May 19, 2023: National Advocacy Update

Senate Committee passes bipartisan PBM legislation

On May 11, the Senate Committee on Health, Education, Labor and Pensions (HELP), passed bipartisan legislation related to the regulation of Pharmacy Benefit Managers' (PBM) industry practices. The Committee marked up S. 1339, the Pharmacy Benefit Manager Reform Act, a bipartisan package from Chairman Bernie Sanders (I-VA) and Ranking Member Bill Cassidy, MD (R-LA). The base text of the bill would require PBMs to pass on all of the rebates they receive from drug manufacturers to employers and policy holders as well as ban spread pricing.

The committee adopted several amendments to the bill aimed at increasing transparency. One of the amendments would direct the Department of Labor to conduct a study on PBMs, while another would require PBMs to disclose certain spending information.

There were two other amendments approved by the committee relevant to AMA priorities. An amendment from Senators Murkowski (R-AK), Hassan (D-NH) and Marshall (R-KS) would include the Safe Step Act in the larger bill. The AMA has long supported the Safe Step Act, which allows for exceptions from medication step-therapy protocols. Another adopted amendment from Senators Markey (D-MA), Braun (R-IN) and Marshall (R-KS) would require the Comptroller General of the United States to conduct a study on actions that may be taken to ensure appropriate access and affordability of naloxone for individuals seeking to purchase it over the counter (OTC).

The AMA applauds the Senate HELP Committee for taking this important step in reforming PBMs and appreciates the committee's inclusion of the Safe Step Act as well as the important focus on ensuring OTC naloxone is affordable. The legislation will now await consideration on the Senate floor.

Prescribing of controlled substances based on telehealth visits extended

The ability to prescribe controlled substances based on telehealth patient visits was set to expire when the COVID-19 public health emergency (PHE) ended on May 11. The U.S. Drug Enforcement

Administration (DEA) initially issued two proposed rules establishing new policies for controlled substance prescriptions based on telehealth visits, one for buprenorphine (PDF) and one for other controlled substances (PDF). The AMA weighed in on the policy with multiple arms of the Biden administration, including the DEA as well as Rahul Gupta, MD, the director of the White House Office of National Drug Control Policy. After receiving more than 38,000 comment letters, however, the DEA has decided to extend the same policies that had been in place during the COVID-19 PHE for an additional six months, until Nov. 11, 2023. The AMA issued a statement welcoming this extension.

Resident Physician Shortage Reduction Act would increase Medicare-supported GME slots

One of the key pillars of the AMA's "Recovery Plan for America's Physicians" is enhancing the workforce and reducing burnout. In fact, the rise in physician burnout that stems, in part, from the additional stress and burden of the COVID-19 pandemic is a key factor behind the United States facing a projected shortage of between 37,800 and 124,000 physicians by 2034. The problem of a declining workforce is truly across-the-board as the nation faces a shortage of between 17,800 and 48,000 primary care physicians, as well as a shortage of between 21,000 and 77,100 specialists.

To help provide sustained relief from the workforce crisis and the associated burnout it produces, on May 9 the AMA sent letters in support of H.R. 2389/S. 1302 (PDF), the Resident Physician Shortage Reduction Act. Introduced by Representatives Terri Sewell (D-AL) and Brian Fitzpatrick (R-PA) in the House of Representatives and Senators Robert Menendez (D-NJ), Majority Leader Charles Schumer (D-NY), John Boozman (R-AR) and Susan Collins (R-ME), this bipartisan legislation provides a total of 14,000 new Medicare-supported graduate medical education (GME) positions over 7 years (2,000 per year). In addition, the latest bill stipulates that at least 10% of the slots must be distributed to hospitals that are within rural or non-contiguous areas (e.g., Alaska and Hawaii), training over their GME cap, located in states with new medical schools or branch campuses, and serve designated health professional shortage areas with priority given to hospitals affiliated with historically Black medical schools. The legislation also builds upon the 1,200 new Medicare-supported GME slots that Congress enacted via the Consolidated Appropriations Act, 2021 and Consolidated Appropriations Act, 2023. The bill is focused on overcoming the negative impact of provisions included in the Balanced Budget Act of 1997, which put caps on the number of federally funded residency positions that were available in the mid-1990s.

The individual letters of support also come on the heels of the AMA joining almost 80 other national medical and hospital associations as a cosigner of the May 8 GME Advocacy Coalition-led letter (PDF) to the lead House sponsors of the Resident Physician Shortage Reduction Act. A similar coalition letter is expected to be sent to the Senate cosponsors in the very near future as the

companion bill was introduced in late April. The grassroots advocacy is already having a tangible effect as H.R. 2389 has generated 76 bipartisan cosponsors so far following its introduction in late March. AMA remains a long-standing champion of this legislation, applauds the bicameral leadership on this policy concept and will continue to work with bipartisan lawmakers in hopes of enacting this legislation that further invests in GME before the end of the 118th Congress.

