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UNITED STATES HOUSE OF REPRESENTATIVES
ENERGY AND COMMERCE COMMITTEE, SUBCOMMITTEE ON HEALTH
HEARING ON "EXAMINING IMPROVEMENTS TO THE
REGULATION OF MEDICAL TECHNOLOGIES"

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MR. CHAIRMAN, RANKING MEMBER GREEN AND MEMBERS OF THE SUBCOMMITTEE:

As a national provider of "in-house" medical equipment service and maintenance management, TriMedx has developed a safe, efficient and effective model to work directly with hospitals and other healthcare facilities to manage their medical equipment and technology. Founded in 1998, TriMedx began as the hospital clinical engineering department for St. Vincent Hospital in Indianapolis, Indiana. Effectively created by healthcare to serve healthcare, TriMedx's focus was and is to enhance the patient experience through innovative on-site equipment management programs designed to optimize equipment service and reduce costs. Ascension Health, the largest non-profit healthcare system in the country, has provided TriMedx the sole responsibility for managing the service, maintenance and repair of equipment for all hospitals within its system. The value proposition contained in the original vision for TriMedx – creating an independent, provider-oriented technology management company driven by core values – has been validated by TriMedx's rapid growth outside of Ascension Health. Over the past decade, TriMedx has become a meaningful and important strategic partner to some of the nation's most prominent healthcare providers, including a broad range of nonprofit health systems, academic medical centers and for-profit health systems. Today, TriMedx:

- serves more than 240 hospitals and 1,800 healthcare provider locations across 32 states;
- maintains data for more than 1.7 million pieces of equipment (including more than 60,000 unique models);
- employs and manages approximately 1,500 associates nationwide; and
- has saved hundreds of millions of dollars in capital expenditures and operating costs for its client partners through its comprehensive program.

EQUIPMENT SERVICE MODELS – ISOS AND OEMS.

The National Healthcare Expenditure Accounts estimate the cost of healthcare in the United States accounted for 17.5% of the nation's Gross Domestic Product in 2014.[1] Reports have shown that a medium size facility can spend $5 million per year on equipment maintenance and an average system can spend $50 million per year on such costs. It is clear that an effective equipment management program is a key component in reducing costs, optimizing services and ultimately freeing up financial resources.

[1] Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.

In an effort to support such healthcare providers, the clinical engineering industry developed managerial programs focused on asset and strategic management of equipment inventory. These programs are typically offered through independent third-party service organizations, or "ISOs" and may include: (i) outsourcing of a traditional in-house clinical engineering department; (ii) medical equipment management services, including consulting services for the acquisition, maintenance and disposal of medical equipment; and/or (iii) the provision of specialty maintenance and repair services.

Independent third-party service providers play a key role in ensuring that healthcare is delivered in a cost-effective manner. By providing alternative and additional service options to original equipment manufacturer ("OEM") services, third-party service providers not only increase market competition but also drive other OEMs to maintain quality and cost-effective programs for healthcare providers.

EXISTING STATUTES AND REGULATORY FRAMEWORK.

Under the Federal Food, Drug, and Cosmetic Act (the "Act"), except for very limited and specific circumstances, the Food and Drug Administration ("FDA") has appropriately exercised little authority related to the manner in which healthcare providers and hospitals service and maintain their own equipment. Likewise, the FDA's regulations do not currently apply to independent third-party servicers of equipment when the independent third-party service provider contracts directly with the hospital or healthcare provider. Therefore, TriMedx interprets the FDA's current position to mean that independent third-party service providers are governed by the same regulatory framework as its hospital customers.

This interpretation is further supported by the fact that a hospital's service, repair and maintenance of equipment is subject to various existing statutory/regulatory schemes and accreditation conditions, including the Clinical Laboratory Improvement Act, the Safe Medical Devices Act of 1990, the CMS Conditions of Participation and conditions of The Joint Commission, depending upon the specific type of equipment at issue. As a hospital service provider, TriMedx is obligated to abide by the rules and regulations applicable to its customers, in addition to several others. Since TriMedx and other ISOs provide services as an agent or arm of the hospital, we are bound by the same laws.

In fact, as we shared in our comments to the FDA, healthcare providers and hospitals are already subject to a substantial amount of regulation and reporting through the existing federal, state and accreditation framework. Given that TriMedx offers a comprehensive medical device management program to its hospital customers, it assists them every step of the way in complying with the existing rules and regulations. Adding an additional reporting and audit burden would, we fear, simply add more cost and confusion to this highly regulated space.

FDA'S REQUEST FOR COMMENTS REGARDING SERVICING OF MEDICAL DEVICES.

