Feb. 18, 2022: National Advocacy Update

CMS urged to allow more time to review draft cost measures

The AMA, along with eight national medical specialty organizations whose members will be most impacted by the measures, sent a letter (PDF) urging the Centers for Medicare & Medicaid Services (CMS) to extend the cost measure field testing period for a minimum of 30 days. CMS is field testing five cost measures for potential use in the Medicare Merit-based Incentive Payment System (MIPS) from Jan. 10 until Feb. 25. The five measures include emergency medicine, heart failure, low back pain, major depressive disorder and psychoses-related conditions.

Field testing provides an opportunity for physicians to familiarize themselves with the draft measures and to provide feedback. However, as the nation continues to grapple with COVID-19 and its variants, we are concerned that physicians are not given sufficient time to adequately review, analyze and provide detailed feedback about the draft cost measures. We are hearing from physicians across the country that they and their staff are facing extreme hardship and staff shortages due to the Omicron surge. Because physician feedback is critical to ensuring these measures are appropriate and field-testing overlaps with the current COVID-19 surge, we are urging CMS to extend the Feb. 25 deadline by at least 30 days.

New COVID-19 therapeutic authorized; Pfizer delays application for COVID-19 vaccine for youngest children

On Feb. 11, the Food and Drug Administration (FDA) authorized a new COVID-19 therapeutic for treatment of mild to moderate COVID-19. Eli Lilly’s bebtelovimab is a monoclonal antibody authorized under an Emergency Use Authorization for treatment in individuals at high risk of progression to severe disease. It is not authorized for use in those already hospitalized or on oxygen for COVID-19. The EUA also notes that bebtelovimab is for use in patients for whom other treatments are not available or appropriate. Eli Lilly has noted that bebtelovimab retains activity against the Omicron variant and its subvariants, making it a potentially important new therapeutic for use in treatment of COVID-19. The United States government has purchased 600,000 doses of the new monoclonal antibody, which it will begin distributing immediately and continue through the end of March.
Additional news broke last week that Pfizer has temporarily suspended its application for authorization of its COVID-19 vaccine for pediatric patients aged six months to five years of age. The initial clinical trial for patients in this age group was designed to evaluate the safety and efficacy of a two-shot series but given the rise of the Omicron variant, Pfizer has chosen to re-evaluate a three-shot series. Submission as a three-shot series will require additional data, which will take additional time to collect, submit and evaluate. It should be noted that the delay of Pfizer’s pediatric application is not due to any safety concerns regarding the vaccine.

AMA urges Administration to save lives by moving naloxone from behind the counter

The AMA asked the Biden administration to take additional steps to remove the prescription status of naloxone—the overdose-reversing drug—to make it more available over the counter.

“As the overdose epidemic has worsened, given the FDA’s clear guidance there is no moral, medical, or safety-related reason for these life-saving overdose reversal agents to remain locked under prescription regulations,” the AMA wrote (PDF) the Office of National Drug Control Policy (ONDCP).

If not for naloxone, tens of thousands of additional Americans likely would have died from overdoses. The AMA greatly appreciates ONDCP has made increasing access to naloxone a high priority and recommended steps that would make it more widely available to harm-reduction organizations and individuals regardless of their insurance status. The letter notes that naloxone manufacturers are dragging their feet on making it more available over the counter.

“The AMA urges removing the prescription status of naloxone as an essential step to save lives from opioid-related overdose because it will help make naloxone more readily available to patients everywhere.”

Editor’s note: The AMA convened more than 25 national, state, specialty and other health care associations in 2014 to form the AMA Substance Use and Pain Care Task Force to coordinate efforts within organized medicine to help end the nation’s opioid epidemic. Additional information on the task force is available. Real-time updates on the AMA’s work on opioids are accessible.

CDC removes arbitrary recommendations from opioid prescribing guideline
The AMA last week thanked the Centers for Disease Control and Prevention (CDC) for listening to the AMA, the CDC Board of Scientific Counselors, its Opioid Workgroup, the medical community and patients with pain by acknowledging the original 2016 opioid prescribing guideline and its hard thresholds on dose and quantity for opioid therapy missed the mark. In its proposed draft update to the 2016 guideline, the CDC emphasized:

“This clinical practice guideline is not:

- A replacement for clinical judgment or individualized, person-centered care
- Intended to be applied as inflexible standards of care across patients, and/or patient populations by healthcare professionals, health systems, pharmacies, third-party payers, or governmental jurisdictions or to lead to the rapid tapering or discontinuation of opioids for patients
- A law, regulation, and/or policy that dictates clinical practice or a substitute for FDA-approved labeling”

“The CDC’s new draft guideline—if followed by policymakers, health insurance companies and pharmacy chains—provides a path to remove arbitrary prescribing thresholds, restore balance and support comprehensive, compassionate care,” said AMA Chair Bobby Mukkamala, MD, who also chairs the AMA Substance Use and Pain Care Task Force. “The previous guidance has harmed patients with chronic pain, cancer, sickle cell disease, and those in hospice. The restrictive policies also failed patients who are stable on long-term opioid therapy, and it has denied care to post-surgical patients and those with an opioid use disorder. The list of misapplications of the 2016 guideline is long, and its impact has been tremendous harm.”

“There’s not a one size fits all,” said Christopher Jones, acting director of the National Center for Injury Prevention and Control, part of the Centers for Disease Control and Prevention. “We’ve heard that quite clearly. When you have hard thresholds like 90 [morphine milligram equivalents] or a specific duration, it makes it too easy for policymakers or others to take that out of context and apply that as a rigid cap.”

The 2022 draft proposed guideline is now open for public comment.

The notice is in the Federal Register. To view the actual draft proposal, please visit and download the “Draft CDC Clinical Practice Guideline for Prescribing Opioids.”

Please see previous AMA recommendations to the CDC in 2016 and 2020.
The role of immigrant physicians in the U.S. health care system

On Feb. 15, 2022, the AMA submitted a Statement for the Record (PDF) to the U.S. House of Representatives Committee on the Judiciary Subcommittee on Immigration and Citizenship as part of the hearing entitled, “Is there a Doctor in the House? The Role of Immigrant Physicians in the US Healthcare System.” The AMA commended the Subcommittee for focusing on the critically important issue of physician immigration and workforce shortages.

Within the statement, the AMA highlighted the need for additional Medicare-funded residency slots, the importance of international medical graduates (IMGs) in combating our current and projected physician shortage and the need to prioritize IMGs during the visa process. Additionally, the AMA noted its support for multiple pieces of legislation including the Conrad State 30 and Physician Access Reauthorization Act, the Healthcare Workforce Resilience Act, the Resident Physician Shortage Reduction Act and the Physician Shortage GME Cap Flex Act. The AMA will continue to advocate on this important issue and will work to achieve bipartisan policy solutions that will ensure that patients are provided the best care and that immigration barriers are addressed to resolve the physician workforce shortage and preserve patient access to care.

HHS announces availability of funding to expand primary care residency programs

The AMA applauds the U.S. Department of Health and Human Services (HHS) for announcing the availability of $19.2 million in American Rescue Plan funding to support and expand community-based primary care residency programs. The expansion will take place through the Teaching Health Center Graduate Medical Education (THCGME) program and will provide additional funds so that the primary care and dental residents working with diverse, high-need patient communities will be increased by approximately 120 full-time resident positions. Existing HRSA THCGME residency program recipients may also apply to increase the number of resident full-time equivalents they support.

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