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Medical Devices Law & Industry Report™

Outlook 2015

Device Tax Repeal, FDA's Actions Affecting Industry Remain Top Issues

Efforts to repeal a medical device excise tax and the potential for greater FDA oversight of laboratory-developed tests are among the top issues that will affect the medical devices industry in 2015.

Bloomberg BNA contacted industry groups, other stakeholders and members of the advisory board for the Medical Devices Law & Industry Report to identify the top issues for the new year.

Other important issues to watch include potential legislative changes affecting the Food and Drug Administration, the FDA's implementation of unique device identifiers (UDI), the potential for FDA regulation of mobile apps and enforcement actions affecting device companies.

A representative for a device trade association said the repeal of the medical device tax and cost reduction efforts throughout the health-care system will be significant issues in 2015. David Nexon, a senior executive vice president at the Advanced Medical Technology Association (AdvaMed), a Washington-based industry association, told Bloomberg BNA the repeal of the tax is a top concern for his group. The tax has burdened the device industry and was poorly conceived, Nexon said.

The Affordable Care Act imposed a 2.3 percent excise tax on device makers, and the tax already is in effect.

According to Nexon, AdvaMed is hopeful that Congress will repeal the device tax in 2015. There's increasing recognition from both Democrats and Republicans that the tax hurts the device industry, he said. Nexon also told Bloomberg BNA he hopes repealing the device tax will be a top agenda item for both parties.

Nexon declined to identify offsets that could be used to pay for repealing the tax. He said identifying offsets is an issue for Congress.

At the beginning of the new Congress, Reps. Erik Paulsen (R-Minn.) and Ron Kind (D-Wis.) introduced H.R. 160, which would repeal the excise tax on medical devices. A Jan. 7 joint statement from AdvaMed, the Medical Device Manufacturers Association and the Medical Imaging and Technology Alliance said the groups support H.R. 160. In part, their statement said H.R. 160 is ''the most recent example of legislation to repeal the medical device tax and underscores the significant bipartisan support this issue has gained.'' A group of senators also introduced a device tax repeal bill Jan. 13.

Advisory board members told Bloomberg BNA that while the Republican majority in both houses of Congress gives repeal of the tax a better shot in 2015, it's by no means a foregone conclusion.

''I believe it has its best chance this year given the change to a Republican-dominated Senate, but, as with everything that Congress looks at, it could be sacrificed for something else of importance,'' Sonali Gunawardhana, of Wiley Rein LLP in Washington, said.

John Manthei, of Latham & Watkins LLP in Washington, said there are several legislative initiatives that could have significant impact on the device industry, including the effort to repeal the excise tax.

According to Manthei, other initiatives include legislation that would expand the FDA's priority review programs for medical devices regardless of approval or clearance pathway and legislation directing the FDA to consider clinical evidence as a means of supporting approval via an accelerated approval pathway for certain breakthrough technology.

In addition, Manthei said, the FDA has indicated a desire to begin discussing user fee reauthorization in 2015, and, although early, the initial conversations could begin to pave the way for key issues that will emerge through that process.

Lab Tests. ''I think we shall see more activity on the legislative front this year,'' Stephanie Philbin, of Goodwin Procter LLP in Washington, said. ''Patients, providers, manufacturers, FDA and Congress all seek to ensure that regulation is smart regulation that does not stifle innovation. How that balance is struck remains to be seen.''

''Specific areas of interest include lab developed tests and health IT,'' she added.

The FDA in the fall of 2014 released draft guidance providing a framework for oversight of laboratory developed tests (LDTs) and is seeking comments through early February. The LDTs have been regulated by the Centers for Medicare & Medicaid Services, and the lab testing industry opposes the FDA's efforts in this area, while some parts of the devices industry support what the FDA is doing.

Gregory H. Levine, of Ropes & Gray LLP in Washington, said Congress ''will be closely evaluating FDA's proposed framework for regulating Laboratory Developed Tests.'' Levine added, ''There is also likely to be a push for an expedited FDA review pathway for certain novel diagnostic tests. Legislative choices on these questions could have a significant impact on the diagnostics sector of the device industry.''

Bradley Merrill Thompson, of Epstein Becker & Green in Washington, said that the FDA's ''regulation

of lab developed tests will be enormously controversial.''

