ALLIANCE
FOR QUALITY MEDICAL DEVICE SERVICING

September 13th, 2019

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Comment to the FTC on "Nixing the Fix" Workshop

Dear Federal Trade Commission:

Thank you for making available the opportunity to participate and contribute to the dialogue on the important issue of right to repair on Tuesday July 16th, 2019 at the "Nixing the Fix Workshop". The Alliance for Quality Medical Device Servicing (the "Alliance") found the meeting both beneficial and informational and would have significantly benefited from the inclusion of medical device servicing in the panels as well as fielding related questions that were submitted to the discussion. As such, the Alliance is taking this opportunity to respond to the FTC request for feedback and data regarding medical devices and to implore the FTC to include medical devices and include them prominently. As we will highlight in this paper, there is significant data over multiple decades that demonstrates third-party service of medical devices is not only safe and effective, but necessary. Additionally, we will highlight practices by original equipment manufacturers (OEM) in this industry, that are not only increasingly anti-competitive, but also directly and negatively impacting safety and efficiencies in healthcare.

Executive Summary

In response to the recent debate around servicing of medical devices, including the 2016 FDA Docket, the resulting Public Workshop, and the congressional charge in FDARA, several leading independent service organizations (ISO) which are providers of healthcare technology management services established the Alliance to represent the voice of a broad segment of the third-party service industry. The Alliance appreciates the opportunity to address the issues raised by the FTC regarding the right to repair as it pertains to medical devices.

The Alliance views this opportunity for comment as a threshold to holistically advance the marketplace and the clinical engineering industry[1] by leveling the playing field and ensuring fair trade and competitive practices. We are guided by the principle that patient care should be delivered in the safest, most effective, and most efficient way possible. The Alliance believes that the current regulations, laws and quality practices effectively ensure ISO servicing and repair is both safe and effective, as supported by independent data. This belief is based on the clear lack of data to support the misleading notion that safety issues do arise or are more prone to arise depending on the party performing the service.

[1] Also referred to as Healthcare Technology Management

The current legal/regulatory scheme, however, does not adequately address unfair competitive practices and ensure a level playing field in the market as it relates to the fair access to servicing and maintenance procedures, methodologies, tools, training, parts, software and documentation (collectively, "Service Materials"). The Alliance strongly believes that there is a need for the FTC to exercise its authority and influence to require manufacturers to provide appropriate access to Service Materials. The Alliance firmly believes that a marketplace which 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 healthcare.

Introduction/ Purpose

The Alliance consists of representatives from TriMedx, Sodexo, ABM, Agiliti, The InterMed Group and Crothall. The Alliance represents the largest participants in the ISO segment of the +$13B U.S. medical device service industry, accounting for a significant percentage of the market employing thousands of employees across all fifty states and actively servicing and maintaining millions of medical devices across the country.

The medical device service market is complex and dynamic with multiple factors to take into account when considering changes, and the intended and unintended impacts of any change. In the medical device industry service is performed in one of three ways: by OEMs, ISOs, or Self-Op service teams which are part of the Healthcare Delivery Organization (HDO). There are multiple types of ISOs in the industry including comprehensive ISOs that are independent organizations that are providing comprehensive clinical engineering services. The Alliance members fall into the comprehensive ISO category. Another type of ISO are limited ISOs that provide medical equipment service but do not provide a comprehensive clinical engineering program. Additionally, in some cases OEM service teams also perform service on devices they did not design or manufacture and therefore are, effectively an ISO for the equipment they did not manufacture. In many cases, the service technicians working for ISOs come from OEMs, or they were formerly Self-Op technicians. In short, there is a great deal of overlap between OEM, ISO and Self-Op service providers. Please refer to Appendix A for a more detailed overview of the medical device servicing industry.

The Alliance members, as ISOs, serve as a truly independent voice and advocate for healthcare providers, offering not only safe and effective service, but also an equipment agnostic perspective focused on improving safety, outcomes and efficiency. In this regard, ISOs are aligned with OEMs to ensure equipment is operating as intended. However, unlike OEMs, ISOs do not design, manufacture or sell medical devices and, as such, ISO success does not rely on new equipment sales. Given this, there is no intrinsic conflict of interest when acting on a healthcare provider's behalf to determine whether, or when, to replace existing equipment. In fact, based on Alliance members' experiences, medical devices are significantly under-utilized and over sold, with utilization rates well below 40% and growing excess inventory. This is one of the unique benefits that ISOs provide, in addition to safe and effective service. ISOs are uniquely positioned to help their customers manage programs and

optimize utilization of existing equipment by extending useful life, providing efficiencies in operations, participating in capital planning, and reducing the purchase of unnecessary and redundant medical equipment and services.

