May 7, 2021: National Advocacy Update

New program covering the cost of administering COVID-19 vaccines

On May 3, the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA) announced a new program covering the cost of administering COVID-19 vaccines to patients enrolled in health plans that either do not cover vaccination fees or cover them with patient cost-sharing.

Since providers cannot bill patients for COVID-19 vaccination fees, this new program, the COVID-19 Coverage Assistance Fund (CAF), addresses an outstanding compensation need for providers on the front lines vaccinating underinsured patients. CAF is focusing on instances where individuals have insurance, but vaccines are either not covered or are, but typically with patient cost-sharing. To address these gaps, the CAF will be compensating providers for eligible claims at national Medicare rates to reflect newer information on the true costs associated with administering the vaccines. CAF also builds on the HRSA COVID-19 Uninsured Program, which has been reimbursing providers for vaccine administration fees associated with uninsured individuals.

Effective for COVID-19 vaccines administered on or after March 15, the national average payment rate for physicians, hospitals, pharmacies and many other immunizers is $40 to administer each dose of a COVID-19 vaccine. This represents an increase from approximately $28 to $40 for the administration of single-dose vaccines, and an increase from approximately $45 to $80 for the administration of COVID-19 vaccines requiring two doses. The exact payment rate for administration of each dose of a COVID-19 vaccine depends on the type of entity that furnishes the service and will be geographically adjusted based on where the service is furnished.

AMA responds to RFI from AHRQ on racial and ethnic bias in clinical algorithms

The Agency for Healthcare Research and Quality (AHRQ) recently issued a Request for Information (RFI) on the "Use of Clinical Algorithms That Have the Potential to Introduce Racial/Ethnic Bias Into
Healthcare Delivery," seeking additional information and evidence on clinical algorithms that may introduce bias into clinical decision making and/or influence access to care, quality of care or health outcomes for racial and ethnic minorities. The AMA recently responded to this RFI (PDF), detailing AMA’s current understanding of the scope of these issues and the efforts to work with the medical community to address biased algorithms.

The AMA has long recognized that racial and ethnic health inequities are an unjust and major public health reality in the United States. Understanding that race is a social and political construct and not a biological risk factor for disease and death, the AMA has publicly acknowledged that racism impacts public health and is a barrier to effective medical diagnosis and treatment. In addition, AMA House of Delegates in November 2020 passed new policy directing our organization “to collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors.” The AMA is currently undertaking an effort to convene a variety of organizations to gather more information about the use of clinical algorithms and create an action plan for how to address these problems. The AMA looks forward to supporting, encouraging, and coordinating its efforts with these organizations to both better understand the algorithms in use today and how they can be improved upon to ensure they help drive equitable care.

The AHRQ is ideally situated to conduct and fund additional research into the use of race and ethnicity data in clinical settings and algorithms, their potential contribution to medical racism and/or bias in clinical decision-making and the methods needed to eliminate such racism and/or bias.

AMA responds to proposed rulemaking on HIPAA

The AMA submitted comments (PDF) in response to a Notice of Proposed Rulemaking on the Health Insurance Portability and Accountability Act (HIPAA) from the Office for Civil Rights (OCR), which contains numerous proposals intended to remove barriers to coordinated care and patient engagement. The AMA’s comments focus largely on ensuring that potential revisions to HIPAA intended to improve information sharing do not compromise patient privacy and the trust so critical to the physician-patient relationship.
The AMA also supports certain policies aimed at reducing physician burden, such as the proposed removal of the requirement that practices obtain a written acknowledgement of the Notice of Privacy practices. Of particular note, the AMA is advocating for OCR to revise its definition of “harm” to include emotional and mental distress. Such a revision would facilitate the Office of the National Coordinator for Health Information Technology’s (ONC) ability to create additional flexibility in its information blocking regulations to accommodate the best interest of the patient, a physician’s professional judgment and adherence to clinical guidelines.

**Engaging employers to help prevent drug overdoses**

The Drug Enforcement Administration (DEA) has initiated a new effort called “Operation Engage” that aims to bring together multiple stakeholders within a targeted set of communities to focus on ending the drug overdose epidemic. The DEA is partnering with the Milken Institute Center for Public Health to engage businesses and employers in communities that are part of Operation Engage, as they play key roles in shaping working environments for their employees and customers, providing health insurance coverage for employees and their families and influencing education and public safety policies in their communities.