''[T]he lab industry is bulking up on attorneys and making threats. It looks like there might be battles on Capitol Hill, in the courts, and before the agencies. This issue will spill over into companion diagnostics. The controversy will probably get worse before it gets better,'' he said.

The clinical labs industry is preparing for a fight over the FDA's plans to exert greater regulatory oversight.

Laurie Clarke, of Jones Day in Washington, said that certain members of Congress, some device companies, and laboratories, as well as the trade association for these laboratories, have questioned whether the FDA has the authority to regulate lab tests as medical devices, and if so, whether the FDA Center for Devices and Radiological Health's ''proposed regulation of LDTs and its current regulation of mobile medical apps exceed the Agency's authority.''

But, she said, other members of Congress, some in vitro diagnostic (IVD) manufacturers, ''and several consumer groups have criticized FDA for not regulating LDTs or not subjecting mobile medical apps to enough regulation.''

''These debates will likely become more intense if FDA moves toward issuing a final guidance on LDTs or revising its mobile medical apps guidance,'' Clarke said. She added it's possible that Congress will pass legislation restricting FDA's regulation of LDTs and/or mobile medical apps ''or that the threat of such involvement will force FDA to rein in its regulation of one or both of those types of products.''

Information Technology. Regulation of health information technology also will get a lot of attention, Thompson said. Federal agencies including the FDA will publish the final report required under the Food and Drug Administration Safety and Innovation Act (FDASIA), and the FDA also will publish guidances on wellness and accessories. In addition, he said, the agency is set to publish a ''long-overdue'' guidance on clinical decision support software.

After Bloomberg BNA interviewed its advisory board, the FDA issued its plans for device-related guidance for 2015. Among the topics on the ''A'' list of FDA high-priority guidance work is a final guidance on regulatory oversight of LDTs and a draft guidance on decision support software. More information is in the Jan. 9 Federal Register (80 Fed. Reg. 1,424).

Congress will continue to debate legislation and host hearings on the health IT issue, Thompson said. ''Given the opportunities to improve public health through innovative health IT, much is at stake. We need to get this right. FDA has been going too slowly, given the opportunities that are present. But at the same time, we do need to make sure that we adequately protect the patient.''

Insofar as health information technology is concerned, Levine said, he hopes to see ''at least draft guidance in 2015.''

''The FDASIA Health IT report issued this past April described FDA's planned policy direction on clinical decision support tools, which remains an area of great uncertainty. FDA has sent letters to developers of software that would appear to fall within the clinical decision support tool category, but the agency has yet to articulate a clear policy in this area. FDA needs to come forward with guidance,'' he said.

''Also of tremendous interest to the Health IT industry,'' Keith Barritt, of Fish & Richardson in Washington, said, ''the FDA is reportedly working on a draft guidance on the interoperability of medical devices.''

''This is a critical issue in the interconnected era, especially if a wireless device is part of a larger network.''

Regarding a potential draft guidance on the dividing line between unregulated general ''health and wellness'' claims and regulated ''medical device'' claims, Barritt said, ''This will be of tremendous interest to the growing community of app developers in the broad 'digital health' space, and especially for software and mobile medical apps.''

On Jan. 16, subsequent to the outlook interviews with attorneys, the FDA released two draft guidance documents that outline the agency's thinking about low-risk devices intended to promote general wellness and the risk classification approach to medical device accessories.

And according to Barritt, regulation of genetic test kits, especially direct-to-consumer tests, likely will be of continued interest, especially following the FDA's very public November 2013 warning letter to the company 23andMe. ''In 2014, 23andMe filed a 510(k) application for assessing the risk of only one inherited disorder (Bloom syndrome, associated with short stature and various cancers). As of Jan. 12, there is no indication on the FDA website that marketing authorization had been granted,'' he said. ''As the technology for and potential use of genetic testing continues to mature, more and more companies will be interested in entering the market.'' A 510(k) is also known as a premarket notification.

Costs. In 2015, a growing emphasis on reducing costs throughout the health-care system will have implications for the device industry, AdvaMed's Nexon told Bloomberg BNA.

New cost constraints could delay the adoption of new and beneficial medical technologies, which may ultimately harm patient health, Nexon said. For example, Nexon said that without some special provisions, there could be significant disincentives to adopting costly new technologies by clinicians and providers. He also said AdvaMed is working on provisions with the CMS that will address this issue. AdvaMed's suggested provisions are somewhat analogous to the new technology add-on payment, Nexon said.

