The Servicing of Medical Devices: In Need of Repair, Regulation, or Redemption?

Long-simmering tensions over the supportability of healthcare technology are bubbling up big time this year, triggered by a Food and Drug Administration (FDA) initiative to scrutinize postmarket activities and, in particular, the provision of third-party services. Whether this initiative turns out to be a tempest in a teapot or a harbinger of new rules or standards is anybody’s guess. Regardless, it certainly has touched a nerve for a broad set of interest groups, including manufacturers, third-party service providers, and healthcare technology management (HTM) professionals in healthcare systems and hospitals.
By June 2016, the FDA had received 176 comments on its March 2016 Federal Register notice requesting comments and information on refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, servicing, and repairing medical devices performed by third-party entities and original equipment manufacturers (OEMs). The FDA is focusing on the quality, safety, and continued effectiveness of medical devices after those activities.

Right off the bat, the Federal Register notice surprised people. “The industry views and talks about three categories of service providers: manufacturers, in-house clinical engineering departments, and third-party, independent service companies,” said Jason Crawford, president of Block Imaging Parts & Service in Holt, MI. “The FDA does not view us that way—even in the phrasing of the questions in the Federal Register notice. There are some in our industry who are surprised to realize that in the FDA’s mind, there are the manufacturers—and everyone else is in the third party.”

The Federal Register notice also surprised people for its reprise of a similar dive into third-party services back in 1997, when the agency published an advance notice of proposed rulemaking. That was “a higher level of request for comments and information” than the current request, noted Mark Bruley, vice president of accident and forensic investigation at the ECRI Institute in Plymouth Meeting, PA. The earlier notice ultimately resulted in no regulatory changes.

An Industry Sector in Flux

The current FDA initiative is calling attention to a slice of the healthcare technology industry that has changed substantially in this century. The same forces transforming healthcare overall—the Affordable Care Act, industry consolidation, the proliferation of complex healthcare technology, and amplified population health and patient safety efforts—are reshaping medical device servicing as well.

Now, traditional and new players are jostling to bring value and efficiency to the business of keeping healthcare technology up and running, safely. “There are now even more competitors in the mix, and they’re all getting better at what they do, which is a good thing,” said Larry Hertzler, vice president of technical operations at Aramark’s Healthcare Technologies business unit in Charlotte, NC. “So there are more options available. Equipment is getting much more complex, while regulatory requirements are getting more stringent. People are buying less and less capital equipment, so manufacturers are trying as hard as they can to hang on to the service dollars in order to maintain their business models. That puts pressure on third parties as well. Everybody is pushing as hard as they can to deliver lower cost and higher quality and value at the same time. We all know hospitals are having a harder and harder time affording anything they need, whether it’s capital or an expense.”

In some respects, the lines are blurring between OEMs, in-house clinical engineering departments, and third-party service providers. Some major OEMs offer multivendor services, which means they take care of equipment produced by themselves and their competitors—a business model that has been on the rise for the past couple decades.

GE Healthcare is a case in point. “We are a manufacturer of medical equipment that happens also to have its own third-party service business,” said Scott Nudelman, general manager of biomedical services at GE Healthcare. “When hospitals outsource their entire biomedical department to GE, we put our BMETs [biomedical equipment technicians] and HTM professionals on site and manage the entire biomedical department.” Servicing non-GE products and on-site services accounts for 12% of the company’s U.S. service business.
One hundred seventy-six—that’s how many individuals, healthcare delivery organizations (HDOs), companies, and professional groups responded to the FDA Federal Register notice on servicing of medical devices.

The published submissions were generally divided along professional lines, with original equipment manufacturers (OEMs) and healthcare technology management (HTM) professionals split over how to best service medical devices. Overall, approximately 40% of respondents appeared to directly oppose FDA regulation of the service industry, roughly 30% seemed to support some type of FDA involvement, and about 13%—including AAMI—were generally neutral in their assessment.

OEMs: Regulation Is Needed
A number of OEMs provided examples in which their technicians were called into an HDO to look at a device and found it contained incorrect parts, was missing parts, or had parts put back incorrectly after being “fixed” by a third-party repairer.

