Sept. 24, 2021: National Advocacy Update

Sweeping $3.5 trillion reconciliation legislation advancing in the House

The House of Representatives is currently taking steps to advance a sweeping $3.5 trillion social spending and tax package known as the Build Back Better Act. The Democratic majority is employing a partisan budget reconciliation process enabling the legislation to circumvent a Senate filibuster and to pass without Republican support.

The legislative package does not currently address the growing financial instability and structural flaws of the Medicare physician payment system confronting physician practices that face cuts totaling 9.75% on Jan. 1, 2022. During the House committee process, Representatives Wenstrup (R-OH) and Buschon (R-IN) attempted unsuccessfully to advance amendments to help mitigate the Medicare cuts.

The emerging package also fails to build on the successful adoption of telehealth during the COVID-19 public health emergency by preserving the Medicare telehealth benefits currently available to patients after the pandemic is over.

The current draft does include favorable maternal health provisions, such as extending mandatory continuous Medicaid and Children’s Health Insurance Program (CHIP) coverage for pregnant and postpartum women for 12 months. It also includes enhanced access to health care coverage by building upon Affordable Care Act (ACA) improvements in the American Rescue Plan Act.

The legislation is still highly fluid as Democratic House members work out disagreements regarding the overall cost as well as various tax and policy provisions. The Build Back Better Act will also be further amended in the Senate where all 50 Democratic members will need to reach agreement on final legislation.

The AMA will continue to advocate for our priorities throughout the aforementioned legislative process.

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Department of Health and Human Services releases drug pricing plan

Earlier this month, the Department of Health and Human Services (HHS) released its new Drug Pricing Plan (PDF). The plan, which includes several legislative and regulatory proposals aimed at reducing high drug prices, was created in response to President Biden’s recent Executive Order on Competition in the American Economy. The drug pricing plan signals the administration’s support for Medicare drug price negotiation in both Parts B and D, redesign of the Part D benefit to lower costs for patients and limit exposure to high drug prices for Part D plans, caps on drug price increases larger than the rate of inflation, ending pay-for-delay arrangements and a number of other proposals.

While the AMA is pleased to see the administration’s support for bold actions to reduce prices, there are some concerns about proposals that seek to hold physicians responsible for lowering drug costs for patients. The plan does propose some changes to reimbursement that could negatively impact physicians’ ability to offer certain physician-administered treatments and seeks to address reimbursement issues that could lead physicians to choosing higher-priced treatment options. The AMA is closely monitoring all legislative and regulatory activity on drug pricing and will continue to support meaningful action to reduce prices while ensuring that physicians and patients are not asked to bear the burden of policy changes to reduce spending on prescription drugs.

FDA Advisory Committee declines to approve COVID-19 booster shots for all populations

The Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee met Sept. 17 to review data on Pfizer-BioNTech’s proposed COVID-19 booster and to vote on whether to recommend that FDA approve the third shot for Americans over 16 years of age. After hearing presentations from the Israeli Ministry of Health, Pfizer-BioNTech, FDA and public comment, the Advisory Committee members expressed concern that there was a lack of adequate data showing an absolute need for a third dose in the general population under age 65 and did not recommend FDA authorize boosters for those 16-65 that are not in certain high-risk groups. The committee did, however, unanimously recommend FDA authorize use of the Pfizer-BioNTech booster for Americans over age 65 and for those in groups at high-risk for exposure, such as health care workers.

The recommendations of the FDA advisory committee are advisory only and non-binding on FDA officials. Before a booster would be made available to any group, FDA will have to grant emergency
use authorization to the product, and the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) will need to issue a positive recommendation for the third dose.

Physicians should be advised that, until FDA has granted authorization for high-risk populations and those over 65, boosters should not be given unless they are given to immunocompromised patients for whom authorization has already been granted. Likewise, children under the age of 12 should not be administered first or second doses of currently licensed or authorized vaccines. The administration announced earlier this month that administering COVID-19 boosters or pediatric vaccinations without FDA authorization could subject physicians and others administering the third doses to liability, as it falls outside the liability protections offered under the Public Readiness and Emergency Preparedness Act.