Michael Bell, a consultant with R-Squared Services and Solutions in Princeton, N.J., told Bloomberg BNA that new contracting models are an important issue. With the confluence of accountable care organizations, gainsharing, and alignment of Medicare payment to hospitals to quality standards, ''medical device manufacturers will face increasing demands for risk-based purchase agreements,'' he said. ''These agreements, which can be based on device performance and meeting clinical end points, avoidance of readmission and revisions, and other quality indicators, will require careful

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planning, clear articulation of outcome measures and payment triggers, and ongoing data collection and monitoring,'' Bell added.

FDA's Work. Nexon also told Bloomberg BNA the device industry continues to grapple with regulatory hurdles that limit innovation. Even with recent initiatives from the FDA to accelerate device approvals, the review process still takes too long and is inconsistent, he said.

According to Nexon, the inconsistency and the long wait times mean devices are approved faster in Europe. He told Bloomberg BNA this isn't good for development of new products in the U.S.

To improve device review times in 2015, Nexon said, the FDA could implement a number of things. For example, he said the FDA could improve reviewer training and streamline processes within the agency.

Nexon also said the FDA is a big bureaucracy that takes time to change. Previously announced efforts to improve device review times are ''on the right track,'' he said.

Attorneys told Bloomberg BNA that 2015 might bring additional guidance from the FDA on the social media front.

''In terms of guidance, we may see more from FDA on social media, an area that presents challenges both for regulators and industry,'' Philbin of Goodwin Procter said.

''FDA regulation of social media will continue to be a hot topic,'' Thompson agreed. ''Now that the major guidances are out, there will be a lot of jockeying. The device industry wants to be separated from the drug industry to avoid some of the onerous provisions. The drug industry will continue to threaten First Amendment litigation. And, in that context, we will continue to struggle to understand exactly what the proposed guidances mean.''

Thompson said 2015 also will bring continuing dialogue between industry and the FDA on reforming the overall guidance development process. ''Right now, industry doesn't feel as though it has any significant input into draft guidances. That's critical, because draft guidances end up taking on a life of their own, remaining in draft form'' for years. ''So, in effect, right now, hundreds of guidance documents are on FDA's website into which industry has had very little if any input,'' he said.

Clarke, of Jones Day, said, ''The device industry and consumer groups have recently criticized CDRH for: (a) taking too long to finalize, or not finalizing, draft guidance; and/or (b) enforcing draft guidances despite the Center's lack of authority to do so and the statements in the draft guidances that will take effect only if FDA finalizes them.'' She added, ''Based in part on FDA's past responses to criticisms about these time lags, the Agency is likely to respond in multiple ways, including, but not limited to, finalizing some existing draft guidances, withdrawing old draft guidances or ones the Agency no longer agrees with, issuing fewer draft guidances, not issuing any guidance on controversial issues, delaying issuance of draft guidance until it is close to final, refusing to extend the comment period regarding draft guidances,'' declining to reissue in draft form a draft guidance and/or relying more on informal guidance.

''Such actions would likely reduce the number of guidance documents that remain in draft for years,'' she said, but ''they may have unintended consequences, such as less information being available from FDA and/or affected parties having less input into the final guidance.''

Also, she said, the CDRH is unlikely to stop the pressure on device companies ''to comply with the Center's positions set forth in draft guidances that the Agency would like to finalize because they reflect the Agency's current thinking even though the draft guidances assert unrealistically that they achieve that status only when finalized.''

However, she said, the FDA ''may be less likely to cite draft guidances to support the Agency's position, especially if Congress intervenes.''

Use of De Novo Process. Another area to watch in 2015 will be the FDA's use of the de novo process to allow devices on the market.

A 2014 report from the California Healthcare Institute (CHI) (8 MELR 707, 10/29/14) said de novo seeks to speed up clearance times for low- to moderate-risk devices as an alternative to premarket approval, which is the route for most highest-risk or class III devices to reach the market.

The de novo process was created in a 1997 law as a way to market devices that aren't substantially equivalent to a device on the market. Then, de novo was revised in a 2012 statute to make it ''more submitter-friendly and increase its use.'' The CHI report said that the number of de novo petitions granted by the FDA has been increasing slowly since 1997.

Attorneys see the FDA using the de novo process more frequently to allow certain medical devices on the market.

