

Reproduced with permission from Medical Devices Law & Industry Report, 6 MELR 38, 01/11/2012. Copyright © 2012 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## Outlook

### Industry Tax, Changes at FDA, ACOs Among Key Issues for Industry in 2012

**H**ealth reform law provisions captured the attention of the medical devices industry in 2011 and will continue to do so in 2012 as the medical device tax, accountable care organizations, and a comparative effectiveness research board move closer to implementation.

In addition, stakeholders and members of the editorial advisory board of Bloomberg BNA's *Medical Devices Law & Industry Report* cited other key issues to watch including changes to the Food and Drug Administration's 510(k) device clearance process, FDA regulation of software and mobile applications, and increased governmental enforcement actions against device companies.

Several advisory board members said the medical device tax was the No. 1 issue on device companies' radar screens. The tax, which was included as part of the Patient Protection and Affordable Care Act, is a 2.3 percent tax on medical device sales, effective in 2013.

"With a sagging global economic outlook, tax issues will be a top concern," MELR advisory board member Michael D. Bell, of R-Squared Services & Solutions in Princeton, N.J., said. "Indeed, several manufacturers already have announced layoffs due directly to the impending device tax."

Industry does not like the tax, and, given the ongoing pressure to dismantle health care reform, some observers told Bloomberg BNA that legislation to repeal the tax could gain traction. "The top concern I am hearing by far is the tax on medical device manufacturers," advisory board member Bradley Merrill Thompson, of Epstein Becker & Green in Washington, said. "At a time when there are so many pressures on companies including slower approvals and lower reimbursements, keeping the device tax on top of that is simply hurting many companies in a very significant way. I think you will see pressure mount for the repeal of the tax."

"I have already seen a dramatic increased interest in the device tax," advisory board member Bethany J. Hills, of Hodgson Russ LLP, in Albany, N.Y., said. "Options to address the issue are being fully vetted by both individual companies and industry groups. This is the single item that has the biggest impact on the industry."

In contrast to the device tax, Hills said, the other items built into health reform are certainly of concern, but they will have a long-term impact and phase in over time.

**Changes to 510(k).** Actions by federal agencies under older statutory authority, in areas like device approvals and clearances, user fee reauthorization, and unique device identification, also will have an immediate impact in 2012.

A key concern for all medical device stakeholders is how FDA may change the 510(k) premarket notification program, which is how most devices reach the U.S. market. In early 2011, FDA released 25 proposals it plans to implement in the coming years to improve the 510(k) process, but held off on making recommendations on issues that spurred resistance from stakeholders until the Institute of Medicine (IOM) completed its own independent review.

In July, IOM released its report, concluding that the current process does not work. It recommended that FDA scrap the 510(k) process and develop a better way of clearing devices for the U.S. market.

---

### Industry is watching how FDA will finalize a guidance on demonstrating substantial equivalence in premarket notifications.

---

The IOM report concluded that the 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old 510(k) process, the IOM committee concluded that FDA's "finite resources would be better invested in developing an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle."

Yet the long-awaited report by IOM, which stakeholders had hoped would provide a catalyst for FDA to change the 510(k) program, was instead roundly rejected by most members of the medical devices industry. FDA also has indicated that it does not think the program needs to be scrapped entirely, although it has not yet issued a formal response.

"Fundamentally, IOM missed the boat," David Nexon, senior executive vice president of AdvaMed (Advanced Medical Technology Association), a devices industry trade group, told Bloomberg BNA in an interview. Nexon said he does not expect FDA to do much of anything with the IOM recommendations. "While there's been no formal reply, it doesn't look like there's much traction there."

Advisory board member Michael M. Gaba, with Holland & Knight LLP, in Washington, predicted "lots of

pushback by industry on the framework governing market entry for the vast majority of medical devices.”

FDA’s Center for Devices and Radiological Health (CDRH) in 2011 launched its “plan of action” for enhancing the 510(k) program, and set a schedule for issuing clarifying guidance documents, including one on clinical trials and another on the evaluation of “de novo” devices—novel lower-risk devices.

As stakeholders comment on the agency’s 510(k)-related guidances in 2012, FDA’s path for the year will become clearer.