Provider Relief Fund announcements

Last week, the Biden administration made three key announcements related to the Provider Relief Fund (PRF) and physician support. First, CMS announced $25.5 billion in new funding available for health care providers affected by the COVID-19 pandemic. This funding, which will be administered by the Health Resources and Services Administration (HRSA), includes $8.5 billion in American Rescue Plan (ARP) resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP) or Medicare patients, and an additional $17 billion for Provider Relief Fund (PRF) Phase 4 for a broad range of providers.

Phase 4 funding is targeted to who can document revenue loss and expenses associated with the pandemic from July 1, 2020 through May 30, 2021. For this phase, the application period will be open for 4 weeks and payments to providers should be distributed by mid-December. Medicare Advantage providers are eligible for this relief. Second, regarding previously distributed Phase 3 payments, CMS has shared the methodology (PDF) used to determine those payments. CMS is providing an opportunity for recalculation and reconsideration of Phase 3 payments for those providers who believe their payments were incorrect. Finally, CMS is extending the Sept. 30 deadline for reporting on funds received to date by providing an additional 60 days to submit through the reporting portal. This deadline is due in large part to the natural disasters that have impacted numerous states but is applicable to providers across the whole country.

FTC issues policy statement on breaches by health apps

The Federal Trade Commission (FTC) recently announced a new policy, Statement on Breaches by Health Apps and Other Connected Devices

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to clarify that the scope of its Health Breach Notification (HBN) rule includes “health apps and connected devices that collect or use consumers’ health information.” The statement follows the FTC’s request for comment on its HBN rule, to which the AMA responded (PDF) last year. Among other things, the AMA asked that the FTC “expand the HBN Rule’s coverage to specifically include direct-to-consumer technologies and services such as mobile health apps, virtual assistants, and platforms’ health tools.” The new FTC statement makes clear that the agency intends to do just that by including smartphone apps (including those connecting to electronic health records via advanced programming interfaces or APIs) in its enforcement efforts.

The AMA’s comments also strongly urged the FTC to increase its enforcement activity. The FTC noted in its press release that while the HBN rule has not been enforced to date, it intends to bring enforcement actions in the future with violators facing civil penalties of over $43,000 per violation per day. Additionally, the AMA noted that disclosures of health information by app developers without user consent must be considered a violation of the HBN rule. The FTC’s new statement confirms that it will consider apps’ disclosures of sensitive health information without users’ authorization a breach under the HBN rule.

As the AMA has noted for many years, the FTC stated that “health apps, which can track everything from glucose levels for those with diabetes to heart health to fertility to sleep, increasingly collect sensitive and personal data from consumers.” AMA applauds the FTC’s attention to this matter and its efforts to create more accountability among data holders. These steps will help to ensure better data governance to protect users of health apps from discrimination and profiling based on health data.

**CMS withdraws Medicare coverage of innovative technologies rule**

On Sept. 15, CMS issued a notice (PDF) that it is repealing the Medicare Coverage of Innovative Technologies (MCIT) final rule. The MCIT program would have offered an immediate four years of Medicare coverage and payment to new technologies gaining market approval through the FDA’s Breakthrough Device pathway. The MCIT program, initially finalized by the Trump administration, had been put on hold by the Biden administration pending further review and questions over how best to operationalize.

The most recent Federal Register notice of the full repeal of the program notes continued concerns over the availability of clinical evidence for products approved with an FDA breakthrough designation. CMS notes that this lack of clinical evidence may mean that immediate coverage and payment may not be in the best interest of Medicare beneficiaries and that it raises patient safety concerns. The AMA submitted comments on the initial proposed rule that supported less-burdensome pathways to
payment and coverage for new technologies but raised similar concerns regarding the lack of clinical evidence prior to payment and coverage for Medicare beneficiaries.

**Hurricane Ida added to automatic extreme and uncontrollable circumstances policy for MIPS**

In response to the Federal Emergency Management Agency (FEMA) designation of Hurricane Ida as a major disaster, CMS has determined that the automatic extreme and uncontrollable circumstances (EUC) policy will apply to Merit-based Incentive Payment System (MIPS) eligible clinicians in FEMA-designated disaster areas of Louisiana, Mississippi, New York, New Jersey and Missouri.

