HHS reverses course on regulation of laboratory-developed tests

In a surprising move, the U.S. Department of Health and Human Services (HHS) announced new policy to rescind previous guidance from the FDA concerning premarket review of laboratory-developed tests (LDT). The notice states that LDTs will no longer require premarket review by the FDA absent formal notice and comment rulemaking from the agency.

LDTs, a subset of clinical laboratory testing services, are tests developed and performed within a single laboratory. Traditionally, the FDA has exercised enforcement discretion with LDTs, and they have not been subject to FDA premarket review. However, over the past several years, there have been increasing attempts to bring more LDTs under FDA purview. The physician community has generally opposed attempts at FDA regulation of all LDTs, as development of these tests is in many cases considered an activity under the umbrella of the practice of medicine for pathologists and others and would severely limit access to many testing services performed in settings such as academic centers. LDTs will continue to be regulated under the Clinical Laboratory Improvement Amendments (CLIA) program administered by the Centers for Medicare & Medicaid Services (CMS).

FTC’s Health Breach Notification Rule more important now than ever

The AMA recently responded to the Federal Trade Commission’s (FTC) request for comment on its Health Breach Notification Rule (HBN Rule). The HBN Rule generally requires vendors of Personal Health Records (PHRs) that are not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to notify consumers, the FTC and sometimes the media when unsecured, individually identifiable information is accessed without a consumer’s authorization. In its request for comment, the FTC stated its intent to ensure the HBN Rule has “kept up with changes in the marketplace, technology, and business models,” noting that “as consumers turn towards direct-to-consumer technologies for health information services (such as mobile health applications, virtual assistants and platforms’ health tools), more companies may be covered by the FTC’s Rule.” The AMA commented that the HBN Rule is more important now than ever, given the passage of the
21st Century Cures Act (Cures Act) and its implementing regulations promulgated by the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services (CMS) earlier this year. The implementation of the Cures Act will likely lead to an increase in patients using apps to access and manage their health care information—a laudable goal that the AMA supports—but this information will not be subject to the privacy and security protections of HIPAA, meaning that it can be broadly shared by app developers. Sharing that health information with data brokers, who can combine it with other consumer information (such as credit score, level of education, and even something as simple as a zip code), creates the perfect recipe for harmful profiling and discrimination.

The AMA’s comments focused on ensuring that technology developers better inform consumers of what information they are accessing, why they are accessing it, who they are sharing it with and how long they are keeping it. The AMA also highlighted the need to advance equity by requiring that this information be communicated in a clear, precise manner that promotes understanding by those with elementary school levels of reading comprehension. Additionally, the comments noted the importance of technology developers publicly disclosing their de-identification techniques to promote greater accountability from developers claiming that they are only sharing de-identified information. These concepts stem from the AMA’s Privacy Principles, released earlier this year, and seek to fortify the trust so central to the physician-patient relationship.

2020 QPP eCQM scoring issue

CMS is alerting physicians to an issue that impacts electronic clinical quality measure (eCQM) scoring during the 2020 performance year. eCQMs are used in several programs, including the Quality Payment Program and the Merit-based Incentive Payment System (MIPS). The issue relates to the timing values for three quality measures. This issue has the potential to impact measure scoring when certain time values are not present in the input data. The erroneous calculation may result in an increase or decrease of cases that fall in the measure population.

Impacted measures are:

- CMS128v8 Anti-depressant Medication Management
- CMS146v8 Appropriate Testing for Children with Pharyngitis
- CMS56v8 Functional Status Assessment for Total Hip Replacement

CMS has published updated measure packages to correct the issues for all three impacted eCQMs. The updates are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center. Physician practices that are reporting on the measure(s) should contact their electronic health record (EHR) vendors to see if EHR system updates are warranted. Additional details and measure specific information can be reviewed in the ONC eCQM Known Issues Tracker.


Copyright 1995 - 2021 American Medical Association. All rights reserved.
Mental health infrastructure should be bolstered to ease burnout of front-line physicians

The challenges and dangers physicians are facing in their continued fight against COVID-19 is exacting an intensifying toll on the mental health of the health care workforce. The AMA is increasingly concerned about reports that more than half of all physicians in the United States are experiencing substantial symptoms of burnout, with the most severe symptoms occurring among those working on the front lines of medicine in fields such as emergency medicine, family medicine and internal medicine. This is why the AMA sent a letter to members of the House and Senate in support of S.4349, the Dr. Lorna Breen Health Care Provider Protection Act. This act would bolster the nation’s mental health infrastructure by:

- Establishing grants for health care professionals to help create evidence-based strategies to reduce burnout and the associated secondary mental health conditions related to job stress
- Establishing a national campaign to encourage health care professionals to prioritize their mental health and to use available mental and behavioral health services
- Establishing grants for employee education and peer support programming
- Conducting a comprehensive study on the mental health and burnout of health care professionals

A recent study showed that as a result of the COVID-19 pandemic, there was a median increase of 60% in physician emotional exhaustion when compared to pre-COVID-19 levels. Although physicians have received accolades from their communities, numerous physicians have described feeling lost, alone and unable to sleep. Not only are physicians in constant fear due to the uncertainty of their patients’ health, but there is also considerable anxiety surrounding the potential risks to their own health and the health of their families.

AMA advocates for operating rules to promote efficiency at NCVHS hearing

The AMA participated in the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards hearing to provide testimony on rules authored by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE). The AMA urged NCVHS to recommend federal adoption of operating rules for medical services electronic prior authorization due to several anticipated benefits for patients and physician practices, including reduced processing time and patient care delays, improved process automation.
and efficiency, and increased transparency in insurers’ opaque clinical documentation requirements. The AMA also supported mandating CAQH CORE’s updated Connectivity Rule, which would set uniform requirements across all revenue cycle transactions, improve security protocols and enhance interoperability. Representation of physicians’ interests before NCVHS plays an important role in the AMA’s overall advocacy efforts to reduce practice administrative burdens through implementation of standard electronic transactions and associated operating rules.

More articles in this issue

- Aug. 28, 2020: Advocacy spotlight on AMA asks FDA for increased transparency with physicians on COVID-19 vaccine development
- Aug. 28, 2020: State Advocacy Update