March 12, 2020: National Advocacy Update

AMA reviewing interoperability rules to determine patient focus, privacy issues

Since last year's release of proposed rules from the Office of the National Coordinator (ONC) and CMS implementing the 21st Century Cures Act's provisions on information blocking and interoperability, the AMA has engaged regularly with policymakers to refine the proposals so they meet the needs of patients and physicians.

"The AMA has been advocating on behalf of physicians and patients for over 10 years to ensure electronic health record (EHR) usability, interoperability, and patient data and safety are top concerns when government agencies develop new policies," said AMA President Patrice A. Harris, MD, MA. "We applied this knowledge and momentum as we worked with CMS and ONC in anticipation of [the] release of the final rule. AMA is reviewing the new rules, paying special attention to policies aimed at creating efficiencies in data exchange, reduction in physician burden, and patient control over and access to their data." The AMA will be looking particularly in the following areas.

- Privacy controls that require apps to be transparent about what data is being collected and how the app developers intend to use it, and security safeguards for patients using apps to access health information
- Rules that prohibit vendors from charging excessive fees, including "gag clauses" that prevent physicians from publicizing problems with their EHRs
- A usage-based fee structure to limit EHR vendor fees and prevent physicians from incurring costs for exchanging health data that complies with federal requirements
- Programming tools to improve physician and patient access to health information
- More stringent requirements on EHR testing and usability
- Limiting unnecessary and inappropriate access to EHR data from insurers and other non-clinical entities
- More clarity and a reduction in the complexity of information blocking exceptions for physicians
- Less aggressive and separate EHR implementation timelines for vendors and physicians

In the coming weeks, the AMA will undertake aggressive action to provide physicians and patients with resources to help understand how these new regulations will affect their medical practices and care, how to reduce confusion around state and federal regulations on data access and EHR interoperability and timelines of when to expect updates to EHR products and vendor contracts.

HHS releases federal strategy to reduce burden

The 21st Century Cures Act requires the Department of Health and Human Services (HHS) to create a strategy to address specific sources of physician burden by coordinating a public and private stakeholder effort to reduce burden associated with health care administration and use of health information technology (health IT), including EHRs. The AMA provided comments on HHS' draft report in early 2019 and is encouraged by the breadth of HHS' recently released final report (PDF). The AMA has identified several areas where health IT and administrative burden impact physicians and patient care. HHS acknowledged many of the AMA's concerns and incorporated several of the recommendations made. The strategies outlined in the report paint a general picture of where HHS' policies should be modified or refocused. HHS also recognizes engagement with the physician community will continue to be a critical factor in success. AMA views the overall strategies as a signal to physicians, patients and Congress of HHS' commitment to coordinate across agencies and act expeditiously to reduce regulatory complexity and physician burden. The AMA will continue to work with HHS to address physician burden and looks forward to assisting in their strategic approach.

House passes legislation banning flavored tobacco and e-cigarettes

The House passed sweeping legislation to curb flavored tobacco and e-cigarettes on Feb. 28. The AMA successfully urged House members to vote in favor of H.R. 2339, the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020, which ultimately passed by a vote of 213-195. The legislation, sponsored by Representatives Frank Pallone (D-NJ), Chairman of the House Energy and Commerce Committee, and Donna Shalala (D-FL), would impose a variety of restrictions on tobacco and e-cigarette products. The bill would remove all flavored e-cigarettes from the market and only permit them to return if the manufacturer demonstrates that the product helps current tobacco users stop smoking, would not lead non-tobacco users to start and would not increase the risk of harm from using the product. All other flavored tobacco products, including menthol cigarettes, would be made illegal. H.R. 2339 also includes provisions that would:

- Ban online tobacco product sales, with the exception of certain high-end cigars
- Increase tobacco user fees as well as allowing them to be assessed on e-cigarettes

- Provide the Federal Trade Commission the authority to enforce the ban on marketing or promoting e-cigarette use among people under age 21
- Levy an excise tax on e-cigarettes and use the corresponding revenue toward providing colorectal cancer screenings for Medicare users
- Require high deductible plans to cover inhalers for people with chronic lung disease

While H.R. 2339 is unlikely to advance in the Senate this year, the AMA will continue to work with others in the physician and public health community to build support for its eventual passage.

AMA weighs in on the FDA Office of Minority Health and Health Equity strategic priorities

The AMA recently submitted detailed comments to the Food and Drug Administration's (FDA) call for input on their Office of Minority Health and Health Equity's (OMHHE) strategic direction. The FDA OMHHE is tasked with promoting and protecting the health of diverse populations through research and communication of science that addresses health disparities and health equity. While OMHHE has in the past focused primarily on communications efforts, as well as work around diversity and inclusion in clinical trials, it is seeking to broaden its impact and work in this space with help from stakeholders to identify additional areas within FDA's work where more of an impact can be made. The AMA's comments urged FDA to focus on three key areas for growth and improvement: research and innovation, health literacy education and community engagement and public health workforce development. AMA comments were provided in conjunction with the AMA's new Center for Health Equity, which will work to elevate the importance and sustainability of the AMA's health equity efforts.

AMA provides comment on FDA drug importation proposals

The AMA recently submitted comments to the FDA on two proposals aimed at creating pathways for importation of prescription drugs. The first proposal seeks to allow drug manufacturers a pathway to bring their drug products marked for distribution in foreign markets back to the United States under new National Drug Codes (NDC), allowing them to potentially be sold at lower list prices than those currently designated for distribution within the U.S. The second proposal would potentially allow for the creation of state-based programs that could seek to import prescription drugs from Canadian suppliers. AMA policy supports drug importation as a method of lowering drug prices, so long as the safety, quality, integrity and authenticity of those drug products can be assured. AMA comments did, however, raise concerns about consistent application of safety standards across potentially numerous state-based programs. The AMA also stressed that any savings generated by importation of prescription drugs must be passed to patients and not otherwise absorbed by the drug supply chain,

which is seen as a high risk under both proposals.

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