Gunawardhana, of Wiley Rein, said it appears that the CDRH has become more comfortable with the process. She said that as more innovative devices are developed, the FDA may rely on the de novo process even more. And she said, ''Hopefully, the time frames for review will shorten as well, given an influx of submissions.''

Clarke, of Jones Day, predicted that the FDA would receive more requests for de novo review of automatic class III classification and would ''downclassify'' more devices via that route in 2015, for several reasons. ''First, CDRH seems to be interpreting terms like 'same intended use' and 'new questions of safety and effectiveness' more narrowly than it did a few years ago,'' she said. ''As a result, it is more common for FDA to reject device manufacturers' proposed predicate devices or their arguments that such devices are substantially equivalent to their predicate devices, even if clinical data demonstrates that the new device is at least as safe and effective as the predicate device(s).''

''Second,'' she said, ''certain CDRH reviewers are likely to continue to insist that device companies use only one predicate device. Despite FDA's recent confirmation that multiple predicates are acceptable if they

meet certain requirements, CDRH leadership appears to have little interest in compelling compliance with that policy other than in response to appeals of such decisions.''

Third, she continued, ''the alternative de novo path, which FDA recently implemented, allows the manufacturer to request de novo review based on the company's determination that the new device does not have a predicate device rather than requiring FDA to make that determination based on the agency's review of a 510(k) notice.''

In many cases, Clarke said, the manufacturer obtains FDA's informal concurrence with that determination through a presubmission before requesting de novo review. ''However, data suggests that overall review times for de novo review have significantly decreased in the last couple of years. There is no reason to believe the average total de novo review times will again approximate review times for PMAs or uncertain outcomes will return next year.''

And a fourth reason, she said, is that the FDA's increased flexibility regarding special controls makes it easier for the CDRH to authorize the marketing of a device based on de novo review once the center has determined that clinical data demonstrates the device's safety and effectiveness for its proposed indications.

Indeed, she said, the ''FDA's increasing insistence on de novo review and the device industry's growing acceptance of that route may mean that it will become the regulatory path for devices for more low to moderate risk devices that have a complex substantial equivalence argument.''

21st Century Cures. The House Energy and Commerce Committee launched its 21st Century Cures initiative in 2014 to spur biomedical innovation, and industry is watching to see what legislation results from the effort in 2015.

Nexon applauded the 21st Century Cures initiative because it looks at the entire health-care ecosystem. According to Nexon, the entire ecosystem has flaws that slow the device development process.

AdvaMed hasn't seen specifics about what will be included in any 21st Century Cures legislation that may be introduced in 2015, Nexon said. However, he said AdvaMed is sharing ideas with the committee about what the legislation should include.

With regard to the 21st Century Cures initiative, Levine said it remains to be seen whether it would result in significant stand-alone legislation in 2015. ''One possibility is it begins to generate and focus legislative ideas that won't finally get enacted until the next round of [user fees] legislation in 2017, which is the more traditional timeline for significant FDA reform legislation,'' he said. ''It's possible we'll see a hybrid: some discrete items this year or next year, with other issues being pushed down the road into the next round'' of user fee law negotiations.

Enforcement, Sunshine Act. On the enforcement front, board members said the Physician Payments Sunshine Act and state reporting laws, and False Claims Act cases based on violations of current good manufacturing practice standards, would be areas of concern for device manufacturers.

''The Sunshine Act and state reporting laws, and compliance with these laws, will be a critical area of focus for companies,'' Mark Langdon, with Sidley Austin LLP in Washington, said.

More whistle-blowers likely will move forward with False Claims Act cases in which the DOJ has declined to intervene.

''I expect we will continue to see enforcement vis-a-vis promotional activities in the device area, particularly in qui tam relator-driven False Claims Act cases and related criminal investigations,'' Laura F. Laemmle-Weidenfeld, of Jones Day in Washington, said. ''We probably will even see an uptick in these cases, as the relator's bar slowly turns its attention from pharma manufacturers to device manufacturers, and as they begin focusing more on the device data now available under the Sunshine Act.''

''These cases are likely to focus primarily on whether the manufacturer improperly promoted the device for off-label use(s), whether the manufacturer improperly advised its customers and/or physicians regarding reimbursement issues, and whether the manufacturer otherwise improperly engaged in providing various forms of remuneration to physicians,'' she said.