TriMedx would like to take this opportunity to commend the FDA for its continued diligence around the refurbishing, rebuilding, remarketing, remanufacturing and servicing of medical devices. On March 4, 2016, the FDA issued a request for public comments, asking that stakeholders provide information regarding the refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices performed by third-party service

providers and OEMs ("Request for Comments"). The FDA received an overwhelming response to this request that included over 175 comments from hospitals, OEMs, independent third party service providers, clinical engineers and other interested stakeholders.

On October 27th and 28th, the FDA held a public workshop, which afforded stakeholders an additional opportunity to share their thoughts and viewpoints. The FDA indicated it would review the findings and recommendations before taking further action. We found the workshop to be an invaluable opportunity to exchange concerns and recommendations. It also helped to ensure that FDA understands the interplay between hospitals, health systems, ISOs and OEMs and the impact that additional regulation may have on each. We left with an even greater appreciation for the complexities that come to bear when one of the pieces of the existing regulatory framework shifts.

In response to a question posed by a member of this Committee during its recent hearing on the Medical Device User Fee Program, Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health, testified that FDA continues to review the feedback it received and "is still in the data gathering mode." We appreciate the time and resources that Dr. Shuren and his very knowledgeable, experienced team at the FDA have dedicated to this and look forward to reviewing their recommendations regarding the current regulatory framework.

MEDICAL DEVICE SERVICING SAFETY AND ACCOUNTABILITY ACT (H.R. 2118).
The Medical Device Servicing Safety and Accountability Act (H.R. 2118) would require ISOs to register with the FDA, establish a complaint handling system equivalent to that applicable to OEMs, and comply with the same reporting requirements. The bill also creates an exemption for in-house service departments. Put differently, if a device user facility, such as a physician office, ambulatory surgery center, or hospital, were to elect to maintain, service and repair its own equipment, without contracting through an OEM or an ISO, these same registration and reporting requirements would not apply.

At TriMedx, as with many other service providers around the country, our number one priority is patient safety. We believe TriMedx can positively impact that priority by ensuring the medical devices are safely and effectively maintained, repaired and available for safe patient use by healthcare providers. As a result, we support any initiatives that clearly advance the common goal of ensuring patient safety. TriMedx appreciates the Committee's interest in furthering the safe and effective use of medical devices. However, we are concerned that H.R. 2118 is only the first step to more comprehensive and burdensome regulatory requirements without a clear and corresponding benefit to patient safety. Therefore, we urge the Committee to approach this issue with caution and offer the following concerns and recommendations regarding the measure as currently drafted.

THE FDA IS WORKING TO ADDRESS THIS ISSUE.
As noted above, the FDA received substantial input through its request for comment and its public workshop. In fact, it is still in the process of gathering information before recommending next steps. Consequently, we are concerned that this legislation is premature and believe, given the extensive work the FDA has already done around this very issue, the agency should be allowed to complete its work before Congress intervenes with legislation.

THE REGISTRATION LANGUAGE IS VAGUE.
In addition to requiring servicers of medical devices to register with the FDA, H.R. 2118 permits the FDA to "specify the timing, format, and information" that must be submitted. While we appreciate the need to provide the FDA with flexibility to determine what information must be submitted, it should not be information that will be burdensome and costly to produce. By itself, the notion of registering with the FDA does not appear to be overly burdensome and we would be happy to comply, but we believe the application and maintenance of the registration should not be unduly burdensome and provide a commensurate benefit.

THE COMPLAINT HANDLING AND REPORTING REQUIREMENTS ARE DUPLICATIVE AND CREATE AN AWKWARD CONSTRUCT.
Federal regulations (21 C.F.R. 820.198) require manufacturers to maintain a complaint reporting process and procedure. This is designed to ensure that any potential concerns with a particular device are relayed to one party, the manufacturer, for further investigation and analysis. If the same reporting requirements are extended to servicers, it is unlikely that the manufacturer will know the number of complaints received and may not be able to understand the scope of a problem, which will hinder its ability to provide a remedy as soon as possible. Additionally, while a servicer may investigate an issue and report its findings to the manufacturer, it is likely that the manufacturer will still conduct its own analysis. These duplicative efforts are unlikely to bring any benefit to our healthcare system and, instead, represent a further diversion from the shared goal of delivering care in a safe and cost-effective manner.

Section 519(a) of the Act (21 U.S.C. 360i) contains two primary reporting categories: subsection (a), which applies to manufacturers and importers; and subsection (b), which applies to device user facilities. The legislation amends Section 519(a) to apply the manufacturer and importer complaint processing requirements to ISOs. Unfortunately, this would be duplicative because, as the manager of a device user facility's medical equipment, ISOs like TriMedx are responsible for helping their hospital customers comply with subsection (b). In fact, these ISOs assist with the internal investigation, gather information and help produce the report that is submitted to the FDA. Thus, they are already indirectly responsible for complying with subsection (b) under this existing regulatory framework.