CMS allows virtual supervision of residents through 2023

In response to AMA advocacy, the Centers for Medicare & Medicaid Services (CMS) announced (PDF) that the agency will continue to allow teaching physicians in all teaching settings to be present virtually, through audio/video real-time communications technology, for purposes of billing under the Medicare physician payment schedule for services they furnish involving resident physicians. CMS will permit virtual supervision of residents through Dec. 31, 2023, and anticipates considering its policy in future rulemaking.

In a letter (PDF) to CMS, the AMA urged the agency to permanently allow the supervision of residents in teaching settings through audio/video real-time communications technology beyond the end of the COVID-19 public health emergency. The AMA noted that the Association of American Medical Colleges (AAMC) had conveyed the importance of permanently continuing this additional supervision option regardless of location, and the Accreditation Council for Graduate Medical Education (ACGME) recently amended its rules to allow for audio/visual supervision of residents. The letter expressed that if ACGME rules are adhered to and the use of audio/visual real time communication equipment is individualized to support the needs of residents, teaching physicians and their patients, then this tool will be effective and will provide appropriate supervision, frequent evaluation and open discussion. The AMA is pleased that CMS is allowing this flexibility through 2023 and will provide comments in response to future proposals on this topic.

FDA advisory committee recommends approval of first OTC oral contraceptive

On May 10, members of two Food and Drug Administration (FDA) advisory committees unanimously recommended that the FDA approve the supplemental new drug application (sNDA) for Opill, a progestin-only oral contraceptive, to be moved to non-prescription status. The recommendation is in line with AMA policy supporting OTC access to oral contraceptives. The AMA submitted comments (PDF) in support of the Opill application prior to the two-day meeting and in January wrote (PDF) to U.S. Department of Health and Human Services Secretary Xavier Becerra urging him to remove barriers to OTC access to oral contraceptives.

The advisors' recommendation comes over concerns raised by FDA officials regarding the ability of adolescents to safely and correctly use the medication. However, the advisors noted that risks of adherence issues and misuse exist currently and are not dependent on the prescription status of the drug. They also noted that the general risk profile of hormonal oral contraceptives is very favorable and that options such as Opill present significantly less risks than pregnancy.

As the advisory committee recommendations are advisory only and not binding upon FDA, the Opill application is subject to a final determination by FDA officials. There is no date for a final determination at this time.

FDA finalizes new blood donation guidelines

On May 11, the FDA finalized new blood donation guidelines that serve to expand the pool of potential donors. The new guidelines were finalized as proposed in January of this year and move away from the existing deferrals required for men who have sex with men (MSM). The new policy moves toward an individual risk-based evaluation versus requiring deferrals from all MSM. Under the new guidelines, all individuals will undergo the same risk evaluation on the same factors regardless of sexual orientation. The new factors focus on recent, high-risk sexual activity of the potential donor and bring U.S. policy in line with other countries such as Canada and the United Kingdom.

The AMA has long advocated for changes in FDA policy for blood and other tissue donation. The AMA submitted comments (PDF) in support of FDA's proposed policy changes in March 2023 and has also urged the agency to extend this policy to other tissue donations.

Physicians who relied on PTANS during the PHE must complete a CMS-855 beginning June 1

During the COVID-19 PHE, physicians and other providers who previously would have had to complete a CMS-855 Medicare enrollment application were granted temporary provider transaction access numbers, or PTANs (a form of temporary provider enrollment that can be obtained by phone from Medicare Administrative Contractors, or MACs). The lifting of the PHE on May 11 means that physicians and other providers who had relied on temporary PTANs for their Medicare enrollment will have to revert back to the normal process of completing a CMS-855 enrollment application.

MACs will begin issuing letters to that effect on June 1. Physicians and other providers will have 90 days from the date of the letter to submit their CMS-855 enrollment application. The temporary PTANs will remain in effect for the duration of the 90 days. MACs will accept CMS-855 enrollment applications

by paper or through the Provider Enrollment, Chain, and Ownership System (PECOS). If using PECOS, please select the revalidation option and validate that all sections are complete and accurate. The MACs will assign the permanent PTAN once processing is complete.

AMA provides input on physician-focused payment models

Responding to a request for input on “integrating specialty care in population-based models,” the AMA wrote (PDF) to the Physician-focused Payment Model Technical Advisory Committee (PTAC) to promote use of the Payments for Accountable Specialty Care (PASC) (PDF) approach in the Medicare program. Many patients who are insured by Medicare and assigned to an accountable care organization (ACO) have health problems that require diagnosis or treatment from a specialist, but these physicians often face challenges delivering the highest quality care to ACO patients due to barriers in both the regular Medicare and ACO payment systems.

Under PASC, specialists would enter into agreements with ACOs in which they would receive extra payments from Medicare to deliver enhanced services to patients with particular conditions who are referred to them by the ACO’s participating primary care physicians. For patients with chronic conditions, for example, care delivered under the PASC agreement could focus on avoiding the use of unnecessary and unnecessarily expensive medications and reducing exacerbations that can result in emergency visits and hospital admissions. Specialists with PASC agreements would also commit to providing feedback to and collaborating with the referring primary care physicians. The PTAC is expected to develop a report for the Center for Medicare & Medicaid Innovation on specialist integration in population-based alternative payment models. Engaging specialists in value-based care is one component to the Innovation Center’s current strategic plan.

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