For example, Dräger described a situation in a children’s hospital in Texas in which a service technician was dispatched to perform preventive maintenance on its anesthesia machines. The technician noticed that the large clip holding the lower roller diaphragm in place was lying at the bottom of the ventilator. Later, the hospital’s biomedical staff discovered several more anesthesia machines with the same issue at a different campus. “Apparently the third party service organization had been in recently and installed three-year kits in the anesthesia machines but did not install the lower diaphragm correctly,” wrote Dräger in its comments.¹

AdvaMed, the trade association representing medical device and diagnostics manufacturers, highlighted the potentially devastating consequences of inadequate repairs.² The group cited an incident with an infusion pump repaired with a non-OEM part that “led to unregulated flow (over infusion), causing serious patient harm and transfer to a higher level of care.” In another case, an unqualified repair on an infusion pump “resulted in an over-delivery such that an 18-hour opioid infusion was completed in less than three hours.”

OEMs conceded that although specific examples and anecdotes of harm can be cited, data confirming the dangers posed by third-party maintenance activities are lacking. However, they asserted that such data are not collected in the absence of regulation.

“We believe it is impossible to provide a statistically valid analysis of the extent of problems that have occurred when there has been no prior scrutiny or any regulatory requirement for non-OEM service providers and other third parties to report problems. Currently, the only way to determine the magnitude of the problems associated with improper performance of these activities would be through regulation of all entities which perform these activities, including registration and reporting,” Douglas J. Thistlethwaite, manager of regulatory affairs, wrote in Hitachi Medical Systems America’s comments to the FDA.³

In general, OEMs called for:
• Third-party repair companies to be required to comply with quality system requirements.
• The verification of repairer competencies.
• The required use of OEM or OEM-qualified parts.
• Testing, verification, and validation of repair work before equipment is put back into service.

HTM: Third Parties Aren’t the Issue
HDOs and HTM professionals expressed their faith in the work of third-party repairs and the processes they utilize to ensure the safe functioning of medical equipment in their organizations. They also expressed concerns that further regulation would increase costs.

“We understand the concern expressed by some stakeholders that some third-party entities may use unqualified personnel to perform service, maintenance, refurbishment, and device alterations and that work may not be adequately documented,” Adventist Health System (AHS) told the FDA.⁴ “However, AHS has been able to ensure that repairs made to our equipment by third-party entities are made by qualified repair technicians and that the repair history is adequately documented.”
Organizations such as the Veterans Health Administration (VA) contended that in-house HTM professionals are more motivated to do high-quality repairs, as they are closer to the patients they serve. “Staff has an added incentive and sense of ownership for the hospital and the equipment they service, which makes them invaluable to the repair and maintenance process,” the VA wrote.5

Like a quarter of the commenters, the VA also noted the need for OEMs to provide training and service manuals to third-party entities to ensure patient safety. “The more barriers that OEMs instill to prevent in-house professionals from accessing training, service manuals, parts, and technical support, the more risky medical device operation becomes. With the proper access to training and resources, in-house staff provides more cost-effective and timely service and also serve as an extra set of eyes to ensure that OEM, or third-party entities, are performing their activities effectively.”5

AAMI Takes a Broad Perspective

Although AAMI usually does not submit detailed comments to Federal Register notices, the association felt it was important to respond. “In this instance, we believe that AAMI has the broadest view of the entire service industry, because it is neutral and multidisciplinary,” the association wrote. “We are hoping that our factual, big picture comments about the industry help provide context and a deeper understanding of how the entire service industry fits together as a part of the life cycle for medical devices.”6

In its comments, AAMI did not take a stance on who should repair or service equipment and it did not address the FDA’s more detailed questions about service. Instead AAMI’s comments summarized:

- The wide diversity of perspectives across the service industry.
- The limited evidence of a problem with improper service.
- The landscape of the service business in terms of history and scope, influences on serviceability, the value of on-site technical support, the refurbishment industry, and the impact of home healthcare.
- AAMI’s initiatives on supportability and HTM competency and certification.
- The importance of risk management.