As part of this effort, the Milken Institute organized a roundtable with employers in the Philadelphia area that featured speakers from the Pennsylvania Chamber of Commerce, CVS Health and DEA personnel in the Philadelphia area. Much of the discussion focused on the need to eliminate stigma in the workplace related to substance use and mental health, remove barriers to treatment and educate employees and their families about the illegal drugs contributing to overdoses in their community as well as safe medication storage and harm reduction strategies.

To assist this effort, the AMA developed a new issue brief to serve as a resource for employers, “The Nation’s Drug Overdose Epidemic: Considerations for Employers,” (PDF) which is now available at End the Epidemic.

**Practice guidelines issued to expand buprenorphine access**

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On April 28, HHS published in the Federal Register new "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder," which allow physicians who are registered with the DEA to prescribe controlled substances to also prescribe buprenorphine for the treatment of opioid use disorder (OUD) for up to 30 patients. With the drug overdose epidemic escalating during the COVID-19 pandemic, the need to increase patients’ access to evidence-based treatment with medication for OUD and eliminate the stigma that often accompanies it has never been greater.

For several years, the AMA has been advocating for burdensome regulatory requirements to be eliminated so that the same physicians who are managing patients’ other chronic diseases can also offer them treatment for OUD. In a statement, AMA Immediate Past President Patrice A. Harris, MD, MA, said, “Treatment with buprenorphine allows patients with opioid use disorder to lead satisfying, productive lives. The policy announced today is a critically important step in making that happen. Going forward, the AMA is supporting legislation to remove the waiver requirements altogether and will advocate for that in Congress.”

The Substance Abuse and Mental Health Services Administration (SAMHSA) provides an online application process for physicians to request a waiver to prescribe buprenorphine, as well as other resources, including a quick start guide (PDF). Although special training is no longer required to prescribe buprenorphine for treatment of OUD, it is important for physicians to become educated in how to screen, treat or refer their patients with OUD for evidence-based care. The AMA’s End the Epidemic offers numerous educational resources for physicians on this topic.

**AMA wants to hear from you as Medicare begins advance payment recoupment**

The Centers for Medicare & Medicaid Service (CMS) announced (PDF) that it began automatic recoupment of COVID-19 Accelerated and Advance Payments, which were an advance of up to three months of Medicare payments to help physician practices keep the lights on early in the COVID-19 pandemic. AMA strongly advocated for improved repayment terms, which Congress and CMS adopted in 2020. Under the revised repayment terms, physicians should be aware that:

- These funds are loans that are required to be repaid.
- Repayment begins one year from when the Medicare advance payment is received, rather than 120 days under the original terms.
- The per claim recoupment amount was reduced from 100% to 25% for the first 11 months, and then 50% for an additional six months.
- If there is an outstanding balance after the 17-month recoupment time frame, the Medicare Administrative Contractor (MAC) will issue a demand letter requiring repayment subject to

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an interest rate of 4%, a decrease from the original interest rate of 10.25%.
Physicians may repay the Medicare advance payment in full at any time by contacting their MAC.

The AMA is interested in hearing from physicians about their experience repaying the Medicare advance payments as it may vary depending on the carrier and whether you are able to check your balance and request an extended repayment option due to ongoing hardships.

To share feedback, contact AMA.Advocacy@ama-assn.org.

For more information about the programs established by the federal government to help physician practices offset the financial impact of COVID-19, access these AMA resources.

### New naloxone formulation approved by FDA

The U.S. Food and Drug Administration recently approved a new formulation of naloxone, the life-saving medication to help reverse an opioid-related overdose. The new medication delivers a higher dose of naloxone in a nasal application device.

“By approving a higher dose of naloxone hydrochloride nasal spray product to treat opioid overdose, the FDA is making sure the overdose-reversing drug is potent enough to counteract the increasingly lethal and illicitly manufactured fentanyl and fentanyl analogs,” said Patrice A. Harris, MD, MA, AMA immediate past president. “Now, we must make sure that the new version of naloxone is placed on the lowest cost-sharing tier with low or no cost-sharing and also available in pharmacies.”

Learn more about considerations for prescribing naloxone to patients at risk of overdose (PDF).

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