Janet Trunzo, executive vice president for technology and regulatory affairs at AdvaMed, told Bloomberg BNA Dec. 21 that she thought the agency’s initial 25-step plan was overly aggressive. Some of the original actions the agency promised to undertake in 2011 have been pushed back, and now will be finalized in 2012.

For example, FDA in 2011 began a priority review program for new, breakthrough medical devices as part of the broader Innovation Initiative, a program to facilitate the development, assessment, and regulatory review of innovative medical devices. In 2012, the program will be expanded to “Innovation Pathway 2.0.”

Trunzo said two major documents will have a profound impact on the regulatory landscape of 2012. One, the so-called 510(k) paradigm guidance, is meant to clarify when clinical data might be needed in a 510(k). That guidance, *The 510(k) Program, Evaluating Substantial Equivalence in Premarket Notifications*, was made available at the end of 2011. Comments are due April 26.

The other important document is a proposed rule concerning FDA’s plans to implement a unique device identification (UDI) system. It has not yet been issued. According to FDA officials, the agency had expected that the draft would be published before the end of November. The proposed rule already has been approved by FDA and Department of Health and Human Services officials. At a conference in November, FDA officials said they still expected the final rule to be published in the fall of 2012.

The FDA Amendments Act of 2007 (FDAAA) required the agency to issue regulations on UDI but did not provide a time line. The agency originally said it expected to publish a proposal by December 2010; it then extended the timeline. The rule is intended to standardize how devices are identified, provide early warning signs of possible device defects, and help expedite recalls.

Trunzo said the UDI rule and the 510(k) paradigm guidance “will drive other FDA plans in the postmarket area.”

**User Fee Reauthorization.** Alongside the issues with premarket clearances, the devices industry also has been critical of the speed of regulatory reviews and inconsistent training of device reviewers.

Gillian Woollett, vice president at consulting firm Avalere Health, said the disagreements between industry and FDA could get played out with the reauthorization of user fees.

The legislative authority for the medical device user fee program, the Medical Device User Fee Amendments of 2007, expires in September 2012, and new legislation will be required for FDA to continue collecting user fees for the medical device program. Final recommendations are due to Congress by Jan. 15.

FDA’s operations are supported by the user fees, as well as congressional appropriations.

CDRH Director Jeffrey Shuren has indicated that insufficient funding is a major contributor to many of the problems associated with the agency’s premarket approval program for medical devices. In November, he told a Senate panel that the agency has embarked on initiatives with the goal of reforming the 510(k) process, but “adequate and stable funding is one key component to our and industry’s success in bringing safe and effective devices to market quickly and efficiently.”

Shuren said the agency and industry are still engaged in negotiations, and are “working hard to bring closure.” He told lawmakers that he was “agnostic” to the source of funding, as long as it was stable.

At an industry conference in September, Health and Human Services Secretary Kathleen Sebelius said if members of the devices industry want to see improvements from FDA, they may need to contribute additional user fees.

Yet during the same meeting, James Mazzo, senior vice president of Abbott Medical Optics and chair of AdvaMed’s board, said he was reluctant to discuss future user fee rates with FDA until more core concerns, like reviewer training and total review time, were met. Mazzo said he was “pleased we are seeing momentum,” but “I’m not a big believer that you can throw money and people at a problem. I believe you first need to identify the problem, and then you address it correctly.”

Mazzo said that just adding more funding to FDA does not address the issues companies have. Once those issues are addressed, the question of funding can be tackled, he said.

Woollett said the position that FDA needs more resources to do its job “is something of a mantra, especially in a user fee [reauthorization] year.”

Still, she said “there is no question at this point that user fees are essential.” Woollett noted the agency has a lot of projects on its plate in the coming years and will need to prioritize where the user fee funding will go.

FDA and industry are prohibited from commenting directly on ongoing negotiations. Trunzo and Nexon at AdvaMed told Bloomberg BNA that industry “always supports a stronger FDA,” but would only note that negotiations are “ongoing.”

**Accountable Care Organizations.** Provisions in the health reform law such as the Medicare Shared Savings Program (which will create accountable care organizations), the Center for Medicare and Medicaid Innovation, and the Independent Payment Advisory Board are intended to change the Medicare payment system into a more quality-driven, low-cost payment system.

A looming concern among many providers, as well as among device manufacturers, is the ACO rule. The final rule was released by the Centers for Medicare & Medicaid Services (CMS) in October 2011, and provider organizations were expected to begin implementing the program Jan. 1.

