Administration finalizes drug pricing actions

On Nov. 20, the administration announced two new rules aimed at reducing prescription drug prices. The first, the Most Favored Nations Model Interim Final Rule, seeks to adjust prices for a select group of 50 "Most Favored Nation" Part B drugs to align with lower prices paid in other countries. The model is structured as a mandatory demonstration program starting Jan. 1 and running for seven years. All Medicare providers administering MFN model drugs must participate in program.

In addition to repricing drugs selected to be part of the MFN cohort, the model will also adjust the add-on payment accompanying payment of the drug. The add-on will shift from an average sales price (ASP) plus 6% calculation to a flat-fee add-on payment. The flat fee for the first model year will be $146.55, representing an aggregate calculation of 6.1224% of historical ASPs across all drugs in the cohort, and will be adjusted for inflation quarterly. It is expected that many specialties will see a decrease in the average add-on payment once the program takes effect on Jan. 1. Physicians will still be eligible to receive payment for administration with the payment amount remaining unchanged under the MFN model.

The MFN model is raising serious concern among many stakeholders, including over the legality of the process used to implement the changes. As an interim final rule, public comments will be accepted until Jan. 26. However, the implementation date of Jan. 1 means those comments will not be considered prior to the beginning of the program. The AMA has tremendous concerns about the policy process for this rule and will continue to evaluate it.

In addition to the MFN Model rule, the administration also finalized an earlier proposal to eliminate safe harbor protections for current drug rebate programs and encourage those rebates to be passed directly to consumers at the point of sale. These changes were first proposed in 2019. The AMA submitted detailed comments, supporting efforts to ensure price concessions are passed directly to patients, but raising concerns about unintended consequences, such as potential increases to insurance premiums and potential for limited price concessions to patients going forward.

AMA seeks controlled substance flexibilities to help fight overdoses and pain

During the COVID-19 public health emergency (PHE), the Drug Enforcement Administration (DEA)
has put in place a number of flexibilities to help patients being treated for pain, opioid use disorder (OUD), and other conditions for which controlled substances are prescribed. For example, controlled substances in schedules II-V, including buprenorphine for the treatment of opioid use disorder, may be prescribed and dispensed based on either in-person, telephone, or audio-video telehealth patient evaluations. After conducting a survey of physicians in which 80% of respondents reported that the flexibilities provided by the DEA during the PHE have been either very helpful or somewhat helpful for treating patients with pain, the AMA has written a letter to the DEA asking that these flexibilities be extended not only until the end of the COVID-19 PHE, but also through the end of the opioid epidemic PHE. The letter also described findings from a second survey targeting physicians and other health professionals who treat patients with OUD. A key finding of this survey is that more than 80% of X-waivered survey respondents who treat patients with OUD want virtual visits and other telehealth options to continue after the COVID-19 PHE ends.

**AMA opposes proposed changes to H-1B visa cap prioritization**

On Dec. 2, the AMA submitted comments strongly opposing the Department of Homeland Security's (DHS) proposed rule "Modification of Registration Requirement for Petitioners Seeking to File Cap-Subject H-1B Petitions." This proposed rule seeks to abruptly and unnecessarily change the selection process for H-1B cap-subject petitions by prioritizing registrants based on the highest prevailing wage or highest proffered wage. The AMA's comments acknowledge that it is false to assume that higher skilled workers are always paid a higher wage and thus, this conclusion made by DHS devalues physicians practicing in medically underserved areas. The AMA strongly urged DHS to withdraw the proposed rule, but if withdrawal is not possible, urged DHS to exempt physicians from this provision.

**Bipartisan House legislation extends Medicare sequester moratorium**

With the COVID-19 pandemic continuing to rage throughout the United States, securing additional financial relief from the federal government remains crucial to physicians. Whether on the front lines treating COVID-19 patients or curbing non-emergent procedures to limit community spread and preserve personal protective equipment (PPE), physicians continue to face immense clinical, fiscal and emotional challenges. To help alleviate some of the financial burden of the pandemic, Representatives Brad Schneider (D-IL) and David McKinley (R-WV) introduced H.R. 8840, the Medicare Sequester COVID Moratorium Act on Dec. 2. This legislation extends the current sequester moratorium through the end of the PHE to provide physicians with a financial boost so they can
continue to navigate the pandemic and deliver effective patient care.

