Oct. 4, 2018: National Advocacy Update

FDA proposes changes for doctor office drug compounding oversight

The FDA released a revised draft guidance (PDF) document on Sept. 25 that proposes significant changes from its previous proposals for oversight of preparation of sterile drug products in physician offices. The guidance, "Insanitary Conditions at Compounding Facilities," was originally issued in draft form in 2016. That version had included physician offices in the definition of "compounding facilities," which would have subjected physicians preparing sterile drug products in their offices to significant environmental and quality controls akin to those found in compounding pharmacies.

However, after significant work by the AMA and physician specialty organizations, the FDA has changed course and has proposed to exempt physicians from federal requirements, noting that they generally do not intend to take enforcement action against physicians who are compounding products for administration to their own patients.

While this move represents a significant shift from earlier FDA thinking and would limit the federal regulatory burdens on practices, physicians will still be subject to possible state regulation of drug compounding. Regulation of these activities at the state level is generally overseen by boards of pharmacy and possible boards of medicine, so physicians preparing sterile drug products in their offices should pay close attention to regulatory activities in their states. Many states have adopted United States Pharmacopoeia (USP) Chapter 797 standards for sterile compounding. USP is currently in the process of revising those standards and the AMA continues to work closely with USP to ensure that physicians can continue to prepare sterile drug products in their offices.

CPT®/RUC workgroup on E/M

The AMA has formed a Current Procedural Terminology (CPT®)/Relative Value Scale Update Committee (RUC) Workgroup to develop an alternative to a provision in the 2019 Medicare Physician Fee Schedule/Quality Payment Program proposed rule that would collapse the current five levels of

evaluation and management (E/M) office visits for new and established patients down to two. The Workgroup has convened five meetings, four two-hour conference calls in August/September and one five-hour meeting on Sept. 29. More than 200 individuals have participated in each meeting. Several CMS staff, CMS medical officers and medical contractors have attended each meeting. The Workgroup has solicited feedback, via a formal survey mechanism, throughout the process to ensure that maximum input is acquired to achieve consensus. More than 60 national specialty societies and national health care professionals have responded to these surveys. The Workgroup continues to make progress and will submit a coding application to the CPT® Editorial Panel in November. All national medical specialty societies will have the opportunity to comment on the CPT® proposal via their CPT® Advisor. The CPT® Editorial Panel will consider this proposal in February 2019. If adopted, the modifications will be implemented in *CPT® 2020*. The next meeting of the Workgroup will take place via conference call the evening of Oct. 23.

House approves ban on pharmacy "gag clauses"

The House passed by voice vote S. 2554, the "The Patients Right to Know Drug Prices Act of 2018," and S. 2553, the "Know the Lowest Price Act," on Sept. 25. The Senate had previously approved both bills, and President Trump is expected to sign them into law. S. 2554, which was introduced by Sen. Susan Collins, R, Maine, and supported by the AMA (PDF), would prohibit health insurers and pharmacy benefit managers from using "gag clauses" that prevent pharmacists from sharing with patients the lower-cost options when they are purchasing medically necessary medication. In addition, the legislation would ensure that the Federal Trade Commission will have the necessary authorities to combat anti-competitive pay-for-delay settlement agreements between manufacturers of biological reference products and follow-on biologicals. S. 2553 would apply similar "gag clause" protections to Medicare and MA plans.

2019 HHS appropriations bill signed into law

President Trump signed HR 6157 into law on Sept. 28, which provides appropriations for HHS, the Department of Defense (DOD) and the departments of education and labor. To move the appropriations process through the regular order, an agreement was reached by all parties to avoid controversial amendments and riders and to provide additional funding for nondefense accounts in the same amount and spending increases provided for the DOD. The resulting bill, which also provides continued funding for much of the rest of the government through Dec. 7, 2018, increased spending for HHS by $2.3 billion for FY 2019 at a level of $90.5 billion for nonmandatory spending accounts.

Significant increases were included for National Institutes of Health (NIH), including increased funding for the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative and an increase for Alzheimer's disease research of $425 million, meaning there was a total funding increase of $2.34 billion. Several CDC offices, including the Office of Public Health Preparedness and Response and the National Center for Chronic Disease Prevention and Health Promotion, received increases as well.

Not surprisingly, the Substance Abuse and Mental Health Services Administration (SAMSHA) substance-abuse programs were funded at $3.82 billion, an increase of more than $555 million. Of that total, $1.5 billion would go to State Opioid Response Grants. Other opioid-related funding included $500 million for NIH, $475 million for CDC overdose prevention and surveillance, and $5 million to address opioid-related infectious diseases.

