STATEMENT OF

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BEFORE THE SUBCOMMITTEE ON HEALTH ON

"EXAMINING IMPROVEMENTS TO THE REGULATION

OF MEDICAL TECHNOLOGIES"

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Mr. Chairman, Ranking Member Green, and Members of the Subcommittee, thank you for the opportunity to offer testimony on behalf of the independent service organizations and small business members of our diagnostic imaging trade association, the International Association of Medical Equipment Remarketers and Servicers, Inc. ("IAMERS") with regard to the "Medical Device Servicing Safety and Accountability Act".

Summary

1. This Legislation is a solution for which there has been no evidence to support there is a Problem.

   The respected scientific research institute, ECRI Institute, after reviewing the FDA MAUDE reports, submitted to the FDA in March 2016 a report (110 pages) which concluded that there

is no evidence to date that a patient safety problem exists. The American College of Clinical Engineering also stated that there is no real-world evidence to support further regulation.

2. This Legislation will require Independent Servicers to absorb the cost of complying with the Quality System Regulations as if the Servicers were Manufacturers or pass these costs along.

3. This Legislation Will hurt Rural and Regional Healthcare. Rural and regional Hospitals rely heavily on independent servicers for competition and lower prices and if the independent servicer is not available, this greatly impacts the rural hospitals. Some servicers will not be able to compete.

BACKGROUND: IAMERS

For almost 24 years, IAMERS has been the leading voice of the secondary market sellers and servicers of diagnostic imaging equipment. The imaging modalities of IAMERS members are MRI, CT, ultrasound, nuclear medicine and general radiography. IAMERS members safely service regional and rural hospitals throughout the United States. IAMERS members offer quality services at a lower cost than the original equipment manufacturers ("OEMs"). IAMERS members offer competition in a healthcare marketplace dominated by the largest companies in the world. IAMERS' Independent Service Organizations (ISOs) are much valued and nowhere more so than in rural America. To the rural hospitals of West Virginia, Kentucky, Alabama, and many other rural areas of the country, ISOs are an essential component in the healthcare ecosystem.

The majority of our members are made up of small independents including sellers and servicers who are alumni of OEMs. IAMERS members work closely with OEMs and are hired to support OEM multi-vendor programs (hospital programs in which the OEM is responsible for handling another OEM's equipment which may be located at a particular hospital). This subcontracting is significant as the OEMs trade organization, the Medical Imaging Technology Alliance ("MITA"), a division of the National

Association of Electrical Manufacturers Association) has claimed for some time on behalf of the OEMs a 'lack of uniform performance' and yet…. its members continue to hire IAMERS ISOs to perform multi-vendor service contracts or to service their customers in remote locations. ISOs are also hired by OEMs to service, install and move the OEM's systems that are now considered legacy and no longer within the expertise of the OEM. OEMs hire ISOs because the ISOs perform their work with skill and dedication to patient safety. Skill and patient safety are at the core of IAMERS values. So, if the ISOs are so bad, why are the OEMs hiring them to fulfill their contractual obligations?

IAMERS ETHICS, EDUCATION AND BEST PRACTICES

Among the things which separate IAMERS from other medical device organizations is that we require our members to adhere to a Code of Ethics. This isn't just lip service. If a complaint is raised by a hospital, group medical practice or other IAMERS member, the complaint is considered by the Ethics Committee. Adverse determinations have resulted in public reprimands or expulsions. No member is excluded from this requirement.

Last year both our American and European members unanimously passed a program for Best Practices. This program now includes specific templates to be customized by a member to supplement the member's business practices. These templates include recommended practices as to inventory management, traceability, complaint management, data management and other key components. It is an extensive voluntary program but it does not require the retention of a compliance officer to address the quality system requirements which the proposed legislation may well *de facto* require.

We have long maintained a robust educational agenda for our members which occurs at every meeting. For much of the last twenty years we have had participation in our meetings and educational programs from the FDA, Compliance Consultants, and others. Past programs have been conducted on

FDA inspections, UDI requirements, reporting of adverse events and many other areas which impact patient safety.

IAMERS WORKS WITH ALL STAKEHOLDERS

IAMERS also has longstanding and much valued OEM members including GE, Siemens, Toshiba and Philips. Several OEMs will join us, as usual, for our annual meeting this week. We welcome their presence. We are fortunate also to have at our meeting this week FDA Chief Scientist Dr. Maisel as well as Mark Bruley, Vice President for Accident and Forensic Investigation at ECRI Institute. We have been fortunate to have past faculty from the Center for Medicare and Medicaid Services, the Medical Device Manufacturer's Association and of course other OEMs. IAMERS has a proud tradition of education, training and outreach and we wish to do more. Our members value quality and understand education and training are important components.