MIPS-eligible clinicians in these areas will be automatically identified and receive a neutral payment adjustment for the 2023 MIPS payment year. During the data submission period for the 2021 performance period (Jan. 3, 2022 to March 31, 2022), all four performance categories for these clinicians will be weighted at 0%, resulting in a score equal to the performance threshold.

However, if MIPS-eligible clinicians in these areas choose to submit data on two or more performance categories, they will be scored on those categories and receive a 2023 MIPS payment adjustment based on their 2021 MIPS final score.

The automatic EUC policy will not apply to MIPS-eligible clinicians participating in MIPS as a group, virtual group or Alternative Payment Model (APM) entity.

**AMA submits written comments to congressional caucus for social determinants of health**

On Sept. 21, the AMA submitted in-depth written comments (PDF) in response to a Request for Information (RFI) issued by the newly formed bipartisan Congressional Caucus for Social Determinants of Health (SDOH). Founded in August by co-chairs Representatives Cheri Bustos (D-IL), Tom Cole (R-OK), G.K. Butterfield (D-NC) and Markwayne Mullin (R-OK), the caucus features 24 additional bipartisan members committed to tackling the many economic and social conditions—such as stable housing, reliable transportation, minimizing exposure to environmental and chemical toxins and access to healthy foods—that dramatically affect a patient’s health care outcomes.

The AMA’s comment letter confirms that the negative effect of social determinants of health (SDOH)
on patients is even more acute during the COVID-19 pandemic. One of the key barriers to physicians properly addressing this growing issue is simply a lack of awareness or education on how non-health care factors affect patient outcomes. Among physicians who have a stronger understanding of SDOH, insufficient time, resources, tools and incentives to effectively screen patients are reasons cited for the inability to mitigate these issues. To help address non-health care factors that impact patient outcomes, AMA supports Congress appropriating $153 million for the Social Determinants of Health program within the Centers for Disease Control and Prevention’s National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Ample start-up funding and a realignment of payment incentives within alternative payment models to encourage practices to address patients’ social needs is an additional policy solution put forward by the AMA to minimize the negative effects of SDOH.

The AMA also reiterated its support for H.R. 2503, the Social Determinants Accelerator Act, and S. 509, the Leveraging Integrated Networks in Communities (LINC) to Address Social Needs Act. Introduced by Reps. Bustos, Cole, Mullin and Jim McGovern (D-MA) and passed by the House Energy and Commerce Health Subcommittee earlier this year, H.R. 2503 provides $25 million in planning grants to state, local and tribal governments to design social determinants accelerator plans to improve the health and well-being of individuals, especially those who qualify for Medicaid. The legislation also requires HHS to establish and convene a Social Determinants Accelerator Council, an inter-agency technical advisory panel dedicated to assisting state, local and tribal governments in the development of the SDOH accelerator plans. The accelerator council also focuses on better leveraging unknown or underutilized existing federal programs and formulating rigorous evaluation guidelines. S. 509 requires the Secretary of HHS to competitively award grants to states to support the establishment of new or enhancement of existing community integration network infrastructure to connect health care providers to social services organizations in hopes of helping patients address accessibility challenges related to various SDOH.

**CDC, FDA issue alerts about Delta-8 THC**

The CDC issued a Health Alert Network (HAN) Health Advisory last week regarding “the increased availability of cannabis products containing delta-8 tetrahydrocannabinol (THC) and the potential for adverse events due to insufficient labeling of products containing THC and cannabidiol (CBD).” Delta-8 THC is a substance that exists naturally in cannabis in small quantities and is less psychoactive than delta-9 THC, the more commonly known compound. The health effects of delta-8 THC have not yet been researched extensively and are not well understood.

According to the U.S. Food and Drug Administration, “delta-8 THC products have not been evaluated or approved by the FDA for safe use in any context. They may be marketed in ways that put the public health at risk and should especially be kept out of reach of children and pets.”
The AMA encourages states to review their cannabis laws and regulations to ensure that marketing, labeling and point-of-sale messaging requirements include appropriate, accurate information regarding the use and potential dangers of cannabis and cannabis-derived products.

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