

Nov. 13, 2020: National Advocacy Update

Ongoing AMA advocacy efforts during the COVID-19 pandemic

Throughout the COVID-19 pandemic, the AMA has been the leading physician and patient ally—voicing recommendations to members of the White House Coronavirus Task Force, key Congressional leaders and agency staff, state policymakers and private sector stakeholders. A new document outlines recent COVID-19 advocacy efforts related to financial relief for physician practices, telehealth expansion, personal protective equipment (PPE), expanding insurance coverage, reducing regulatory impediments and addressing workforce issues.

Learn more.

Physicians request insurer compensation for COVID-19 infection control costs

The AMA, along with close to 130 state medical associations and national medical specialty societies, recently urged both public and private health plans to compensate physician practices for the additional costs associated with providing safe patient care during the COVID-19 public health emergency (PHE). In letters to the Centers for Medicare & Medicaid Services (CMS), insurer trade organizations (America's Health Insurance Plans and Blue Cross Blue Shield Association), and major national commercial insurers (Aetna, Anthem, Cigna, Health Care Service Corporation, Humana, and UnitedHealth Group), the AMA and other physician organizations requested that payers immediately implement and pay for Current Procedural Terminology (CPT®) code 99072 with no patient cost-sharing to compensate physician practices for increased expenditures associated with heightened infection control protocols during the COVID-19 PHE.

According to CPT guidance, 99072 is to be used to report the additional supplies, materials, and clinical staff time over and above the practice expense(s) included in an office visit or other non-facility service(s) when performed during a PHE, as defined by law, due to respiratory-transmitted infectious disease. Payment for these increased expenses is critical to address the financial stresses currently facing many physician practices, as detailed in an AMA survey of 3,500 physicians.

AMA opposes DOL rule increasing wage requirements for H-1B physicians

On Nov. 9, the AMA submitted comments strongly urging the Department of Labor (DOL) to rescind the Interim Final Rule (IFR) titled "Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States."

Changes included in this IFR discriminate against H-1B physicians and the communities that they serve by drastically altering the distribution of the four-tiered wage system, causing an increase in the required prevailing wage determinations that employers must pay to H-1B employees. As such, this IFR will cause immediate and lasting harm since it will likely make it more difficult to hire H-1B physicians in rural and medically underserved communities across the United States which will worsen our growing physician shortage and make it even harder to serve communities throughout the COVID-19 pandemic. Therefore, the AMA has continued to strongly advocate that current international medical graduates should not be hampered by additional unnecessary regulations especially in the midst of helping the U.S. fight COVID-19.

FDA approves emergency use authorization for COVID-19 monoclonal antibody treatment

The U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy Bamlanivimab for the treatment of mild-to-moderate COVID-19. The authorization permits Bamlanivimab to be distributed and administered as a single dose intravenously by health care providers.

In the statement provided by the FDA on Nov. 9, the agency notes "[w]hile the safety and effectiveness of this investigational therapy continues to be evaluated, Bamlanivimab was shown in clinical trials to reduce COVID-19-related hospitalization or emergency room visits in patients at high risk for disease progression within 28 days after treatment when compared to placebo." This therapy is not indicated for patients hospitalized due to COVID-19 or who may require high-flow oxygen.

Data used to support issuance of this EUA are based on an interim analysis from a phase two randomized, double-blind, placebo-controlled clinical trial. This trial showed promising results from predefined secondary endpoints of COVID-19-related hospitalizations or emergency room visits within 28 days after treatment. For patients at high risk for disease progression, hospitalizations and emergency room visits occurred in 3% of Bamlanivimab-treated patients on average compared to

10% in placebo-treated patients.

See FDA's Fact Sheet for Health care Providers regarding the EUA of Bamlanivimab.

FDA provides guidance for false-positive results by rapid detection SARS-CoV-2 antigen testing

On Nov. 3, the FDA released a report alerting clinical laboratory staff and health care providers that false-positive results may occur with antigen testing for rapid detection of SARS-CoV-2. While false positives are more likely to occur when instructions are not followed appropriately, the report notes that "laboratories should expect some false positive results to occur even when very accurate tests are used for screening large populations with a low prevalence of infection." Therefore, diagnostic test results should always be considered carefully in the context of available clinical, diagnostic and epidemiological information.

The FDA highlights several recommendations for physicians who use these antigen tests to help mitigate false positive results:

- | For antigen tests that have been granted an Emergency Use Authorization, laboratories are to follow the manufacturer's instructions for use.
- | Processing multiple specimens in batch mode may make it more challenging to ensure the correct incubation time for each specimen; refer to antigen test package insert for guidance on specimen timing.
- | Minimize risk factors for potential cross contamination of patient specimens including inappropriate use of protective equipment, insufficient cleaning of workspace and disinfection of instruments. See CDC guidance for specimen handling and processing.
- | Consider positive results in combination with clinical observations, patient history and epidemiological information.
- | Authorized Laboratories must report any suspected occurrence of false-positive or false-negative results.

FDA finalizes drug compounding guidelines

On Nov. 6, the FDA finalized long-awaited guidance impacting physician's ability to prepare sterile drug products in their offices. The Insanitary Conditions at Compounding Facilities final guidance represents a significant victory for physicians' in-office preparation of compounded drug products, as

the guidance notes that the FDA generally does not intend to regulate physicians so long as those physicians are preparing drug products in the office setting for administration to their own patients within the same office.

The initial draft Insanitary Conditions guidance would have subjected physician offices to significant sterility and engineer control requirements, similar to that of full compounding pharmacies. Physicians have also been largely successful in ensuring the United States Pharmacopoeia (USP) chapters on sterile compounding allow for physician in-office preparation of sterile drug products without overly burdensome requirements. The AMA has worked closely with a large coalition of physician specialty organizations over several years to maintain the ability of physicians to prepare sterile drug products in their offices for administration to their patients.

New AMA survey shows broad use of increased DEA prescribing and treatment flexibility

Eighty percent of pain medicine physicians responding to a new AMA survey said that enhanced flexibilities to use telemedicine for treatment during the COVID-19 pandemic has been helpful to treat patients with pain. The prescribing and treatment flexibilities were authorized by the U.S. Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration early in the COVID-19 Public Health Emergency.

A major finding of the survey is that 80% of physician respondents said that the flexibilities provided by the DEA during the COVID-19 pandemic have been either very helpful or somewhat helpful for treating patients with pain. The AMA strongly supports these flexibilities, including the authority "to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation," as long as certain requirements are met.

In addition to support for the ability to treat patients with pain via telehealth and telephone visits, and to call in needed controlled substance prescriptions to the pharmacy, survey respondents described their concerns about barriers to care during the pandemic, including:

- | 77% of respondents said they were "very" or "somewhat" concerned about unnecessary delays caused by prior authorization
- | 78% were "very" or "somewhat" concerned about patients waiting too long before making an appointment if they need treatment
- | 79% were "very" or "somewhat" concerned about unnecessary delays for new patients in access needed medication

Learn more about the survey.

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