HHS would have to submit a reunification plan for migrant children to Congress by Nov. 15 or face restrictions on accessing nonrecurring expenses funds until the plan in submitted. The bill did not include any new restrictions on family planning funding, though Hyde-amendment abortion restrictions remain, as do Dickey amendment prohibitions on advocating for gun control.

On education, the bill would provide an additional $350 million to cancel loans under the Public Service Loan Forgiveness Program.

On the Defense side of the bill, provisions were included for a Government Accountability Office review of the implementation of the DOD's new electronic health record system. The bill would also require two reports back to Congress to ensure that the DOD is taking the necessary steps to ensure that full and accurate information is provided to databases used by the National Instant Criminal Background Check System for firearms purchases.

AMA submits comments on the OPPS and ASC proposed rule

The AMA submitted a comment letter (PDF) to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule for calendar year (CY) 2019 for the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System.

The Sept. 24 letter expresses appreciation for CMS proposals that encourage care in the lowest-cost setting. However, it points out that the current OPPS payment policies and proposed policies in the rule are complex, confusing and not truly site neutral because the policies do not apply equally to all hospital outpatient clinics. Furthermore, payment differentials stem in part from inadequate Medicare physician payment rates and any savings from site-neutrality proposals derived from OPPS should be reinvested in improvements elsewhere in Medicare Part B, including payments to physicians.

Positive elements of the proposed rule include that it:

- Replaces the Consumer Price Index for Urban Consumers with the hospital market basket as the annual update mechanism for ASC payments
- Revises the definition of surgery for 2019 to account for "surgery-like" procedures in ASCs
- Improves patient access to non-opioid treatments for pain management by separating their payment out from other services in the ASC setting

There are also policies included in this proposed rule that concern the AMA. These include:

- Site-neutrality policies that do not adequately accomplish the goal of encouraging care in the lowest-cost setting
- Insufficient actions to prevent the unnecessary shift of Medicare services from physician offices to hospital outpatient departments
- Potentially using prior authorization as a method for controlling overutilization of services;
- Rescaling the ASC relative weights to achieve a perceived budget neutrality objective instead of applying the OPPS relative weights
- Delaying the immediate removal of the Communication about Pain composite measure from the Hospital Consumer Assessment of Healthcare Providers and Systems and from public reporting

AMA's complete comments can be read here (PDF).

2017 MIPS targeted review deadline closes Oct. 15

CMS recently released the 2017 Merit-based Incentive Payment System (MIPS) performance feedback and opened the targeted review process. Based on the AMA flagging calculation-error concerns and the initial targeted review requests CMS received, CMS has revised the scoring logic and reissued the 2017 MIPS final scores (PDF) for the physicians who were impacted. In addition, to ensure CMS maintains the budget neutrality that is required by law under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), some physicians will see slight changes in their payment adjustment because of the reapplication of budget neutrality.

The revisions were made to the performance feedback on the Quality Payment Program (QPP) website on Sept. 13. The AMA encourages physicians and groups to sign in to the QPP website as soon as possible to review their performance feedback. If an error still exists with any 2019 MIPS payment adjustment calculations, the targeted review process is available, but claims must be filed by Oct. 15.

CMS has several resources available in the QPP Resource Library to help physicians and practices understand their performance feedback and the targeted review process. For assistance, please reach out to the Quality Payment Program Service Center at 1-866-288-8292, (TTY) 1-877-715-6222 or at QPP@cms.hhs.gov.

Virtual groups election period for MIPS 2019 now open

The election period is now open to form a virtual group for the 2019 Merit-based Incentive Payment System (MIPS) performance year. To form a virtual group, first there is an election and then the election must be submitted to CMS via e-mail by Dec. 31. Forming a virtual group provides the opportunity to effectively and efficiently coordinate resources to meet requirements under each MIPS performance category, and potentially increase performance. Virtual groups may be formed based on location, specialty, or shared patient population and can be a variety of sizes and compositions.

Download the 2019 Virtual Groups Toolkit to learn more about the election process and how to participate in MIPS as a virtual group. The toolkit also contains sample templates for the submission e-mail and the virtual group formal agreement.

AMA supports strong competition by biosimilars in comments to FDA

The AMA submitted a letter (PDF) to the FDA in response to the agency's Biosimilar Action Plan and subsequent public meeting on facilitating biosimilar competition. In the Sept. 21 letter, the AMA stated its strong support for FDA efforts aimed at enhancing competition in the generic drug space, including biosimilars, and urged the agency to continue its work to limit anticompetitive actions by brand manufacturers. The AMA also stated its support for a robust biosimilar marketplace and urged the FDA to take action to ensure biosimilars are quick to market and that no regulatory actions are taken that may hinder physician and patient uptake of these products. The AMA continues to work with FDA to ensure the success of biosimilars in the market and to educate physicians on these important products.

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