Oct. 9, 2020: National Advocacy Update

Register for AMA webinar next week: CDC update on COVID-19 vaccine development and distribution

This vital webinar series addresses the science, evidence and process of vaccine development, regulatory review and what physicians need to know. Hosted by AMA physician leaders, each installment aims to gain fact-based insights from the nation’s highest-ranking subject matter experts working to protect the health of the public.

Register to attend a webinar on Oct. 13 at Noon Central time, where the Centers for Disease Control and Prevention (CDC) will discuss vaccine development and distribution. Hosted by Susan R. Bailey, MD, AMA President, the presentation will provide a comprehensive overview of the CDC’s role in vaccine review and immunization programs. Nancy Messonnier, MD, Director NCISD at the CDC and Amanda Cohn, MD, Acting Chief Medical Officer, NCIRD and Executive Secretary for the Advisory Committee on Immunization Practices (ACIP) will address the prioritization and allocation of vaccines, distribution of vaccines and data systems to monitor distribution and uptake, and the role physicians will play in vaccine distribution and vaccine hesitancy. When you register, you will also have an opportunity to submit your questions to be answered during the presentation. Register now.

ICYMI: Recorded webinar with the FDA on its review process for COVID-19 vaccine candidates

Earlier this week, the AMA held a webinar with the Food and Drug Administration (FDA) as part of its webinar series exploring COVID-19 vaccine development. View a recording of the webinar, "FDA review process for COVID-19 vaccine candidates" hosted by Susan R. Bailey, MD, AMA President. In the presentation Peter Marks, MD, PhD, Director of the Center for Biologics Evaluation and Research at the FDA, provides a comprehensive overview of the FDA vaccine review process. Dr. Bailey and Dr. Marks also discuss what the process looks like for COVID-19 vaccine candidates and the differences between the Emergency Use Authorization (EUA) and Biologic License Application (BLA) pathways.
Administration announces actions on drug pricing

On Sept. 24, the Trump Administration announced several new actions aimed at lowering the prices of prescription drugs. In advancing the Food and Drug Administration's (FDA) Safe Importation Action Plan, the Administration finalized an earlier proposal that would allow states to create drug importation programs that would seek to import certain drugs at lower prices directly from Canada. The Administration also announced they had finalized guidance to help prescription drug manufacturers re-import their drug products intended for sale in foreign countries. There are ongoing concerns about both programs. Primarily, questions continue about Canada's willingness and ability to participate in state importation programs, as well as around the ability of imported drugs to properly meet U.S. track and trace requirements. There are also questions regarding the re-importation guidance and how it will impact manufacturer's existing agreements with insurers and pharmacy benefit managers. There is no clear savings estimate for either program, and the ultimate financial impact on American consumers is not clear.

On the same day, the Health Resources and Services Administration (HRSA) announced a proposed rule that would require community health centers participating in the 340B drug discount program to offer certain drugs to low-income patients at 340B prices. Under this proposal, insulin and injectable epinephrine would be provided to certain low-income patients at 340B acquisition prices.

The announcements follow a flurry of activity from the White House on drug pricing in recent weeks, including a number of executive orders seeking action on not only importation, but also drug rebates and "most favored nation" pricing plans. Several of these proposals had been publicly announced in past rulemaking activity but have yet to be finalized. The AMA continues to closely monitor Administration activity on drug pricing and to advocate for meaningful action to reduce burdensome financial impacts on consumers.

Physicians eligible for additional COVID-19 Provider Relief Funds

The U.S. Department of Health and Human Services (HHS) announced that it will be disbursing another $20 billion in CARES Act Provider Relief Funds. Under this Phase 3 General Distribution allocation, physicians who have already received Provider Relief Fund payments may apply for additional funding that considers financial losses and changes in operating expenses caused by the coronavirus. Recognizing that the COVID-19 pandemic has increased anxiety and depression in the country and behavioral health providers have continued to provide care through telehealth and other means, HHS is also announcing that the nation's behavioral health care providers, including psychiatrists, are now eligible for funding. Previously ineligible physicians, such as those who began
practicing in 2020, will also be eligible to apply. Physicians will have from Oct. 5 through Nov. 6 to apply for Phase 3 General Distribution funding.

Key provisions in the continuing resolution

On Sept. 30, 2020, the U.S. Senate passed the Continuing Appropriations Act 2021 and Other Extensions Act (by an 84 to 10 vote). This legislation, known as the continuing resolution or "CR", extends funding for the federal government through Dec. 11, 2020. The House of Representatives passed the same measure on Sept. 22, 2020 (by an 359 to 57 vote). President Trump signed the bill on Oct. 1, 2020.

Among other items, the continuing resolution (CR) extends flexibilities to 2019 novel coronavirus (COVID-19) pandemic measures and other pandemic-related health care funding programs. It also extends several Medicare and Medicaid provisions through Dec. 11, 2020. Below are the details on key health care provisions in the CR for providers:

- **Revises the Medicare Accelerated and Advance Payment (AAP) Program.** The CR includes a provision that delays repayment and revises CMS AAP program. Although the AAP is currently suspended by CMS for any new requests from Medicare Part B providers and suppliers, the previous payments allowed most Medicare Part B providers and suppliers to request anticipated Medicare payment amounts for a three- or six-month period as a repayable advance. The repayment terms were challenging to many physician practices - the AAP payments would need to be repaid by a 100% offset against Medicare claims beginning 120 days after the payment was made to the provider or supplier, and a 10% interest rate began to accrue as soon as 210 days after the payment date. Though the CR, claim offsets are limited to 25 percent of the full Medicare payment for 11 months followed by six months with claim offsets limited to 50 percent of the full amount. The CR extends repayment for a full year before recoupment of the AAP payment begins. This change effectively provides 29 months to repay the AAP amount in full. Thereafter, the CR reduces the interest rate on the unpaid balance of any AAP amount to 4 percent, provided the AAP payment was made between passage of the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136 (CARES Act) and the end of the COVID-19 public health emergency.