The passage of the Budget Control Act of 2011 initiated the 2% across-the-board reduction in Medicare physician payments. The Coronavirus Aid, Relief, and Economic Security (CARES) Act temporarily suspended the 2% sequestration adjustment on Medicare fee-for-service payments between May 1 and Dec. 31. Absent additional Congressional intervention, the 2% sequester is scheduled to be restored on Jan. 1. In response to this looming deadline, AMA, along with the American Hospital Association, American Health Care Association, and the National Association for Home Care and Hospice, sent a letter in October to House and Senate leadership urging continued reprieve from the sequester. More recently, AMA joined more than 30 diverse health care stakeholders in a November letter urging Congress extend the sequester moratorium. The continued negative fiscal impact of the COVID-19 pandemic on physician practices is undeniable. Results from an AMA-commissioned survey of 3,500 practicing physicians conducted from mid-July through August 2020 found that 81% of respondents are still experiencing lower revenue than before the pandemic. In fact, survey respondents reported an average revenue reduction of 32%. Extending the sequester moratorium will help physicians continue to provide high quality care throughout the remainder of this public health crisis. AMA applauds Reps. Schneider and McKinley for introducing this bipartisan bill and will continue to advocate for its inclusion in a larger legislative package that Congress is expected to pass before the end of the year.

CMS finalizes rule overhauling the organ procurement system

On Nov. 20, CMS issued a Final Rule overhauling the organ procurement system. The Final Rule establishes minimum quality measure thresholds that organ procurement centers must meet in order to receive payments from CMS. These new measures, which will replace organ procurement organization (OPO) self-reported data, aim to incentivize the procurement and transplantation of as many organs as possible. The rule follows the July 2019 Executive Order on Advancing American Kidney Health that prioritized the development of policies designed to increase the supply of donated organs and reduce the number of people on waitlists. Performance data will be available to the public in order to identify OPOs that are in the bottom quartile in donation and transplantation rates and to encourage performance improvement.

New final rules issued to reform Stark Law and anti-kickback statute regulation

The AMA submitted comments on both the Anti-Kickback Statute (AKS) proposed rule and the Stark Law proposed rule in December 2019. AMA staff are analyzing the final rules, but a topline summary of key issues is available now
The agencies modified the final regulations in a manner that accepted a number of the AMA's recommended changes from the proposed rule, including not limiting a target patient population to patients with at least one chronic condition; extending the "pre-risk" period from six months as proposed, to 12 months in the full financial risk exception; and not requiring the value-based enterprise or its accountable body or responsible person to have a compliance program or to review patient medical records periodically. The Stark and anti-kickback statute (AKS) final rules give an effective date of Jan. 19, for most of the provisions, with the exception of certain changes to the definition of a "group practice," which have an effective date of Jan. 1, 2022, to give physician practices additional time to adjust their compensation methodologies.

There are fundamental differences in the statutory structure, operation, and penalties between the Stark Law and the AKS, and as a result, complete alignment between the exceptions to the Stark Law and safe harbors to the AKS is not feasible. The differences between the two rules create somewhat of a dual regulatory environment, where a value-based arrangement could meet the requirements for protection under one law but not the other, which could hinder the transition to a value-based health care delivery and payment system. CMS, in the final rule, acknowledged the "dual regulatory environment" and the challenges for stakeholders in ensuring compliance with both. As a result, the AMA strongly recommends physicians consult with health care counsel experienced in the federal Stark Law and AKS laws and regulations prior to taking any actions in association with the CMS and OIG final published rules.

AMA works with coalition aimed at reducing the number of uninsured patients
The AMA is promoting Get Covered 2021, a campaign being bolstered by a coalition of states, medical societies, patient and consumer advocacy groups and others working to lower the nation's ranks of the uninsured and encouraging people to wear a mask to prevent the spread of COVID-19. Of the 28 million Americans without health insurance, 16 million are eligible for financial assistance to help pay their costs of coverage. This includes 6.7 million who are eligible for free or low-cost coverage through their state's Medicaid program and 9.2 million who are eligible for subsidies through a state or federal insurance marketplace.

Due to significant federal budget cuts to ACA outreach and marketing efforts, your patients may not be receiving the information they need to know about enrolling in an ACA marketplace plan, and importantly, about the financial assistance available that could lower their premiums and cost-sharing responsibilities. There is still time to select a plan before the Dec. 15 deadline, and it is critical that to get the word out.

Visit GetCovered2021.org to learn more the coalition and how to help spread the #GetCovered2021 message on social media.

More articles in this issue

- Dec. 4, 2020: Advocacy spotlight on 2021 Medicare Final Rule: E/M improvements, budget neutrality cuts to payments
- Dec. 4, 2020: State Advocacy Update
- Dec. 4, 2020: Judicial Advocacy Update