Because what constitutes ''off-label'' can be vague and the appropriate way to seek reimbursement for the use of the devices can be very complex and unclear, there's room for misunderstanding and error on the part of all parties. In addition, ''whereas the pharma companies have become fairly sophisticated on these issues, many device companies are closer to the start-up phase and lack deep knowledge on these issues, potentially leading to them unwittingly cross the legal line,'' Laemmle-Weidenfeld said.

The CMS in 2014 began to publish Open Payments data, as required under the Physician Payments Sunshine Act, part of the ACA, at http://www.cms.gov/openpayments/. The 2013 data on doctor-manufacturer relationships were initially published in the fall of 2014.

The CMS has indicated that it will audit the next round of Open Payments data, for 2014, ''and will impose penalties for violations,'' Bell, of consulting firm R-Squared, told Bloomberg BNA. ''Many device manufacturers continue to process this data manually and perform little-to-no audit of the data prior to submission, which is inherently risky,'' Bell said. This is because any audit ''could result in a broader investigation of relationships under federal and state anti-kickback laws,'' he said.

Laemmle-Weidenfeld said the publication of the Open Payments data by the CMS may have a few effects on doctor/company relationships. ''Smaller manufacturers who previously may have viewed themselves as being 'below the radar' will now begin paying more attention to compliance issues around these relationships,'' she said. ''Some physicians will be very uncomfortable with having their names publicly associated with manufacturers and will stop engaging in financial relationships of any type with the manufacturers. On the flip side, some physicians may seek arrangements with additional manufacturers so as to appear less biased. Some manufacturers may choose to reduce the

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number of physicians with whom they engage in these reportable relationships.''

She said, ''On the other hand, manufacturers still need to partner with physicians for legitimate product development, research, and marketing purposes, and some physicians are very enthusiastic about helping specific manufacturers with these efforts. As a result, we may see a smaller number of physicians each doing a proportionately larger amount of Sunshine Act-reportable work with manufacturers.''

''We can also expect to see more qui tam actions resulting from the publication of this payment data,'' she said.

Laemmle-Weidenfeld also predicted that more whistle-blowers likely will move forward with FCA cases in which the DOJ has declined to intervene. ''This is a general trend we're seeing elsewhere in the enforcement arena,'' she said. ''As the number of qui tam cases continues to increase, the DOJ is declining proportionately more matters, and the perception of many in the relators' bar is that a number of those matters nevertheless have merit and are worth pursuing. Therefore we are seeing relators' counsel move forward with a much higher proportion of declined cases.''

Manufacturing Standards. Gunawardhana expects to see a rise in the Department of Justice's enforcement of FCA cases because of violations of current good manufacturing practices (cGMPS) on the medical device side, with heavier penalties levied that mirror those levied on their pharma industry counterparts.

Laemmle-Weidenfeld agreed. ''We will continue to see DOJ investigations, again arising out of FCA actions brought by whistle-blowers, into allegations of cGMP/QSR [quality system regulation] violations in the device industry. In many cases these may just be thrown in with the other allegations the whistle-blower brings (like off-label or kickback allegations), particularly if the whistle-blower is aware that the FDA already has expressed concerns, e.g. through a warning letter, to the manufacturer about its compliance with any aspect of the cGMPs.''

But Levine noted that, ''for manufacturers with a strong record of quality, FDA may be willing to allow greater autonomy and less regulatory oversight, for example, through less frequent inspections.'' Within the FDA, he said, some are pushing the ''case for quality'' and other pilot programs intended to allow greater transparency and cooperation between the FDA and manufacturers. But, he said, it remains to be seen what will happen with these initiatives.

And Levine said he expects the FDA to continue ''to try to deal with the challenge of regulating foreign manufacturers and foreign plants.''

Bell noted that China, Brazil, Russia and numerous other countries recently have enacted or updated laws to fight corruption. ''With considerable dependencies on third party distributors, reimbursement and regulatory consultants, and other contractors, and that physicians and hospitals are considered foreign officials'' under the Foreign Corrupt Practices Act, device manufacturers ''have greater exposure to allegations of fraud and corruption,'' he said. ''Coupled with Dodd-Frank whistleblower protections and awards, and personal liability in some instances, device manufacturers are well advised to shore up internal compliance controls throughout the world,'' he added.

