professionals, health systems, third-party payers, organizations, or governmental jurisdictions.” [8]

From a regulatory perspective, the most important change in the 2022 Guideline is likely the removal of language suggesting that primary-care physicians should “avoid increasing dosage” to 90 MME per day. The 2022 Guideline notes that “[t]hough not the intent of the 2016 CDC Guideline, design and implementation of new laws, regulations, and policies also drew from its recommendations.” [9] While these laws and regulations “might have had positive results for some patients, a central tenet of the 2016 CDC Guideline was that the recommendations are voluntary and are intended to be flexible to support, not supplant, individualized, patient-centered care... Such misapplication includes... rigid application of opioid dosage thresholds [and] patient dismissal and abandonment.” [10]

The revised CDC guidance also underscores concerns about penalizing good-faith prescribing. Critics have accused the government of “us[ing] legal ambiguity for tactical advantage” and noted that the government “will not readily clarify lines it expects doctors to follow at their peril.” [11] The strict enforcement of a voluntary guideline presents a due process concern for physicians because it does not provide clear notice as to what conduct would subject them to liability—even criminal liability. The revised 2022 Guideline appears to suggest more deference to physicians. Indeed, the CDC states expressly that “[t]he Guideline should not be used by payers and health systems to set rigid standards related to dose or duration of opioid therapy.” [12]

Practices and corporate entities that employ or credential providers who prescribe opioids should continue to track these developments. These entities—and the providers themselves—will continue to face difficult choices and tensions in ensuring that patients have access to appropriate medical care while managing the bundle of risks—including patient-safety and regulatory risks associated with opioid therapies. Thoughtful policies and practices for opioid prescribing must be provider-driven and focused on balancing the risks of opioids with the needs and circumstances of individual patients.

CONCLUSION

Healthcare organizations face a complex array of evolving regulations, guidance and case law. Staying abreast of the latest developments can help these organizations maintain a robust compliance program, minimize risk, and pursue their mission.


6. Id.


8. Id. (emphasis in original).


10. Id. at 12.
