Nov. 1, 2018: National Advocacy Update

Trump administration announces new proposal to lower drug prices

On Oct. 25, the administration announced a new plan to lower prices paid by Medicare for physician-administered drugs paid under Part B. The new "International Price Index Model for Part B" would create a payment system where certain included drugs would be reimbursed at the lower levels paid for those drugs by other countries. Also, private third-party vendors would contract with physicians and hospitals to supply drugs included in the plan.

The Centers for Medicare & Medicaid Services (CMS) would then reimburse vendors for the drugs with prices capped at a predetermined level based on prices in the international market. Physicians and hospitals would still bill for a drug-administration fee. They would also be paid a flat "add-on" fee that will equate to 6 percent of the historical average sales price for the drug in question.

The proposal was released as an Advance Notice of Proposed Rule Making (ANPRM) and at this point is largely conceptual. CMS anticipates a formal proposed rule to be issued this spring with a final rule possibly taking effect in 2020.

The agency is currently seeking feedback on many questions included in the ANPRM that it plans to consider prior to entering the formal rulemaking process. While appreciative of the administration's work to move toward lower drug prices for patients, the AMA has questions about this proposal and will be working closely with CMS to provide feedback.

Physicians oppose prolonged detention of migrant families

The AMA submitted comments (PDF) to the secretaries of the departments of Homeland Security (DHS) and Health and Human Services (HHS) in response to a proposed rule titled, "Apprehension, Processing, Care, and Custody of Alien Minors and Unaccompanied Alien Children." The AMA stated its opposition to the DHS-HHS proposal to expand long-term detention of migrating families. The AMA has policy specifically opposing the expansion of family immigration detention in the U.S.

The proposed rule seeks to dismantle the Flores Settlement Agreement (FSA), a decades-old court settlement put in place to ensure the safety and proper care of children in immigration detention. The FSA set strict national standards for the detention, treatment and release of all minors (both accompanied and unaccompanied minors) in immigration custody. The FSA generally requires that children be held in the least-restrictive setting appropriate for a child's needs and that they be released without unnecessary delay to a parent, designate of the parent or responsible adult as deemed appropriate.

The proposed rule seeks to undermine the FSA by allowing minors with their parents to be detained in DHS-licensed family detention facilities for the entirety of their immigration proceedings. The AMA voiced concern about the proposed rule's potential negative impact on immigrant children and their parents or caregivers and urged the administration to withdraw the proposed rule.

The AMA urged the administration to give priority to supporting families and protecting the health and well-being of the children within those families, stating: "Prolonged detention of migrant children and their parents is not a solution to the earlier immigration issue created by the administration's zero-tolerance policy which led to the forced separation of thousands of children from their parents and caregivers at the U.S. border."

The AMA urges FTC to act on insulin prices

The AMA expressed strong concern to the Federal Trade Commission (FTC) in an Oct. 26 letter (PDF) about the sharp rise in insulin prices among manufacturers. The AMA urged the agency to monitor insulin pricing and assess whether anti-competitive actions were driving higher insulin prices.

The AMA asked that the FTC recommend enforcement action against manufacturers that were engaged in anti-competitive practices to the U.S. Department of Justice. In the letter, the AMA cited lawsuits filed in 2017 against insulin manufacturers on behalf of patients that noted there were "rapid and lockstep price increases of more than 150 percent."

New Medicaid model addresses maternal opioid use

The Center for Medicare and Medicaid Innovation has announced a new delivery model, Maternal Opioid Misuse (MOM), aimed at expanding access to comprehensive care for opioid-use disorder (OUD) among pregnant and postpartum women and their infants. The model is designed to foster coordination of medical care and all the other services needed to support maternal health and recovery.

Morbidity and mortality related to OUD has been growing rapidly among pregnant and postpartum women. The MOM model will award cooperative agreements in up to 12 states that will support state Medicaid agencies and health care professionals working to address fragmentation in the care of pregnant and postpartum Medicaid patients with OUD. Medical societies interested in potentially working with state Medicaid programs as "care delivery partners" in the MOM model can register to learn more through webinars scheduled for Nov. 8 and Dec. 6.

Physicians provide comments on EHR reporting program

The 21st Century Cures Act, signed into law December 2016, directs the HHS secretary to establish an electronic health record (EHR) reporting program to engage stakeholders and gather information about EHR performance to help physicians better choose products. EHR developers will be required, as a condition of their products' certification, to submit reporting criteria on EHR usability, interoperability and security. The Office of the National Coordinator for Health Information Technology (ONC), the HHS agency responsible for regulating EHRs, recently released a request for information to gather physician and end-user feedback on how best to structure the EHR reporting program.

The AMA provided extensive feedback (PDF), encouraging ONC to focus the program's goals on:

- Increasing the expectation that EHR vendors must respond to and focus on their customers' needs, rather than simply comply with federal EHR program requirements
- Coupling EHR performance, functionality and cost with physician satisfaction, burden and frustration as a key domain for measuring and comparing EHRs
- Capturing EHR reporting information without further burdening physicians or their staff, be automated wherever possible, and deliver value to those being measured
- Requiring comprehensive, consistent and comparable reporting requirements for all EHR developers, with attention to product cost, safety and security
- Leveraging industry standards and frameworks for measuring and scoring an EHR's usability assessment—such as those developed by the AMA, Pew and MedStar Health
- Including information on EHRs' capability to connect to regional and state health information exchanges, registries, and prescription drug monitoring programs
- Reducing physician burden by utilizing EHR developer-submitted reporting information as an alternative, supplement or direct replacement for reporting programs like Promoting Interoperability

AMA urges OIG to create value-based anti-kickback safe harbor

In a comment letter (PDF) responding to the "Request for Information regarding the Anti-Kickback Statute, and Beneficiary Inducement Civil Monetary Penalty," the AMA urged the Office of Inspector General (OIG) to create a new value-based anti-kickback safe harbor to facilitate coordinated care and to promote well-designed alternative payment models (APMs). AMA calls for the safe harbor to be broad, covering both the development and operation of a model to allow physicians to transition to an APM, and to provide adequate protection for the entire care delivery process—including downstream care partners.

The AMA also recommended that OIG create an anti-kickback safe harbor for the sharing of cybersecurity tools and resources. The AMA stressed that any cybersecurity safe harbor be easy to understand, interpret and enforce so that donors and recipients can readily distinguish permissible activities from those that violate the anti-kickback statute. The AMA suggested that the current EHR safe harbor may act as template for a new cybersecurity safe harbor.

Other recommendations from the AMA include:

- Allowing personal services and management contracts that reward value and allow for incentive payments for efficient and better care
- Expanding the warranty safe harbor to include bundled payments
- Making the EHR safe harbor permanent and include covering replacement technology
- Creating policy guidance that meeting the promoting access to care Civil Monetary Penalty (CMP) exception gets Anti-Kickback Statute protection
- Establishing a new CMP exception from remuneration to allow for beneficiary incentives for adherence and management activities
- Asking for policy guidance to waive cost-sharing when the amount is nominal (i.e., when reasonable collection efforts cost more than would be collected)

AMA urges changes to the QIO appeals process

The AMA sent a letter (PDF) regarding the lack of recourse for providers or patients who are unhappy with the outcome of the CMS Quality Improvement Organization (QIO) appeals process. The Oct. 22 letter was in response to physicians' concerns that the QIO appeals process, and particularly redeterminations, lacks fairness and is singularly focused on a final determination providing no opportunity for further discussion or appeal. The AMA urged CMS to require QIOs to give both parties appropriate notification and to provide the same opportunity to comment during reconsiderations of initial decisions.

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