Gunawardhana said the FDA will continue to issue warning letters and take enforcement actions in regard to GMP/QSR violations as well as clinical trial violations. ''I think you may see more enforcement correspondence in the area of promotion with the new division now established as well as 'It has come to our attention' letters for marketing mobile apps that the FDA feels should have a 510(k) clearance, given they fall outside of what the FDA considers a wellness app.''

She also said, ''We may see some additional 'It has come to our attention' letters as well as untitled letters where inappropriate marketing is cited due to social media postings.''

Expanded Labeling Requirements. Two private organizations concerned with patient safety issues separately told Bloomberg BNA the FDA's unique device identifier (UDI) program will affect device makers in 2015.

The UDI system, required by a September 2013 FDA final rule (78 Fed. Reg. 58,785; FDA-2011-N-0090), requires the labels and packages of devices distributed in the U.S. to include a unique device identifier, unless the agency grants an exception or alternative. The final rule required some devices to include a UDI by September 2014. However, compliance dates vary according to a device's type. The latest compliance dates occur in September 2020.

Jim Keller, the vice president of the device evaluation program at the ECRI Institute, a patient care and safety organization based in Plymouth Meeting, Pa., said the UDI program will continue to affect device makers in 2015. The FDA has said that by Sept. 24, 2015, non-class III (highest risk) implantable, life-supporting, and life-sustaining (I/LS/LS) devices will require UDIs. Types of devices that will need to have UDIs in 2015 include anesthesia machines, ventilators, dialysis machines and autotransfusion systems, which are class II (general control) devices, Keller said.

Josh Rising, the Pew Charitable Trusts' medical devices director, told Bloomberg BNA that as more devices carry UDIs, it will allow stakeholders the opportunity to collect more data about device safety and performance. Pew is looking forward to the public launching of the FDA's Global Unique Device Identification Database (GUDID) in 2015, Rising said. According to Rising, the GUDID will let stakeholders see that UDIs can be used to improve device safety.

UDIs in Claims. In addition, there are a number of efforts aimed at capturing UDI data in claims forms, Rising said.

However, the CMS may be against efforts to incorporate UDI data in claims. In December 2014, Sens. Elizabeth Warren (D-Mass.) and Charles Grassley (R-Iowa) wrote the CMS and asked it to work with health-care groups to incorporate data captured from UDIs into electronic health information, including claims forms. Warren and Grassley's letter expressed concerns about the CMS's potential opposition to putting UDI information in claims forms as part of a standards-setting organization.

Rising told Bloomberg BNA that capturing UDIs in claims would provide an important way to understand devices' health-related outcomes and would better help stakeholders detect devices with unexpected safety problems.

Postmarket Safety, Expedited Access. Over the past year, the FDA and the Brookings Institution have convened a group to give guidance to federal agencies and other stakeholders about what needs to be done to build an infrastructure for improved device postmarket surveillance, Rising said. Known as the National Medical Device Postmarket Surveillance System Planning Board, he said, the group should release recommendations in 2015 that provide a road map on the next steps for constructing the improved device postmarket surveillance infrastructure.

In addition, Rising told Bloomberg BNA that the Medical Device Epidemiology Network Initiative (MDEpiNet), which is part of the Epidemiology Research Program (ERP) at the CDRH, is due to come out with device registry recommendations in 2015. The expected MDEpiNet recommendations should lay the groundwork for better device registries, Rising said.

Moreover, he said the FDA's expedited access program will be a key program in 2015.

The proposed Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions program (known as EAP) ''will help patients have more timely access to these medical devices by expediting their development, assessment and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval,'' the FDA said in an April 23 draft guidance document.

Rising told Bloomberg BNA that Pew supports the FDA issuing a final guidance for the EAP. Pew also wants the FDA and others to develop infrastructure needed to implement the EAP, he said. He noted that the FDA's list of 2015 planned guidance documents has the final EAP document on the A list.

The FDA will need to focus more attention on mobile health issues in the future, ECRI Institute's Keller said. He told Bloomberg BNA that it will be challenging for the FDA to manage mobile health apps on smartphones because it is such a high-growth area.

Also in the area of mobile health, care expanding outside the hospital setting creates a number of safety concerns, Robert Maliff, the ECRI Institute's director of applied solutions, said. He also told Bloomberg BNA that safety concerns arise because many devices aren't designed for patient use in the home. It's hard to take devices that are designed to be used by clinicians and then pass it along to the patient for use, Maliff said.

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