References


Major third-party service providers play in the same space. “There is a big part of our business where we are the outsourced department for clinical engineering,” Hertzler said. “We are their department. Most of our clients will tell you that our programs operate identically to a self-operated program from the way we work within the walls of the hospital. They see us as a department of their hospital.”

Other third-party service providers offer more targeted services. Block Imaging Parts & Service, for example, focuses exclusively on medical diagnostic imaging devices—and on refurbished systems. The company buys, sells, and refurbishes imaging systems; offers service contracts, time-and-materials services, and on-site services; and tests, repairs, and sells spare parts.

“In the last 20 years, the shift by the healthcare system in the United States toward acceptance of refurbished imaging equipment has been significant,” Crawford said. “Twenty years ago, the number of hospitals that would consider buying refurbished MRI [magnetic resonance imaging] or CT [computed tomography] was very, very low. It was first and foremost manufacturers who legitimatized the refurbished industry,” when GE, Philips, Siemens, and other OEMs began marketing refurbished systems.

That shift has come about because healthcare systems are operating more outpatient imaging centers and freestanding diagnostic clinics. “These facilities are oftentimes serving regions where it isn’t about the highest volume,” Crawford said. “It comes down to the most cost-effective system they can provide that’s going to serve the population.” Even if healthcare systems put the “latest and greatest system in their flagship hospital,” they see refurbished systems that function at or above the OEM standard of performance as an attractive alternative for quality patient care elsewhere. Buying a three-to-five-year-old imaging system rather than a new system, for example, could reduce the cost by 30% to 50%, Crawford said.

Third-party service providers also can help healthcare systems yield better returns on investments—and better manage their vast inventories of healthcare technology. “Hospitals are looking for better cost and also looking for help reducing suppliers,” said

THE FDA’S INTENT AND NEXT STEPS

Valerie Flournoy, deputy director in the Office of Compliance, Division of Manufacturing and Quality, at the FDA, responded to questions about the agency’s third-party initiative.

What spurred the FDA’s initiative on third-party entities that service medical devices?

We recognize that the topic of refurbished medical devices has been discussed for many years, and the FDA has previously issued guidance and requested input from stakeholders to provide clarity on the issue. The FDA is taking action now, in part, because various stakeholders continue to express concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities.

Will there be a report on the comments to the Federal Register notice?

The FDA is in the process of analyzing the comments since the docket closed on June 4. The comments come from a variety of stakeholders offering varying perspectives on the questions posed and to be discussed at a public workshop this fall. We expect to summarize our analysis of comments and feedback received in a white paper that will be published in follow-up to the public workshop. In the meantime, all public comments can be viewed online at www.regulations.gov.

What next steps are planned?

We have planned a public workshop for Oct. 27–28 at the FDA’s campus in Silver Spring, MD, so we can hear from key stakeholders directly regarding challenges relating to third-party servicing activities (e.g., refurbishing, remanufacturing, reconditioning). The formal title of the workshop is “Refurbishing, Reconditioning, Rebuilding, Remarking, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.” The registration deadline for the workshop is Sept. 23. The Federal Register notice for the meeting is available at http://bit.ly/2bg7YyU.

Following the public workshop and upon completion of review of input received, the FDA will prepare a white paper to summarize recommendations and identify next steps it will pursue. The FDA will wait until after the public workshop to determine what additional action, if any, should be conducted.
Greg Sharp, vice president and general manager at STERIS Integrated Medical Systems International (IMS), the third-party service arm of STERIS. “Let’s use the example of endoscope repair: A hospital could have five, six, seven, eight different companies repairing its endoscopes. It’s very complicated for them to manage and difficult to figure out their costs and what’s justified, what’s not. They thought they were paying too much and didn’t have options.”

STERIS IMS tracks service histories and costs across device brands and models, and across its client base, which can help healthcare systems make smarter purchasing decisions, Sharp said. The company also categorizes repairs as preventable and nonpreventable. Endoscopes and other surgical instruments, for example, are subject to expected wear and tear, but their fragility also makes them prone to damage from clinical use, transport, reprocessing, and handling. STERIS IMS can monitor and analyze device use and care processes in healthcare facilities and provide on-site training to reduce the incidence of repairs.