While members of the device industry generally have been supportive of ACOs, there is some concern that ACOs could limit patients’ access to medical technologies.

Nexon at AdvaMed said the incentives in the health care system need to be changed to encourage quality of care over quantity of service. However, he said there is

a concern over the unintended consequences of ACOs, even though the final rule was substantially different from the proposed rule.

If they are not implemented properly, ACOs could limit patient access to lifesaving devices, Nexon said. There is always a danger that improper incentives could lead to shortchanging people, so protections need to be built into the rule, he said.

**Software Regulation.** According to stakeholders and MELR advisory board members, the agency will head into new waters in 2012 as it begins to address the issues of software regulation.

“The agency appears to be broadening its scope in this venue,” Gaba said, potentially drawing into its jurisdictional boundaries software developers and companies not traditionally in the medical device space.

Woollett of Avalere noted that the possibility of FDA regulating software as a medical device is “somewhat inevitable” given the ongoing technology changes, and given how many medical devices incorporate software. She said more products will come under the scope of FDA, but it should not be considered a broadening of regulatory scope.

“It’s not a positive or a negative” for either industry or FDA, she said. “It’s just inevitable” as software becomes an increasingly large and important component of medical devices.

In July, the agency issued a draft guidance for medical applications designed for use with smartphones and other mobile devices. Stakeholders at the time said the draft was a step toward appropriate regulation of mobile health technologies, but that there is more work to be done.

---

### **Attorneys cite the importance of FDA’s stance on regulating medical software as a device.**

---

A subset of the software regulation is clinical decision support (CDS) software. The July guidance mentioned CDS software, but did not make any recommendations, stating only that additional guidance would be released at a later date.

Thompson said FDA is expected to publish a draft guidance on CDS software early in 2012. Thompson said stakeholders have been expressing concern that FDA might be too restrictive when it decides to regulate CDS software. Over the years, FDA has been regulating many software packages that perform decision support functions, but the precise rules never have been clear.

FDA released its *Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications* in July 2011, proposing an approach for how it will oversee software applications designed for use with smartphones and other mobile devices for health care purposes. But industry criticized the approach as overbroad and unduly burdensome.

Thompson noted that the July guidance drew more than 700 pages in comments. “It’s a difficult issue from a technology standpoint, but it’s also an area where the administration wants to encourage innovation,” he said. “FDA is in a bind, because they really ought to re-propose an approach based on such significant com-

ments, but they’re in a hurry to produce the final guidance so that everyone knows the rules of the road.”

Advisory board member Keith Barritt, of Fish & Richardson PC, in Washington, said the “growing boom in wireless technology and interconnectedness” means that “many companies are interested in this space, often without prior FDA experience.” The same lack of prior experience with FDA is often true of developers of mobile medical applications as well, he said. Thus, guidance in both areas is needed, he said. “FDA guidance may also be applicable to software generally, mobile or not, which is in great need of clarity,” Barritt said. “Hopefully the FDA will move forward and finalize the draft ‘mobile app’ guidance document to give further structure to this burgeoning area.”

“Ideally,” he said, “the FDA will abandon the unnecessary limitation of the draft guidance’s focus on ‘mobile’ apps only and address software generally.”

And advisory board member Gregory H. Levine, of Ropes & Gray LLP, in Washington, predicted that FDA will continue its efforts to regulate mobile apps “and will take baby steps towards regulating laboratory developed tests.”

**Diagnostic Devices.** FDA in 2012 will continue its recent efforts to attempt to regulate laboratory-developed tests (LDTs) and other diagnostic devices. The agency has held public meetings and solicited comments from relevant stakeholders.

House Republicans in October issued a slate of FDA reform bills, including one that would clarify that FDA does not have authority over laboratory-developed tests (LDTs). The bill (H.R. 3207) would establish a notification and review process at CMS—which now regulates the safety of clinical labs—that would allow the agency to evaluate the clinical validity of all LDTs and direct-to-consumer tests.

Currently, FDA regulates diagnostic tests only if they are developed and sold by device manufacturers as diagnostic kits, regardless of whether they were developed by clinical laboratory companies for in-house testing or by manufacturers for use in kits. The lab tests that are developed internally by a company generally are not subject to FDA review. CMS regulates those types of lab tests under the Clinical Laboratory Improvement Amendments (CLIA).

