Put It on the Board, 7/14

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Ethics of laboratory billing at stake in AMA's code

Proposed revisions to the American Medical Association's *Code of Medical Ethics* would remove language that supports direct billing and condemns clinicians who charge markups for laboratory or pathology services. The changes could weaken efforts to rein in billing practices that CAP leaders argue are not in the best interest of the patient and that the AMA currently defines as unethical.

"The importance of this is that many states utilize the AMA's code of ethics as their code of ethics for things related to medicine. . . . So, if you change the AMA code of ethics that these laws are based on, then people can make the argument that since these ethics principles have changed, perhaps these laws need to be changed," Daniel C. Zedek, MD, tells CAP TODAY. He is an alternate delegate to the AMA House of Delegates for the CAP and is director of dermatopathology at the University of North Carolina School of Medicine.

Dr. Zedek offered feedback regarding the proposed code revisions to the AMA's Council on Ethical and Judicial Affairs during an educational session at the association's annual meeting in June. Since 2008, CEJA has undertaken an ambitious project to review, update, and reorganize the *Code of Medical Ethics* to make it more user-friendly.

In his remarks, Dr. Zedek cited the American Academy of Dermatology's March 2013 position statement on pathology billing. The policy states that the AAD "urges against purchased service arrangements for ancillary dermatopathology lab tests provided by an outside pathology lab to a dermatology practice that then inappropriately marks up the cost and bills for work not performed by the billing dermatology practice.

"This arrangement," the AAD's policy says, "results in a lowering of the level of resources available for providing pathology services to patients, invites scrutiny from state regulators, and is clearly unethical."

Mark Synovec, MD, also spoke before CEJA on behalf of pathology leaders. Dr. Synovec is a CAP delegate to the AMA and chairs the Pathology Section Council (PSC), a coalition within the House of Delegates that includes the CAP, USCAP, ASCP, American Society of Cytopathology, and National Association of Medical Examiners.

Dr. Synovec told the council that he and the PSC firmly agreed with CEJA's earlier communication on

the modernization project, which said, “Ethics is the foundation on which law should rest.” He told CEJA, “If you have laws based on ethics and you remove the ethics, it seems like you’re threatening the laws.”

Nineteen states require direct billing for laboratory and pathology services, as does Medicare. Seventeen states require disclosure to patients of the actual cost of lab testing services. Eight states bar markups. The CAP supports direct billing for anatomic and clinical pathology services for all private and public payers.

Three opinions of the AMA code are at issue. The first is ethical opinion E-6.09—Laboratory Bill, which states: “When it is not possible for the laboratory bill to be sent directly to the patient, the referring physician’s bill to the patient should indicate the actual charges for laboratory services, including the name of the laboratory, as well as any separate charges for the physician’s own professional services.” In comments included as part of the proposed changes, CEJA said the “guidance is outdated in light of significant changes in health care delivery.”

In a June 16 letter to the AMA council, CAP president Gene N. Herbek, MD, said that language should be retained in the ethics code. He also objected to deleting a key portion of opinion E-6.10—Services Provided by Multiple Physicians, which supports direct billing, says that doctors should not bill for services they don’t perform, and warns that “a physician should not charge a markup, commission, or profit on the services rendered by others.”

The third proposed revision that has pathology leaders concerned is opinion E-8.09—Laboratory Services. CEJA’s rationale for rescinding that policy in its entirety is that the “guidance is predominantly legal, not ethical, and focuses on operational instructions.” But in his letter, Dr. Herbek argued that some portions of the opinion ought to be retained, including another explicit warning against markups. Opinion E-8.09 says “a markup is an excessive charge that exploits patients if it is nothing more than a tacked on amount for a service already provided and accounted for by the laboratory.”
CEJA members expressed their appreciation to the AMA open forum’s participants for candidly sharing their views.

“That’s just the sort of detailed feedback and review that we count on,” said James E. Sabin, MD, who serves on the council and also directs the Harvard Pilgrim Health Care Ethics Program. CEJA vice chair Stephen L. Brotherton, MD, echoed the point, giving credit to pathologists for effectively communicating their apprehensions about the proposed changes.

“You all have done a very good job on this,” Dr. Brotherton said. “You’re doing exactly what we want. You’re getting back to us, and letting us know what your concerns are.”

But what had been a fairly sleepy—and collegial—hours-long discussion of a mostly routine and uncontroversial reorganization of chapters in the *Code of Medical Ethics* was upended when a Chicago-area dermatologist repeatedly rose to voice her objections to retaining the code’s language on direct billing.

Amy Derick, MD, spoke on behalf of the Illinois Dermatological Society and criticized “the pervasive misinformation provided by pathologists around the country” about indirect billing. Dr. Derick said the practice guarantees that patients will get in-network benefits and “also protects the lowest-income patients. . . . Pathologists are putting their own financial perspective ahead of patients’ best interest.”

She operates a seven-physician dermatology practice with three offices in the Chicago suburbs and employs a dermatopathologist.