The churn in the service market comes with benefits and drawbacks to healthcare systems and hospitals. SSM Integrated Health Technologies (SSMIHT), a 20-hospital system based in St. Louis, MO, prefers to service its healthcare technology in-house, but that’s not always possible.

“While approximately 30% of our costs are for service contracts, 30% for noncontracted parts and vendor labor, and 40% for in-house staff, our in-house staff performs more than 90% of the PMs and repairs,” said Heidi Horn, vice president of the Clinical Engineering Services Department at SSMIHT. “That is telling about how much more expensive manufacturer service can be. The cost ratio has become increasingly heavier on the service contract side, as many manufacturers have made it more difficult and expensive to maintain the equipment in-house by making training difficult to get and parts more expensive, which has forced us to take out more service contracts than we’d like with some vendors.”

Still, competition also gives healthcare systems and hospitals leverage in procuring services. SSMIHT expects its third-party vendors to meet its quality standards. “On those occasions where they don’t, we hear about it very quickly, and we have them correct the situation or we stop doing business with them,” Horn said. “The same applies if the equipment is serviced improperly by the manufacturers themselves. While the manufacturers have shared stories about unscrupulous in-house organizations and third parties who have put patients at risk due to improper service techniques, we could cite just as many occasions where the manufacturers’ own service technicians took down entire clinical systems for days and flooded whole departments because of mistakes they made while servicing our equipment. I’m sure almost every hospital has had similar experiences.” (For more on the SSMIHT approach to servicing, see page 324.)
Much Ado About Nothing?

Most stakeholders applaud the FDA for examining service concerns and making patient safety the common denominator for all organizations that service medical devices—regardless of their affiliation or position on the topic. (For more on the FDA's intent and next steps, see page 320.)

However, some caution against moving toward new regulation before the facts and comments are fully aired, while others already believe more oversight is needed. The crux of the issue is this: Is there a safety problem with the ways in which healthcare technology is serviced today?

Two experts who have crunched quite a few numbers don’t think so. Even with substantial increases over time in medical devices in use in healthcare and in medical device incident reports, “we are now two orders of magnitude smaller” in the percentage of reported incidents of deaths, injuries, malfunctions, or other safety issues associated with postmarket services, according to Bruley of ECRI Institute.

“It’s the denominator issue,” Bruley said. “What we had in 1998 was a total of 137,500 FDA adverse event reports” on capital equipment. “The full database had about 700,000 reports back then. Now we have more than 4 million reports, of which approximately 2,115,000 are on capital equipment.”

—Mark Bruley, vice president of accident and forensic investigation at the ECRI Institute in Plymouth Meeting, PA
Medicine databases. Over the past decade (2006–15), 0.005% of reported incidents (i.e., 96 of 2,115,523 reports) were related to postmarket services, compared with 0.2% from 1977 to 1998. Comparison data over time are shown in Figure 1. Detailed data from the past decade are shown in Table 1.

Bruley hypothesizes that built-in safety design of electromechanical capital equipment is contributing to the decline in the percentage of service-related safety incidents, despite many more devices in use. “Ventilators, physiologic monitors, infusion pumps, defibrillators: you turn them on, they go through a self-check initially,” he said. “If they have failed, then they are not going to get into use in the first place. The increase in safe design based on advances in electronics might be one reason that problems with servicing have simply not been occurring. That’s simply a hypothesis; there’s no data to support that, but it’s an observation in regard to the change in technology in the last 18 years. I don’t know that anybody has discussed that.”

A different analysis of service-related sentinel events published in Biomedical Instrumentation & Technology resulted in similar conclusions about the evidence. Three (0.6%) sentinel events collected by The Joint Commission in 2011 and 24.6 (0.4%) root causes from 2004–11 were related to equipment failure “in the worst case.” Of these, less than one per year was likely due to a maintenance omission. Maintenance omission was estimated to be 0.024 to 0.286 per million equipment uses, including correction for possible underreporting.

“My concern is that the FDA information in the Federal Register notice states very clearly that stakeholders are bringing to them concerns about service,” said Binseng Wang, director of quality and regulatory affairs at WRP32 Management LLC & Greenwood Marketing LLC in Charlotte, NC, as well as lead author of that analysis. “They don’t share the data about those concerns. How often are incidents happening? One in a million is very different than one in 100.”