2016 FDA PUBLIC DOCKET ON SERVICING And FDA OCTOBER WORKSHOP DO NOT SUPPORT THIS LEGISLATION

This Legislation is, however, a solution for a problem which has not been shown to exist. In March 2016, the FDA opened a public docket to solicit comment on (among other things) whether to regulate servicers. The FDA received comments from 177 interested parties. See https://www.regulations.gov/docket?D=FDA-2016-N-0436. It is interesting to note that there was almost a complete absence of negative comments from hospitals and group medical practices with respect to independent service organizations. It is perhaps worth repeating then…..if this legislation is truly addressing a serious health care issue, why is there no clamor from the hospitals to impose a change? Respectfully we urge the Committee not simply to accept the statement of IAMERS but look at the comments submitted on the FDA Public Docket by independent industry observers. The nationally recognized leader in performance measurement, the Joint Commission, in its comment filed in the FDA

docket, stated that the Joint Commission "has no knowledge of any statistically significant level of safety problems resulting from the activities of any kind of maintenance/service provider." In its comment, Penn State Health stated "[v]ery little evidence of systemic problems exists." Citing four statistical analyses which reviewed the root cause of events, Penn State further stated the "analyses above clearly show that inappropriate servicing and maintenance is not a statistically significant root cause for safety events"

In October 2016, the FDA held a two-day workshop on October 27-28, 2016 entitled the "Public Workshop-Refurbishing, Remarketing, Remanufacturing and Servicing of Medical Devices Performed by Third Party Entities and Original Equipment Manufacturers. Over 500 people attended in person and many more attended via web access. Over 40 speakers presented and 20 additional attendees voiced their opinions. MITA showed pictures of equipment issues, attributed to nameless independents and advocated for further regulation. The American College of Clinical Engineering offered that there was a lack of real world evidence to support MITA's advocacy for additional regulation. IAMERS advocated that the FDA should not regulate by anecdote. The FDA has advised that it is preparing a summary of the information gathered at the workshop. In the last few months, the FDA has contacted stakeholders to clarify and confirm stakeholder information and identify takeaways from the workshop. The FDA report has not, yet, issued.

IF THERE IS A HEALTH SAFETY ISSUE: WHY HAVE NOT THE MAJORITY OF THE HOSPITALS ADVOCATING FOR ISO REGULATION?

If independent servicing is such a significant healthcare problem, we respectfully inquire again: why has the Committee not heard from hospitals clamoring for further regulation of ISOs? Perhaps the more relevant question is: why is it that the OEM trade organization, MITA, advocating so strongly for passage? We believe that the motivation is because ISOs represent a competitive and viable alternative to OEM domination of the hospital servicing marketplace. Such domination may well result in an ever upward spiral in the cost of providing diagnostic imaging services.

INDEPENDENT SERVICERS ARE A COST-EFFECTIVE ALTERNATIVE

To offer a brief cost contrast: the cost of a service call by an independent service organization ("ISO") is typically in the range of $150-$250 per hour. The cost of a service call by an OEM is reportedly in the range of $500-$600 per hour with a 4- hour minimum requirement. Plainly ISOs offer competitive choices for hospitals who are keenly aware that capital equipment costs are often 45% of their budget. Time after time ISOs provide appropriate high quality maintenance services and do so at lower cost to the healthcare provider, thus easing their budgetary restrictions. How good are the ISOs in servicing medical devices? As noted, the OEMs routinely hire ISOs to perform their multi-vendor work or to service medical facilities in remote areas and in facilities in which they have a system wide contract (and may lack the knowledge required to service imaging devices of other OEMs and older versions of their own devices). OEMs have advocated for the further regulation of ISOs with the possible intent of making it even more challenging for the ISO segment of the market to exist and be able to offer competitive services as a cost-effective alternative to the OEM.

RIGHT TO REPAIR: NOT EVERY REPAIR HAS TO BE UNDERTAKEN BY THE MANUFACTURER

To borrow from the auto industry: every time you need an oil change, tune-up, or any other auto repair, the manufacturer is not the only option. Perhaps that is why some states have pending for consideration 'right to repair' legislation.

