Oct. 18, 2019: National Advocacy Update

Key updates to the Quality Payment Program

The AMA has been urging the Centers for Medicare & Medicaid Services (CMS) to distribute 2019 incentive payments to qualifying participants in advanced alternative payment models (APM) based on 2017 APM participation.

CMS is finally releasing the incentive payments. The APM incentive payment is a lump sum based on the paid amounts for Medicare Part B covered professional services furnished by the physician across all groups during calendar year 2018. CMS’ fact sheet (PDF) provides additional details.

Additional updates and important dates to watch in the Quality Payment Program (QPP) program include:

- The virtual group election process is underway for the 2020 Merit-based Incentive Payment System (MIPS) performance year. Solo practitioners and group practices with 10 or fewer clinicians have until Dec. 31 to submit a virtual group election to CMS. CMS has released a toolkit with instructions for interested physicians and groups.
- The deadline to submit a "Promoting Interoperability Hardship Exception" and/or "Extreme and Uncontrollable Circumstances" application is the end of the year.
- CMS updated its QPP status tool, which shows whether a physician is a qualifying participant in an advanced APM in 2019 and therefore will receive a 5% incentive payment and exemption from MIPS in 2021.

Administration action needed to improve Medicare Advantage networks

Responding to policies adopted by the AMA House of Delegates, the AMA is asking CMS Administrator Seema Verma to adopt a suite of policy proposals (PDF) to enhance Medicare Advantage (MA) physician network adequacy, stability and directory accuracy, improve communication with patients about MA plans’ physician networks, and ban no-cause network terminations. The AMA urges CMS to boost its efforts to ensure directory accuracy by requiring MA
plans to submit accurate network directories to CMS every year prior to the Medicare open enrollment period and whenever there is a significant change to the status of the physicians included in the network.

CMS should also take enforcement action against MA plans that fail to maintain complete and accurate directories. To ensure that network adequacy standards provide adequate access for patients and support coordinated care delivery, CMS should require plans to report the percentage of physicians in the network, broken down by specialty and subspecialty, who actually provided services to plan members during the prior year. Citing a July 2019 Government Accountability Office report (PDF), the AMA notes that physician networks have been found to be important in Medicare beneficiary decisions about MA plans, and recommends that CMS improve the physician network information provided on the online Medicare Plan Finder website.

For calendar year 2020, the Medicare open enrollment period runs from Oct. 15 through Dec. 7, 2019. During this time, people with Medicare can compare coverage options like original Medicare and MA, and choose from among the MA and Part D prescription drug plans available in their locality for 2020.

### Stark and anti-kickback regulatory changes proposed

CMS and the Office of Inspector General at the Department of Health and Human Services separately issued proposed rules to modernize and clarify the regulations that interpret the physician self-referral law (often called the "Stark Law") and the anti-kickback statute. The proposed rules include provisions meant to advance the transition to a value-based health care delivery and payment system that improves the coordination of care among physicians in both the federal and commercial sectors.

The proposals also include clarifying key terms like "fair market value" and "commercial reasonableness," updating existing safe harbors and exceptions including the group practice exception and electronic health records safe harbor and exception, and creating new safe harbors and exceptions such as allowing the sharing of cybersecurity software and services. If finalized, the proposals may present significant opportunities for new financial arrangements but may also require revisions to current arrangements involving physicians, hospitals, patients and others involved in the health care industry. The proposed rules state that comments for each will be due 75 days from the date of publication in the Federal Register (which is currently scheduled for Oct. 17).

### FDA releases updated draft guidance for clinical decision support software


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Last month, the Food and Drug Administration (FDA) issued updated draft guidance outlining the agency's current thinking on regulation of clinical decision support (CDS) software. The updated draft guidance outlines the agency's proposed framework for regulating CDS tools, explaining which tools the FDA plans to review and which it will not. In a shift from the FDA's initial draft guidance, released in 2017, the updated version moves to use of a risk-based framework for determining review status. The 2017 version proposed to make review determinations based upon the level of human involvement with the CDS, meaning whether a physician was capable of independently reviewing the software's output.

Along with the updated CDS draft guidance, FDA also finalized guidance aimed at bringing existing FDA software policies in line with the 21st Century Cures Act. Notably, this final guidance outlines the types of products FDA will not consider to be medical devices and will therefore not regulate. These include items such as software for facility administration, electronic patient records, general health and wellness apps, and software intended for storing, transferring, formatting, or displaying data and results.

AMA applauds federal ruling on the public charge

On Oct. 11, judges in separate cases before the U.S. District Courts for the Southern District of New York (SDNY) and Eastern District of Washington preliminarily enjoined the U.S. Department of Homeland Security (DHS) from implementing and enforcing the final rule related to the public charge ground of inadmissibility. The AMA submitted a comment letter (PDF) to the DHS in December vigorously opposing the public charge proposed rule and the harm to immigrant children and families the proposal would cause if implemented. The public charge rule has already had a chilling effect, leading many immigrant families to avoid accessing vital health, nutrition and housing programs. The AMA also joined with other health care organizations in submitting amicus briefs (SDNY: amicus 1 and amicus 2; Wash.: amicus) in the separate cases.

The DHS' final rule was slated to take effect on Oct. 15, but the two injunctions are nationwide and prevent the U.S. Citizenship and Immigration Services (a component of the DHS) from implementing the rule anywhere in the United States until there is final resolution in the cases.

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