Avalere’s Woollett noted that the advance of another type of diagnostic, an in-vitro companion diagnostic test, would help spur collaboration between FDA’s different agencies, such as the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

An in vitro companion diagnostic device (IVD companion diagnostic) provides essential information for the safe and effective use of a corresponding therapeutic product. A guidance document issued in July 2011 should also help stimulate early collaborations between drug and device makers.

Because drugs and devices are being used and developed in tandem with one another, Woollett said that CDRH’s role would become more conspicuous. “There is potential for more integrated centers if the technology fills the promise we are hoping for,” especially the value of diagnostic tests in health care outcomes.

However, Woollett noted that tests are not “black and white. How you use them and capture the information . . . is an opportunity for CDRH” in 2012.

**Enforcement a Concern.** Another key area flagged by most advisory board members for 2012 is enforcement, especially the increasing volume of government prosecutions of individuals and executives at device companies for violations of federal food and drug law, including those involving off-label promotion of devices.

“FDA enforcement is on the increase, and, indeed, we are seeing more criminal prosecutions,” Thompson said. “Companies need to understand many of the rules better to protect themselves from FDA enforcement. The amount of compliance remediation going on is enormous.”

And board member Gerard J. Prud’homme, of Hogan Lovells, in Washington, told Bloomberg BNA that “FDA’s ramped up focus on enforcement has led to some unusually harsh positions being taken by investigators and the Office of Compliance.” He said the increase in use of the *Park* doctrine [after *United States v. Park*, 421 U.S. 658 (1975)] to prosecute senior executives for health care fraud at their companies—even if they did not know about or condone the activity—“should be interesting—Synthes executives have been sent to jail and other cases will likely be litigated in early 2012.”

In late 2011, former officials of medical device company Synthes Inc. were sentenced to prison time for their role in undertaking “rogue” clinical trials of unapproved bone cements, one of an increasing number of cases in which the government is going after key corporate individuals for health care fraud at their companies.

Gaba said that the devices industry also should “expect continued and increased scrutiny on post-market surveillance issues, e.g., registry requirements and data collection—it’s important because the FDA is under a lot of pressure from Congress to ensure that products approved remain safe and effective during their whole life cycle.”

Looking at global concerns, Bell said that the Department of Justice is focusing on the sector’s overseas relationships, and several companies have announced Foreign Corrupt Practices Act investigations. He said that other nations, such as the United Kingdom, have stepped up their legislative and enforcement efforts, making global anti-bribery concerns a top issue for company officers and attorneys.

**Physician Payments Sunshine Act.** Another issue mentioned by board members was compliance with the Physician Payments Sunshine Act, part of the 2010 health reform law.

During the new year, CMS will be reviewing comments on its Dec. 14, 2011, proposed rule to implement the sunshine provisions. The rule is intended to provide information to the public about doctors’ financial ties with manufacturers. Comments on the CMS proposal are due Feb. 17.

“These requirements touch all aspects of operations and will drive changes to policies and procedures, contracts, and relationships with researchers and other physicians,” Bell said. “With the impending disclosure of detailed information . . . , device manufacturers are beginning to focus and apply much stronger internal controls on physicians interactions that result in reportable data such as consulting services needs assessments, focus on fair market value, and revisions to gift and meal policies,” he said.

**Off-Label Promotion.** Advisory board members also mentioned that 2012 may bring attention to court cases on off-label promotion of devices and potential criminal liability for the same.

“I think you will see more activity in these areas,” advisory board member Stephanie Philbin, of Goodwin Procter LLP, in Washington, said.

Levine said resolving and avoiding government enforcement actions initiated by whistleblower complaints, particularly those involving off-label promotion, is a top issue for device companies.

Bell noted that “there are a couple of big criminal liability cases where the government seems to be proceeding with both guns blazing over conduct that we would not expect to provoke that kind of reaction. There is a considerable debate about exactly what circumstances ought to trigger personal liability under the *Park* decision,” Bell said. Bell said he did not expect the off-label promotion issues to be resolved at the agency level.

And in the new year, FDA will be reviewing comments on its late 2011 draft guidance, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*. Comments are due March 29.

BY NATHANIEL WEIXEL AND DANA A. ELFIN