In this document, the Alliance will highlight challenges ISOs face with certain OEMs that deliberately limit or prevent access to Service Materials, or which link incentives for equipment purchases to exclusive OEM service. It is the Alliance's belief that collaboration between ISOs and OEMs is paramount to providing the highest level of quality, safety, efficiency and cost-effective service to healthcare facilities.

The Alliance strongly believes that the current regulatory scheme is appropriate, effective and sufficiently comprehensive and has ensured that the primary goal of patient safety is achieved. This belief is evidenced by existing industry, market and regulatory data, which clearly demonstrates that there are not safety issues related to servicing medical devices. This data will be presented and discussed in more detail in the body of the document. We are unaware of any statistically relevant data that supports the premise that there are unique safety issues resulting from service of medical devices by ISOs, which was confirmed in the 2018 FDA findings as reported in the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices[2]. Furthermore, no significant risks specific to servicing medical devices have been identified.

The Alliance wishes to ensure that healthcare dollars are spent wisely. As noted above and discussed further in this document, we believe that the medical device service industry would benefit from regulations or legislation designed to increase opportunities for collaboration between third-party servicers and OEMs. For example, the FTC may consider requiring healthcare providers and hospitals (collectively "End User(s)") and ISO access to Service Materials at a reasonable price. This would be consistent with existing requirements of OEMs by the European Union, for instance.

The Alliance welcomes the opportunity to thoughtfully respond to the FTC's request for feedback and data on this topic. We also welcome the opportunity to collaborate with the FTC and provide additional comments and information as it considers this important charge. Alliance members have implemented well-established equipment and patient safety programs that serve as guideposts for the development of model patient safety programs that work seamlessly with the regulatory framework currently in place. The Alliance believes that the next logical step is to establish "Right to Repair" requirements, standards and legislation, like those which exist in other industries such as the automotive industry.

We aim to deliver information, pertinent examples and recommendations that the Alliance believes are vital to encouraging future open dialogue and the development of holistic solutions that address the concerns of all stakeholders. As such this response provides the following:

(i) Purpose and Role of the Alliance; Its Members and Aim;

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[2] This report, published in May, 2018, is available at https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/UCM607469.pdf

(ii) Brief Background on the Clinical Engineering Industry; Current Quality and Safety Pillars;

(iii) Current Regulatory and Accreditation Landscape;

(iv) Industry Data and Evidence of Medical Device Service Safety;

(v) Opportunities for Improvement in the Regulatory Landscape – OEM Collaboration; and

(vi) Conclusions and Recommendations.

I. Purpose and Role of the Alliance; Its Members and Aim

As a result of the recent congressional actions and the requests of FDA and Congress for a consolidated industry voice regarding third-party medical device service, the Alliance is an unprecedented example in the medical device service industry of competitors coming together to address common industry issues. The purpose of the Alliance is to respond to the common issues and questions around safety, efficacy and fair competition and to help guide thoughtful, effective and appropriate discussion, review and action. The Alliance is bonded by the common goals and beliefs of: (i) ensuring the delivery of safe, effective and high-quality patient care through superior service at reasonable costs, (ii) maintaining fair competition, and (iii) advancing this mission and the industry through improved and evolving standards and practices.

The Alliance in total represents many decades of expertise in the Healthcare industry comprising a large segment of the medical device service market. Our members have forged meaningful strategic partnerships with 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. In total Alliance members provide full-service programs to more than 3,000 healthcare provider locations across the United States, maintain equipment data for millions of medical devices, including tens of thousands of unique models, and employ thousands of people. Our members effectively and swiftly complete the delivery of OEM recall safety corrective actions and cybersecurity patches for OEMs to hundreds of thousands of devices each year ensuring the prompt resolution of safety threats preventing further risk, when the OEMs make this information available. Collectively, the Alliance has saved hundreds of millions of dollars in capital expenditures and operating costs for its client partners through its comprehensive programs, playing an important role in reducing and eliminating waste and overall cost in the market. In addition, Alliance members spend millions of dollars and invests tens of thousands of hours every year on advanced technical and safety training to ensure safe and effective service for medical equipment.