Consideration of the implications of the "Medical Device Servicing Safety and Accountability Act" raises a significant question: Will the U.S. healthcare ecosystem become like the European model, where there are very few ISOs or will we support our hospitals having choices? Perhaps the system works in Europe where most hospitals are reportedly single payer government supported institutions. As this Committee is aware, the private hospital system is different in the U.S.

The hospitals and the regulatory bodies including CMS, the Joint Commission, and other accrediting agencies require third parties to use manufacturer's recommendations for servicing equipment. Hospitals have the ability to detect and as appropriate, weed out inadequate players. Stated otherwise, these hospitals and group medical practices can (and do) vote with their feet by imposing contractual consequences which all parties need to observe if services are inadequate.

The Proposed Legislation Will Impose Significant Additional Costs On ISOs

Under Sec. 2 of the proposed legislation, entitled "Registration of Servicers of Devices" section 510 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360) would be amended by requiring all servicers to be registered:

> "… not later than 18 months after the date of the enactment, the FDA is to issue final regulations requiring any person who owns or operates any establishment in any State engaged in the servicing of a device….. to register…"

Registration would impose the reporting requirements of a manufacturer or remanufacturer. Among the requirements to be mandated is that the FDA require the ISO to implement a complaint handling system

equivalent to the manufacturer's requirements under 820.198 of title 21. This complaint system requires virtually every repair to be recorded even where no adverse event or MDR is involved. According to existing FDA regulations as they apply to manufacturers, a complaint means:

> "any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution (emphasis supplied)"

ISOs would need then to consider any repair service work as a complaint and keep a complaint record in accordance with 820.198. This imposes substantial extra work and may well require a quality control or compliance officer to be employed. It is not altogether clear that this extra cost and extra work on the part of the ISO, would substantially advance information on device failures. We are informed that most of the service calls relate to scheduled maintenance or repair of the device. However, the ISO would be required (if the provisions of 820.198 were to be followed) to undertake the burden of record keeping for the extremely rare instance when an adverse event occurs. A web based request system would have to be implemented to capture more data. ISOs would likely need to purchase new systems.

Manufacturer lobbyists have long been pushing for this requirement so that ISOs would fall under the same FDA quality system regulations as the manufacturers. The measure at its core benefits the original equipment manufacturer by burdening the independent servicer with substantial additional costs without a concomitant safety benefit. ISOs will have to charge more to absorb the costs. Additional staff such as quality managers would be needed for the documentation requirements. At a minimum, an ISO would need to have training provided to at least one employee or perhaps multiple employees for a quality management system and to address the FDA requirements. The average cost of quality system management training has been reported to IAMERS to be no less than $3,000 per employee. If the ISO elects at one location to become either 9001 or 13485 certified by a registered body the minimum cost might be $10,000 for the first year. An external auditor, if retained to audit the

quality management system, might well charge $5,000. On average, the ISO might well be required to pay in addition to the retention of an employee, possibly $20,000 exclusive of the costs of training other employees on processes and on additional regulatory or state requirements as they are imposed.

If FDA applies the same registration process that currently exists for manufacturers and importers, it could be rather costly for small service companies. The registration fee for a small manufacturer was reported as approximately $4000 in 2016. We understand that an increase has been proposed. These costs, when considered as a whole, will have a significant effect on the ability of the ISO to offer the ISO's services at competitive rates.

If Patient Safety Is The Goal- Why Does The Legislation NOT Require OEMs To Cooperate in Providing AIAT and Service Key Information At A Reasonable Cost

If the genesis of this legislation was truly to address patient safety, provisions could have be included which require the delivery by the OEMs at reasonable cost of equipment manuals, passwords and training. Each year including this year, IAMERS receives reports of ISOs who encounter resistance by the OEMs to providing this information.

Conclusion

As one respected Stephen Grimes has noted, many hospitals are spending 8 to 10 times over what they spent annually 10 years ago on medical capital equipment. These hospitals welcome competition and service from independent service organizations. Imposing manufacturer quality system and reporting requirements upon independent servicers only serves to burden the ISO with additional costs—which are either passed on or absorbed—if the ISO's cost structure permits. This legislation, if implemented, may well jeopardize the independent servicer business model without real world evidence as to the need. The additional compliance burdens of the new legislation will make them challenging for small business owners to comply. In the absence of real world evidence establishing the

need for further regulation of ISOs, the “Medical Device Servicing, Safety and Accountability Act” should not be supported.