FDA authorizes first COVID-19 vaccine; provides instruction to providers and patients

The Food and Drug Administration (FDA) granted an emergency use authorization to the first vaccine for COVID-19, developed by Pfizer and BioNTech. The vaccine, a two-dose mRNA vaccine, is already being provided to front-line health care providers and long-term care facility staff and will continue to be rolled out to other groups over the coming months. The FDA’s Advisory Committee on Vaccines and Related Biological Products reviewed the safety and efficacy data provided by Pfizer and BioNTech on Dec. 17 and voted overwhelmingly in support of authorizing the vaccine to most individuals 16 and older. The safety and efficacy data provided on the vaccine shows it was effective in preventing serious COVID-19 illness in 95% of the over 36,000 clinical trial participants, with no significant adverse events reported among participants.

Along with authorization of the vaccine, FDA has provided guidance and instruction to providers offering the vaccine to patients, as well as a patient-facing fact sheet for more information about this new vaccine. Understanding that both physicians and patients may have significant questions about these new vaccines, AMA has been working closely with FDA, the Centers for Disease Control (CDC), and other regulatory bodies overseeing the vaccine development and distribution process to provide ongoing education about the development, review and distribution processes. The AMA has engaged top Health and Human Services (HHS) officials, such as Dr. Peter Marks, Director of the FDA Center for Biologics Evaluation and Research and Drs. Nancy Messonnier and Amanda Cohn from the CDC’s National Center for Immunization and Respiratory Diseases to participate in educational webinars for physicians, aimed at providing a deeper look at the FDA and CDC processes for bringing these new vaccines to the public. The webinars are archives and available to watch here.

Senators introduce legislation to stop E/M cuts

The worsening COVID-19 health crisis has put a massive strain on the health care system in our country, including the physicians who are on the front lines of the pandemic and now is not the time to cut physician Medicare payments.
Under current law the Centers for Medicare & Medicaid Services (CMS) is required to make budget neutrality adjustments to the Medicare physician payment schedule whenever changes in relative value units (RVU) generate a payment increase or decrease by $200 million. Changes made for 2021 to the Medicare physician payment schedule, including revised coding and payment rules for office-based evaluation and management services, triggered such an adjustment this year that would result in ill-timed dramatic cuts many for frontline physicians during a pandemic.

Thankfully, some members of Congress are listening. Bipartisan legislation was introduced in the House to address these concerns and now a group of Senators led by Sen. John Boozman (R-AR) has introduced a companion bill in the Senate. The “Holding Providers Harmless from Medicare Cuts During COVID-19 Act” (H.R. 8702/S. 5007) would freeze payments at 2020 rates for services scheduled to be cut in 2021 for a period of two years, while allowing the scheduled E/M increases to take place. Analyses of this approach show improved overall impact numbers for all physician specialties.

Momentum is building but time is running out. If Congress does not act in the next few days these budget neutrality adjustments will negatively impact many physician practices across the country.

Please contact your Senators and member of Congress, ask them to support the "Holding Providers Harmless from Medicare Cuts During COVID-19 Act" (H.R. 8702/S. 5007), and request the bill’s inclusion in a larger, end-of-the-year legislative package today.

Cybersecurity legislation passes the House

Health care organizations are constantly under attack from bad actors seeking to disrupt their operations through cyber-attacks. A recent House bill (H.R. 7898) gives much-needed protection to physicians who follow recognized cybersecurity practices to fend off these attacks. Specifically, this legislation would require the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to consider a covered entity’s use of recognized cyber best practices when assessing fines and audits related to the Health Insurance Portability and Accountability Act (HIPAA), a policy the AMA has advocated for since early 2018. The AMA has voiced support for this bill and continues to advocate for more positive incentives for physicians. Rather than adding more penalties or burden on already overworked physicians and their staff, physicians should not be penalized by OCR when they have acted in good faith to defend their information technology networks from attackers. Resources to assist physicians in fending off cyber attacks can be found here.

Opportunities available for physicians interested in two new
payment models

The CMS Innovation Center is seeking physicians interested in participating in two new voluntary Medicare alternative payment models (APM): the Value in Opioid Use Disorder Treatment (ViT) initiative and the Geographic Direct Contracting (Geo) model.

ViT is a four-year demonstration that creates two new payments to participating clinicians: a per patient per month care management fee and a performance-based incentive payment. These new payments will be made in addition to the treatment services Medicare currently covers for patients with opioid use disorder, including the monthly bundled payments for office-based care and weekly bundled payments for opioid treatment programs. Applications are due by Jan. 3, and selected participants are expected to implement the demonstration by April 1, when demonstration payments will also start. To access the Request for Application (RFA), please click here.

The Geo model is one of several Direct Contracting initiatives and seeks to build upon the types of networks and relationships developed in Medicare accountable care organization models. Geo will employ payment models using partial and full capitation instead of fee-for-service to give participating organizations more flexibility to redesign and improve patient care in their geographic regions. Geo is for beneficiaries in Original Medicare, and they will retain the ability to seek care from all physicians, other health professionals, and facilities that accept patients with Original Medicare, although enhanced benefits may be available through the Geo entities. CMS is soliciting nonbinding letters of interest from organizations in 15 regions until Dec. 21. A request for applications is expected to be available to all eligible organizations in a subset of these regions (whether or not they submitted a Letter of Interest) starting in January 2021, with the Geo model scheduled to start in January 2022. More information is available in a fact sheet located here.

COVID-19: What physicians need to know webinar series

Hosted by AMA physician leaders, each installment of this webinar series aims to gain fact-based insights from the nation’s highest-ranking subject matter experts working to protect the health of the public, particularly during the COVID-19 pandemic.
Episode one: AMA webinar series: FDA review process for COVID-19 vaccine candidates

In the first episode, AMA leaders and experts from the FDA provided a comprehensive overview of the COVID-19 vaccine and an inside look at the FDA development and approval process of a vaccine.

Episode two: CDC update on COVID-19 vaccine development

The second episode focused on the CDC’s role in vaccine review and immunization programs. The purpose of this discussion was to help physicians and the public have a better understanding of the vaccine development process, as well as allocation and distribution of a vaccine, or vaccines, when they become available.

Episode three: Project Firstline–CDC’s new national training collaborative for infection control

Join Susan R. Bailey, MD, AMA President, and Mike Bell, MD, Deputy Director of Division of Healthcare Quality Promotion, CDC, to kick off Project Firstline, CDC’s new national training collaborative for infection control.

Episode four: What physicians need to know about vaccine development

Experts discuss the latest developments on the road to effective COVID-19 vaccines, including a deep dive into the Emergency Use Authorization (EUA) process, specifically how the timeline has been shortened from a matter of years to a matter of months.

Register now for the 2021 AMA National Advocacy Conference

Feb. 23-24: The National Advocacy Conference gives attendees the opportunity to connect with industry experts, political insiders and members of Congress about current federal efforts to improve health care and advocate on crucial health care issues affecting attendees and their patients.

Register now. If you also register to attend the AMA State Advocacy Summit, you will get a $50
discount.

More articles in this issue

- Dec. 18, 2020: Advocacy Update spotlight on first look at “No Surprises Act” favors commercial health plans
- Dec. 18, 2020: State Advocacy Update
- Dec. 18, 2020: Judicial Advocacy Update
- Dec. 18, 2020: Advocacy Update other news