A one-in-100 scenario could indicate there is a systemic problem that the FDA has an obligation to correct, Wang said. For the one-in-a-million occurrence rate, the FDA already has the authority to take action against any company for misconduct.

For example, if a service provider makes device modifications that affect safety, performance, or intended use, Wang advocates for a “surgical type of intervention” rather than new regulation that would affect the entire industry. “If we’re talking about a handful of organizations, then report them, investigate their misconduct, and have them prosecuted. They are definitely putting people’s health and life in jeopardy. But if you have thousands of organizations or people doing this, then yes, there has to be a rule created to stop people from doing this.”

**Better Visibility and Reporting**

Some OEMs have different takes on the matter. First off, if a problem results from a medical device, they are involved, regardless of whether they serviced the device. If their brand name is on the device, their name will be on the lawsuit, if it comes to that.

“First and foremost, the medical equipment failures that cause patient injury or death are really low,” said Nudelman of GE Healthcare. “If you look at it as just a number, it’s negligible. You also need to separate out equipment failure from operator error or misuse, but the statistics might not tell the whole story.”

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**Figure 1.** Number and percentage of reported incidents related to medical device servicing over time. Source: Comment from ECRI Institute to FDA’s Refurbishing, Reconditioning, Rebuilding, Remarking, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers (June 1, 2016).
How does SSMIHT approach servicing and repairs of medical equipment?

SSMIHT has 20 hospitals and 62 outpatient care sites in Missouri, Illinois, Wisconsin, and Oklahoma. Our Clinical Engineering Services Department approaches the servicing of its 80,000 medical devices with the philosophy that whenever it is financially beneficial, and we have trained, competent in-house technicians available, it is always preferable to perform the maintenance in-house versus calling in the manufacturer or a third-party vendor. There are a number of reasons why this is the case for SSMIHT, as well as most high-performing in-house HTM departments across the country:

1. **The Centers for Medicare & Medicaid Services and The Joint Commission, as well as other accreditation bodies and regulatory agencies, have regulated that the hospitals themselves are ultimately responsible for their own medical equipment management plans and the safety of their medical equipment.** We have found that the best way to ensure we are meeting those requirements is to take ownership of the maintenance work. This allows us to respond immediately to repair requests (something an off-site vendor can’t do), especially in the case of emergencies, and to develop a very good understanding of the nuances, user workflows, and interfaces of all the equipment in our hospitals. Our BMETs and diagnostic imaging engineers at our hospitals feel a deep sense of ownership of the equipment and responsibility toward the clinicians they serve and their patients. They have to look these people in the eye every day and work alongside them. This sense of ownership is a major motivator to them to maintain the equipment properly and ensure it is safe and reliable.

2. **Our department has documented that it can maintain the entire inventory of 80,000 clinical devices at SSMIHT for about 5% of the total purchase cost of the equipment.** This includes Clinical Engineering Services’ salaries and benefits, close to $1 million a year in service training and associated travel costs, test equipment, CMMS [computerized maintenance management system] software, overhead, plus all service contracts and noncontracted parts and vendor labor. An independent service organization is typically around the 6% to 12% range, and manufacturers will charge an annual average of 10% to 20% of the purchase value for a contract. So for my health system, it would cost us approximately $16 million to $75 million more a year to have the manufacturers maintain the equipment. Furthermore, if there was an FDA edict that only manufacturers could maintain the equipment, there would be no more service competition for the manufacturers and thus the hospitals would be completely at their mercy on their contract pricing.

3. **Just because a manufacturer will no longer service the equipment does not mean parts aren’t readily available from reliable parts vendors, nor does it mean the device no longer is valuable to patient care.** A common revenue generator for manufacturers is to come out with new models of equipment and end their service support of older models. We have received end-of-service support letters on devices we purchased new one year prior. In addition to the probability that service costs would increase dramatically if only manufacturers were allowed to maintain the devices, hospitals could be forced to spend billions to replace perfectly good equipment that the manufacturers deemed “end of life” and refuse to support.