Protecting physician choice and patient safety key themes to CMS in OPPS letter
On Oct. 5, the AMA submitted its comments to CMS on the 2021 Medicare Program Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center Payment System. The AMA put the hard work and sacrifices of the physicians during the COVID-19 public health emergency (PHE) into perspective, and also noted the impact of the pandemic on patients, especially marginalized and minoritized communities. The AMA noted it is just as important as ever before to ensure our physicians are leading patient care teams so patient care and quality remains the top priority. The AMA made a number of comments, some of which are highlighted here:

- **CMS' proposal to eliminate the Inpatient Only (IPO) list entirely may decrease patient safety and increase physician documentation burden.** The AMA urged CMS to adopt a more measured approach to the IPO list of services, and to continue the removal of services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely.
- **The AMA supported the proposed change from direct supervision to general supervision for non-surgical extended duration therapeutic services (NSEDTS), noting CMS has indicated that hospitals can continue to retain higher levels of supervision based on their own needs and their own determination.**
- **The AMA supported CMS' proposal to add 11 procedures, including total hip arthroplasty, to the Ambulatory Surgical Centers (ASC) Covered Procedures List (ASC-CPL).**
- **The AMA recommended CMS end its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective. Instead, the AMA suggested the ASC services apply the OPPS relative weights.**
- **The AMA urged CMS to increase ASC payments to level the playing field between hospital outpatient departments (HOPDs) and ASCs. The AMA continues to strongly support CMS replacing the CPI-U with the hospital market basket as the annual update mechanism for ASC payments.**
- **The AMA also strongly supported repealing the federal ban on physician-owned hospitals. The AMA supported the flexibilities CMS proposed for physician-owned hospitals serving greater numbers of Medicaid patients, noting that expanded capacity of physician-owned hospitals would increase competition and choice as well as patient access to high-quality care.**

**AMA calls for information blocking enforcement discretion**

The Trump Administration's Final Rule on information blocking requires all physicians to come into compliance with the Rule's requirements by Nov. 2. While the rule makes several important changes to electronic health record (EHR) vendor technology, including improving usability and interoperability, the rule also creates a new and complex set of administrative and regulatory requirements that
physicians must follow in order to be compliant with the information blocking provisions. Specifically, physicians are required to establish a new compliance framework to handle all medical record requests coming into their office. Information blocking rules require physicians to respond to and release patients’ medical records for nearly every request they receive unless an appropriate exception can be claimed. Physicians must also examine, create, modify and update all policies and procedures their organization uses to manage medical record requests. Documenting how a physician applies exceptions—and their organizational policies—to each information request will be important in maintaining compliance with the information blocking rules.

The AMA, along with several professional associations and provider organizations, sent a letter to the Office of the National Coordinator for Health Information Technology (ONC) asking for enforcement discretion for at least one year to allow physicians time to come into compliance with the new rules without fear of being penalized. The COVID-19 pandemic is straining physician resources and office staff and will make coming into compliance with the Nov. 2 deadline impractical. The AMA is also developing a resource to help physicians better understand the rule’s requirements. Additional fact sheets and webinars on the rule can be found on ONC’s website.

**AMA and radiation oncologists call for new model implementation to be postponed to 2022**

Recently CMS published a rule with final details of an APM that would provide episode-based payments for radiation oncology (RO) services. The RO APM would be mandatory for practices that account for 30% of RO episodes provided to Medicare patients. The AMA has joined with the American Society of Radiation Oncology, American College of Radiation Oncology, American Society for Clinical Oncology, and several other organizations in a letter to HHS Secretary Azar and CMS Administrator Verma seeking a one-year delay in the implementation of the RO APM from Jan. 2021 to Jan. 2022. The letter points out that RO practices "are not immune from the severe challenges brought on by the pandemic" and have seen revenue decline an average of 20-30%. It continues by stating that a "90-day timeline for implementation was unrealistic under the best of circumstances" and expresses concern about the distraction from patient care and additional fears of financial strain that the rapid implementation timeline would present. The joint letter also urges CMS to reduce the discount factors in the RO APM's episode payments, as the final rule projects payments to participating group practices would be cut by 6%.

**AMA joins other organizations in supporting prior authorization operating rules**
As previously reported, the AMA participated in the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards hearing on Aug. 25 to provide testimony on prior authorization (PA) rules authored by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE). The AMA recently partnered with the American Hospital Association, Arthritis Foundation and Medical Group Management Association in a follow-up letter to NCVHS highlighting the strong and uniform support across health care professional and patient representatives for adoption of these rules. The letter reiterated the anticipated benefits of the rules for patients and physicians, including faster PA processing time, reduced patient care delays, improved process automation and efficiency, and increased transparency in insurers’ opaque clinical documentation requirements. NCVHS is expected to issue its recommendations on the CAQH CORE PA rules at its November meeting. Representation of physicians’ interests before NCVHS plays an important role in the AMA’s overall administrative simplification advocacy efforts and in the FixPriorAuth reform campaign.

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