We appreciate the need for these current regulations and believe the reporting requirements in subsection (b) are designed to provide the FDA with the information that is necessary to identify and manage equipment that is not safe or effective. Likewise, subsection (a) is tailored to require manufacturers and importers to provide information to which they are privy and which allows the FDA to ensure that devices are safe and effective for their intended use. While manufacturers and importers are governed by the same regulation, the reporting requirements applicable to each vary under part 803 of title 21 of the Code of Federal Regulations. Part 803 provides more specific guidance regarding the amount of information to be reported, the reports that must be maintained and the follow-up work that may need to occur in the event of a report. The guidelines under Part 803 are different for manufacturers, importers and device user facilities.

Put differently, there are already carefully crafted reporting requirements in place which strike the balance of ensuring that the right information is delivered at the right time. As mentioned above, many ISOs are already working with their clients, the device user facilities, to deliver this

information to the FDA. We believe the current reporting framework is sufficiently comprehensive and appropriately tailored to require delivery of information that is most readily available to the reporting party. However, if it is determined that changes are needed, we recommend that the legislation take into account existing reporting requirements in order to avoid redundancy.

Finally, by adding "servicers" to the manufacturer and importer reporting requirements additional regulatory action will need to be taken to craft reporting requirements that identify the information ISOs must produce. Simply adding the term "servicers" into obligations intended for manufacturers creates an awkward and unintended construct and has the potential of creating more confusion when it becomes unclear as to where the ISOs' obligations end and the OEMs' responsibilities begin. Moreover, we strongly believe the result would be reporting requirements identical to those of the device user facilities, which would result in a surplus of duplicative information being provided to the FDA that only adds to the cost of the device user facilities and to our already overburdened healthcare system.

THE LEGISLATION COULD REDUCE COMPETITION.
TriMedx firmly believes a marketplace that encourages equipment owners, operators, their chosen service providers and OEMs to work openly and collaboratively to further advance quality outcomes and decrease costs is one that will present the best opportunity for optimization, innovation and continued advancements in the delivery of safe patient care. As noted herein, hospitals and the ISOs who act as their agents are subject to certain regulations designed to ensure that equipment is maintained in a manner that best facilitates the provision of high quality patient care and ensures patient safety. The registration and reporting requirements add another layer of administrative tasks and, consequently, costs that smaller ISOs may not be able to bear. Therefore, we are concerned that H.R. 2118 may have an adverse impact on a competitive marketplace.

PROVISIONS THAT REQUIRE AND PROMOTE COLLABORATION SHOULD BE ADDED.
TriMedx believes a regulatory framework that promotes collaboration and information sharing between OEMs and ISOs would benefit healthcare providers, hospitals and patients. Since the Quality System Regulation rule was proposed in 1993, many OEMs have been unwilling to share servicing and maintenance procedures and methodologies with their customers. In fact, a 2013 CMS memorandum on servicing and maintenance acknowledges that, "*Hospitals may find that manufacturer's recommendations for some equipment are not available to them or their contractors* . . ." At a meeting on November 6, 2012, relative to revising its position, CMS inquired, "*It seems that manufacturers keep their manuals proprietary and do not share the information needed to maintain equipment. What happens in cases where no service manual is available for the equipment?*"

CMS's current position recognizes that OEMs generally do not provide this information to their customers, that it lacks the authority to compel the OEMs to provide such information and that, without such information, a healthcare provider, hospital and their respective agents may not be able to comply with OEM-recommended maintenance schedules, procedures and specifications. TriMedx has also encountered OEMs that have precluded it or the hospital customer from purchasing supplies or parts needed for repairs unless the hospital entered into an OEM service

agreement. These practices frustrate those customers' preferences, as they are ultimately prevented from implementing a comprehensive in-house program or purchasing the same services from independent third-party service providers.

The end result is an increase in the overall cost of healthcare and a diversion of the healthcare dollar that could otherwise be allocated to enhancing the patient experience, improving population health or serving the disadvantaged. The needs of our current healthcare landscape demand that OEMs be required to work collaboratively with ISOs and their hospital customers. Indeed, if this legislation is truly intended to place the same requirements on ISOs as OEMs, then it is only fair that those OEMs who do not cooperate with qualified ISOs be required to provide the materials, tools and support necessary to ensure not only patient safety, but a level and competitive playing field.

CONCLUSION.

TriMedx is guided by the principle that patient care should be delivered in the safest, most effective and efficient way possible. While we will always support initiatives that are intended to improve the quality of patient care, we believe this legislation, as drafted, may be trying to solve a problem that has not properly been defined and would create additional and duplicative regulatory requirements without a clear and corresponding benefit to patient safety. Thus, we hope the concerns and recommendations set forth herein will receive your careful consideration.

Thank you for the opportunity to provide this written testimony and we look forward to working with the Committee on these important issues.

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