4. **If for some reason our in-house team is unable to fix a device, the manufacturer will be called in to assist, so it is not as if we don’t have access to them when we need them.**

5. **From a purely logistical standpoint, it would be impossible for every manufacturer to have trained technicians in close proximity to every hospital.** We have thousands of different equipment models across the system. In some cases, there are only one or two of a manufacturer’s devices at a particular hospital. It is not feasible for every manufacturer to place service staff in every region where their equipment is located, and the hospitals often need an immediate response. It makes much more sense to have competent in-house technicians who have the ability to read the service manuals and work on a wide variety of equipment so the equipment is available for use.
What factors does SSMIHT consider in making decisions about servicing medical equipment?

We look at a number of things:

- **The number of like devices compared with trained personnel in a geographic area.** In some regions, we may have only one or two similar high-end and/or high-risk devices (e.g., one MRI or one of a particular anesthesia machine model). In those cases, the cost of training and placing an in-house senior diagnostic imaging engineer at that location exceeds the cost of getting a contract, so we would get the contract. However, if we had three or more similar high-end or high-risk devices in a region, then the cost of training the staff may be less than three service contracts, so we would send someone to the manufacturer’s training and maintain them in-house.

- **The competency and training of the in-house HTM staff.** There have been occasions where the person trained on a particular device left, and we no longer had someone trained on the device. In those cases, we have successfully worked with the manufacturers to either take out a short-term full-service contract or just go “time and material” with them until we can get someone trained.

- **Frequent and expensive repair history.** In some cases, it makes sense to take out a service agreement when a device has had frequent and expensive repairs relative to the contract cost. When we are spending more on parts and labor than the cost of a full-service agreement, then we will most likely make the decision to put it under contract.

- **Complex repair.** We take first look on almost all noncontracted devices, but occasionally we’ll run into an intermittent issue or repair that stumps us. If after a certain amount of time we are unable to identify the issue or feel we need some additional expertise, we will call the manufacturer in and pay time and material.

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“If we’re talking about a handful of organizations, then report them, investigate their misconduct, and have them prosecuted. They are definitely putting people’s health and life in jeopardy. But if you have thousands of organizations or people doing this, then yes, there has to be a rule created to stop people from doing this.”

—Binseng Wang, director of quality and regulatory affairs at WRP32 Management LLC & Greenwood Marketing LLC in Charlotte, NC

Pat Baird, a medical device engineer and long-time AAMI member, raised the possibility that service-related safety issues by third-party or in-house providers might be underreported: “I know that some OEMs have seen some near misses and other instances that absolutely concern us as manufacturers. I also believe that fundamentally there will be underreporting by third-party or in-house providers because it’s not always obvious that an adverse event or a near miss was related to a repair or servicing operation—people often don’t think to look there. One action that some manufacturers are taking is to start reporting incidents of unauthorized repairs.”

And even with service manuals, tools, and specifications, Baird has sometimes seen service providers fail to adhere to procedures or requirements. “What is needed for a repair may look obvious to a service provider. Invisible to them, though, are some of the subtleties of the repair. You have to follow all of the process steps that are in our manual. You can’t skip some steps because you don’t think they’re value-added. We have those steps in there for a reason.”

The invisibility issue extends to parts as well. “Batteries are good example,” said Julie Anne Berry, senior director of global service quality at Baxter. “People think it’s simple, but not all batteries are the same. With medical equipment, your choice of battery is more critical.” Baxter is an OEM that also partners with third-party service providers and self-service
organizations for training, certification, and spare part management and offers remote and on-site technical support.

People don’t always understand that there are unintended consequences and risks to taking shortcuts, Baird said. And it’s not just a matter of raising the visibility and awareness of this issue with those who repair medical devices. “It’s also their management that needs to understand,” Baird said. “I suspect HTM professionals are under a lot of pressure to keep their costs down and reduce their backlog of inventory of devices to repair and upgrade.”

### Different Providers, Different Standards

It’s a point of contention for some OEMs that neither third-party service providers nor in-house service providers are held to FDA standards. That can put OEMs at a disadvantage cost-wise in the service business.

