June 14, 2019: National Advocacy Update

AMA, medical societies ask Congress to refine MACRA

The AMA along with 120 state medical and national specialty societies sent a letter to congressional leaders (PDF) calling for refinements to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA remains an improvement over the sustainable growth rate formula it replaced, but the joint letter urges Congress to build on the lessons learned during the initial years of implementation to help physicians succeed and patients thrive.

Specifically, the AMA and medical societies urged Congress to replace the scheduled physician payment freeze from 2020 through 2025 under MACRA with positive payment updates to reflect increases in practice costs and preserve patient access. In addition, to provide physicians with a longer on-ramp to move to alternative payment models (APM), Congress should extend the APM incentive payments for an additional six years. Finally, the letter advocates that Congress work with the medical community to make technical improvements to MACRA, such as providing the Centers for Medicare & Medicaid Services (CMS) with greater flexibility to streamline reporting under the Merit-based Incentive Payment System (MIPS) and adjust APM participation thresholds.

AMA Immediate Past President Barbara L. McAneny, MD, recommended these improvements and other refinements to MACRA during her testimony at a U.S. Senate Finance Committee hearing on May 8.

Physicians respond to proposed health information exchange rules

The AMA has submitted comprehensive comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to its sweeping proposed changes to health information technology (health IT) certification and implementation of the 21st Century Cures Act, and to CMS in response to its proposal on patient access and interoperability. The AMA supports several of the proposed changes, especially around health IT vendor practices, technology development and electronic health record (EHR) performance. However, the AMA has also identified proposals that could prove problematic and run counter to the goals of improving patient care.

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ONC's proposed rule updates technical standards and vendor requirements that will help improve interoperability and EHR performance. Consistent with AMA's recommendations, ONC is promoting greater access to medical information, requiring the widespread use of application programing interfaces, and limiting excessive fees and contractual limitations that prevent interoperability. Yet, the AMA is expressing concern that ONC and CMS' proposals will hurt patient privacy and impact physician autonomy.

The AMA strongly supports patients having access to their own health information. At the same time, the proposed rules are complicated, intertwined, and may result in a patient's information being shared or sold. ONC's proposals give software applications and their developers equal protections and benefits with those of patients. The AMA cautions that smartphone apps share sensitive health information with third parties, often without an individual's knowledge. Much of this information can end up in the hands of data brokers or be used for advertising and marketing. These practices jeopardize patient privacy, commoditize an individual's most sensitive information and threaten patient willingness to utilize technology to manage their health. The AMA is requesting that ONC include mechanisms to strengthen patients' control over their data.

The AMA also outlines how the rules conflate a payer's desire for data with a clinician's need to access, exchange and use health information. The rules could empower payers to demand more information than is needed, whether for compliance with CMS' rule or for other purposes. Physicians who deny payer requests for this information may be accused of information blocking—regardless of whether the request is fully warranted. Further, payers could use CMS and ONC's proposals to request direct access into a physician's EHR. This raises significant concerns about payer overreach, increased prior authorization and patient profiling—potentially limiting coverage and access to care and intruding on physician medical decision-making. The AMA is requesting that CMS prohibit payers from using these proposals to place additional contractual demands on physicians and that it impose meaningful penalties for payer noncompliance with this new prohibition.

The AMA press release and links to both comment letters can be found here.

**Final federal pain task force report released**

The AMA strongly backs the comprehensive, common-sense proposals put forth by the U.S. Department of Health and Human Services Interagency Pain Task Force (PDF), sending a clear signal to the physician community that policymakers understand the treatment required for patients in pain.

The recommendations balance the need to effectively manage patients' pain while also advancing
policies to end the epidemic of opioid-related deaths. "These recommendations are a lifeline to pain patients who have been caught in the middle of policy efforts that have produced harmful unintended consequences," said AMA President Patrice A. Harris, MD, MA, chair of the AMA Opioid Task Force. "This is a road map to help physicians and policy makers take sustainable steps to end the epidemic and improve pain care."

New VA Community Care Program rolls out

The AMA has supported the Veterans Choice Program and other Department of Veterans Affairs (VA) initiatives that give veterans who meet certain eligibility criteria the option to see community-based physicians and other health care professionals. The recent passage of the MISSION Act built on these efforts by consolidating all of the VA's purchased care authorities into the Community Care Program beginning June 6. Unlike the Choice Program, the Community Care Program signifies a long-term commitment by the VA to partner with private practitioners, hospitals and other community-based providers to deliver care to veterans. There will be one contracting process, one set of rules, one set of eligibility criteria, a new claims processing system that should reduce payment delays and, significantly, there is no sunset date for the Community Care Program.

In the Community Care Program Proposed Rule, the VA specifically acknowledged that many community-based providers will be small businesses and that the impact on such entities will be considered in subsequent rulemaking. The Community Care Network administrators have yet to be finalized in most regions and the VA has yet to publish rules on claims processing and payments, so the program will be rolled out with some unanswered questions. The Triwest provider network will be a critical bridge during this transitional period and payment rates will be carried over from the Veterans Choice Program until the VA issues rulemaking that is expected to align VA payment rates with Medicare. The ability of the VA to coordinate care with community-based physicians is the biggest question mark, given the reliance on untested information technology that allows community-based physicians to interface with the VA.

USP finalizes chapters for sterile compounding

On June 3, the United States Pharmacopoeia (USP) released several new chapters outlining standards for safe compounding practices. New final chapters include USP Chapter 797 for sterile compounding, Chapter 795 for non-sterile compounding and Chapter 825 for compounding, preparing and handling of radiopharmaceuticals. The new chapters are the result of the USP revision cycle intended to update compounding standards and will be effective starting December 2019. The AMA has been working closely with USP on the revision process, as earlier proposed changes would have

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severely limited the ability of physicians to prepare sterile drug products in their offices for administration to their patients.

The new Chapter 797 includes significant changes from the initial proposed chapter, including a new provision applicable to physicians for "Immediate Use Compounding Sterile Preparations." Under the immediate use provision, physicians will be able to prepare sterile drug products in office settings without complying with the remainder of the chapter so long as the time from preparation to administration to the patient is no longer than **four hours**. In addition to the four-hour time frame, the immediate use provision requires physicians to practice proper aseptic technique, ensure chemical compatibility of the drugs being combined and ensure any single-dose vial is discarded after a single use. If preparation begins more than four hours from the time of administration, physician offices will be subject to the full requirements of Chapter 797, similar to pharmacies. The new chapter also clarifies that compounding according to manufacturer labeling or following manufacturer's instructions will not be subject to the requirements of the chapter.

Physicians preparing allergy and immunotherapy injections in an office setting will be governed by a separate section within Chapter 797. This section provides separate standards specific to those products that physicians practicing in this space should comply with if their state requires compliance with 797.

In addition to Chapters 797, 795 and 825, Chapter 800 for "Handling of Hazardous Drug Products" will become effective December 2019. For physicians with practices located in states that require compliance with Chapter 800, this chapter will apply to those that are engaged in compounding of drugs deemed hazardous by the National Institute of Occupational Safety and Health. Chapter 800 provides standards that facilities must meet to help ensure the safety of health care workers handling hazardous drugs. For those that may be subject to the requirements in Chapter 800, USP has prepared educational materials regarding the application of Chapter 800 and the requirements therein.

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