“No one fusses about this,” she added. “The only people who fuss about this are pathologists.”

Dr. Synovec rose to speak in response, arguing that indirect billing has been tied to overuse of tests. He objected to pathologists being “cast as money-hungry, greedy people in the laboratory.” At the heart of the debate is a matter of equity, he said.
“You, as a physician, should be able to bill directly for your services. Everyone should be allowed to continue that process, and be paid fairly for those services. This is not an issue of gouging the patient,” said Dr. Synovec, president of the Topeka Pathology Group in Kansas.

The deadline for comments on the revised AMA ethics code was June 30. The full draft of the code was posted to an AMA members-only webpage in January, and aside from pathology’s concerns, no other major concerns have been raised. CEJA will continue working on the *Code of Medical Ethics* this summer and fall. The council is expected to put the final, revised version forward for consideration at the AMA House of Delegates’ next meeting, in November.

Also expected at that meeting this fall is a report from the AMA related to the laboratory provisions of the Protecting Access to Medicare Act of 2014, also called HR 4302. A resolution proposed at the June meeting called on the AMA to “seek changes in law to eliminate private sector laboratory reporting requirements in HR 4302 and prohibit the use of such reporting information for rate setting,” but the House of Delegates voted to refer the matter for further study. CAP leaders supported referral, believing an AMA study would buttress their case with the Centers for Medicare and Medicaid Services. *—Kevin B. O’Reilly*

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Innovators may find relief in FDA’s medical device guidance

Draft guidance released in June by the Food and Drug Administration is sending a strong signal to makers of certain kinds of basic hardware and software components used in medical devices that they will be relieved of regulatory obligations imposed on technologies that present greater risk of patient harm.

The FDA advice applies to medical device data systems, medical image storage devices, and medical image communications devices. These are devices the FDA says “transfer, store, convert formats, and display medical device data or medical imaging data” from other devices—glucose meters, blood pressure cuffs, infusion pumps, ventilators, and more—but that do not “control the functions or parameters of any connected medical device.”

In the document—“Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Draft Guidance for Industry and Food and Drug Administration Staff”—the agency said it “does not intend to enforce compliance with the regulatory controls” that have traditionally applied to these kinds of devices. The move is intended to help encourage medical device innovation, says Bakul Patel, senior policy adviser in the FDA Center for Devices and Radiological Health.

“We believe that medical device data system products pose little risk,” Patel wrote in a blog post at the

FDA's website. The agency's move "allows developers of medical device data systems to focus on making these products better able to operate amongst various devices and technology systems—resulting in stronger products," he added.

The FDA plans to devote its attention to medical devices that have a greater likelihood of causing patient harm, Patel said. This kind of prioritization comes on the heels of April's "FDASIA Health IT Report" from the FDA and other federal agencies that lays out a risk-based framework for regulating health information technology.

Mark Dahlby, a lawyer who specializes in FDA matters at the law firm of Hall, Render, Killian, Heath and Lyman, says the draft guidance has far-reaching implications.

"These products are completely pervasive. They're everywhere," he tells CAP TODAY. Moreover, existing regulation of these devices applies to hospitals and physicians as well as IT developers and device-makers. The guidance, if finalized as is, would mean that makers of these systems would not have to register their products annually with the FDA or follow adverse-event reporting requirements, Dahlby says. Yet the agency could still decide to take enforcement action against a device-maker.

"They can always step in," he says. "That's on an individual manufacturer or product basis, and they can pull the rug out from underneath anybody at any time." Dahlby says he hopes the FDA will pursue this guidance through the federal regulatory framework so that his clients will have more assurance when making or modifying these kinds of medical devices.

In September 2013, the FDA offered final guidance on mobile medical apps for use on iPhones and other smartphones. With this June 2014 draft guidance on medical device data systems, the agency has clarified that mobile apps that merely display, store, analyze, or transmit medical data will not be subject to FDA regulatory controls.

That is good news, says Stephen M. Hewitt, MD, PhD, clinical investigator in the Laboratory of Pathology at the National Cancer Institute.

"This will move forward the mobile device space in tools for mobile diagnostics, as well as for physicians in the clinical setting," Dr. Hewitt says. "The FDA is trying to responsibly promote the use of these technologies in this fashion, so that if you develop improved apps in this space and Apple changes the iPad, you don't have to redo every element of your validation."

The FDA's draft guidance is on the Web at http://j.mp/mddsdraft. The deadline for public comments is Aug. 19. *—Kevin B. O'Reilly*

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Biocartis, Abbott to develop multiplex companion diagnostics

Biocartis and Abbott will collaborate to develop and commercialize companion diagnostic tests. Under the agreement announced June 13, the companies will leverage Biocartis' molecular diagnostics system, Idylla, and Abbott's regulatory, scientific, and commercialization expertise. In partnership with

pharmaceutical companies, Biocartis and Abbott will create various biomarker panels for use on Idylla.