Not that there aren’t many quality service providers or that only OEMs should service healthcare technology. “The problem statement is that there’s too much variation,” Nudelman said. “There’s no requirement that says, ‘Here’s what you need to do to service medical equipment if you’re not the OEM.’” He advocates for some regulation on quality control, change control, and documentation of service.

Crawford of Block Imaging Parts & Service agrees that manufacturers are held to a higher level of accountability by the FDA. “But they have designed, built, and produced a product with an intended use,” he said. “The manufacturers know that the vast majority of medical devices in this country are serviced by someone other than that manufacturer and they bear a responsibility for making sure that the products that they have designed and manufactured are safe for patient use. And the accountability on third-party service organizations should be to follow the guidelines of the manufacturer.”

“From a quality perspective,” said Sharp of Steris, “other than the fact that we’re not under the Quality System or Good Manufacturing Practices regulations, through our ISO quality systems, we have robust quality control and monitoring mechanisms.” Increasingly, healthcare systems and hospitals are reviewing the quality processes of third-party service providers, he said.

Hospitals, too, are under close supervision from The Joint Commission or other accrediting organizations as well as insurers, especially Medicare and Medicaid, for reimbursement. “So those people who either are directly employed by hospitals or have a contract with hospitals are under some scrutiny already,” Wang said.

### An Opportunity for Industry

The experts interviewed for this article believe the FDA initiative is an opportunity to improve postmarket servicing. Here’s a sampling of their advice:

- **Cooperate.** “This is an opportunity for us as an industry to move to a higher level of cooperation for the sake of patient care. At Block Imaging, we have changed our

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**Table 1.** Reported incidents related to medical device services, 2006–15. Source: Comment from ECRI Institute to FDA’s Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers (June 1, 2016).
perspective of the manufacturers. There’s a level of cooperation we need to have with each other to ensure that medical devices are being serviced and maintained and refurbished in a way that is safe and that provides for good patient care. The relationships that we have with the manufacturers today are better than they have ever been. This has come from a place of us going to cooperation instead of competition to get information and support.” —Jason Crawford, Block Imaging Parts & Service

- **Support in-house, on-site service.** “Mandating that only manufacturers can maintain medical equipment would not solve any of the issues and would create many additional problems for the hospitals. If manufacturers are truly concerned about patient safety, they should focus their efforts on designing user-friendly equipment that prevents human errors; build equipment out of more durable parts that don’t break so easily; make service training and manuals very accessible and affordable; provide ongoing user training to identify and correct end user issues; and when equipment issues are identified with the product, quickly communicate it out to all equipment owners and correct it instead of hiding it. Most of the manufacturers we work with do a great job at supporting our efforts to provide exceptional patient care and understand that by working together, they win, the hospitals win—but more importantly—the patients win.” —Heidi Horn, vice president of the Clinical Engineering Services department at SSM Integrated Health Technologies in St. Louis, MO

- **Focus on talent recruitment, retention, and development.** “Talent recruitment and retention is a very serious challenge because service depends on people. If you want to recruit and retain good people, it’s not just about providing a good compensation, it has to do with a lot of other factors, such as extensive travel, work location, and career opportunities. All of these factors are quite important and they eventually translate into the quality of the people that we can recruit and retain, and that obviously translates into the quality of the service provider.” —Binseng Wang, WRP32 Management LLC & Greenwood Marketing LLC

- **Resolve the “invisibility issue” by reaching the right audience.** “Certainly competencies should be part of the discussion. We’re not saying that if you’re not an engineer you can’t possibly perform services. But I also wonder sometimes whether the people we’re talking to at AAMI committees and conferences aren’t really the target audience we need to reach. It’s the invisibility issue again. I worry about the people who are under lots of cost pressure and are inclined to take shortcuts.” —Pat Baird, medical device engineer and long-time AAMI member

With the many different perspectives and the complexity of the challenge, one thing is certain when it comes to the debate over the
service of medical devices: In many ways, the conversation is just starting, and the FDA’s workshop this fall is not likely to be the last word on the subject. But most stakeholders say the debate will be more informed and insightful as more experts come forward with their own experiences and data. As that happens, clearer answers could emerge.

References