As national providers of medical equipment service and maintenance management programs (i.e., clinical engineering), each member of the Alliance has developed unique, appropriate and effective quality-focused models to work directly with hospitals and other healthcare facilities to manage their medical equipment and technology. These models are designed to ensure safety, reduce the total cost of equipment ownership, ensure operational efficacy, and

promulgate innovation in the marketplace. As evidenced by the lack of safety issues related to service, the Alliance members' programs and processes have proven robust, safe and effective. Members of the Alliance provide a unique, beneficial and necessary function in the medical device market. In many cases, service technicians working for ISOs were formerly in-house technicians, OEM technicians, or the ISO has assumed management of the in-house service team for the customer and is physically located on the customer site. This gives ISOs a unique perspective on the challenges and opportunities related to the service of medical devices and working with OEMs and other industry participants.

Members of the Alliance have been active participants and contributors to safety standards and have helped create and update standards such as the ANSI/AAMI EQ56:2013 standard "Recommended practice for a medical equipment management program," AAMI EQ93:2018 standard "Medical Equipment Management—Vocabulary used in Medical Equipment Programs," and the ANSI/AAMI EQ89:2015 standard "Guidance for the use of medical equipment maintenance strategies and procedures," as well as participating in, commenting on and meeting with the FDA on a variety of topics including cybersecurity, service vs. remanufacturing and clinical engineering. Thus, the Alliance is well positioned to evaluate the topics of medical equipment and medical device ("Equipment") service, maintenance and repair and provide an expert opinion.

The Alliance firmly believes that a marketplace which 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 outlined below, ISOs and hospitals are already subject to certain quality 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 Alliance believes that collaboration between ISOs and OEMs is paramount to providing safe, high quality and cost-effective service to healthcare facilities and believes that the FTC should require that OEMs submit and make available at a reasonable cost relevant service and maintenance documentation and associated tools, training and parts necessary to maintain the Equipment, which some OEMs choose to deny. This is already required for installation documents for imaging equipment, so this would be an extension of a current practice. For the reasons outlined herein, the Alliance is concerned, on behalf of itself and its many hundreds of hospital customers around the country, that failure to act or include medical devices will serve as encouragement to OEMs and unintentionally reinforce existing anti-competitive practices, increase medical device downtime and as result delay treatments, expose patients to needless safety risks and add significant costs to an already overburdened healthcare market. Failure to act could also potentially reduce the number of servicers available to perform necessary Equipment maintenance, thus undermining the industry goal of innovating to achieve the Quadruple Aim (enhancing patient experience, improving population health, reducing costs and improving the work life of healthcare providers).

Finally, End Users generally advocate that ISOs play a vital role maintaining and servicing their Equipment and that ISOs are critical to ensuring a competitive marketplace for the maintenance and repair of Equipment.

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II. Brief Background on Clinical Engineering Industry; Quality and Safety Pillars

The clinical engineering industry arose in the 1960s with the increased development and use of complex medical equipment that required more than just routine electric safety inspections. The creation of this industry was further accelerated by Ralph Nader who wrote an article in 1970 claiming that 1,200 patients per year were being electrocuted in hospitals because of faulty equipment design and inadequate precautions. Nader recommended that hospitals retain qualified engineers and technicians who could help ensure the safe use and maintenance of medical equipment. Clinical engineers entered the hospital environment to address safety, maintenance and repair of complex medical equipment and safety and electrical standards were developed. Clinical engineers developed routine safety and performance programs focused on preventative maintenance and inspection to ensure that medical equipment continued to operate within OEM specifications. With the introduction of clinical engineers, hospitals began developing clinical engineering departments to manage medical equipment, vendor and manufacturer relationships and to provide needed operational education to clinical users. The primary objective of these departments was to provide a comprehensive program addressing all facets of medical equipment support. Clinical engineering grew on the notion of thinking about the customer, not just the device, and how patient care is positively impacted by a more holistic approach.

As medical equipment has advanced to keep pace with technology, clinical engineers have become an integral member of the risk management team. These clinical engineers may be employed directly by the hospital or system, an ISO, or an OEM when providing a comprehensive clinical engineering program. They are called upon to take a proactive stance on equipment management and work closely with healthcare administrators, OEMs and ISOs to mitigate risk and maintain patient safety. Coupled with evolving changes in healthcare such as capitated payments and consolidation, cost containment and increased competition, healthcare providers continue to seek opportunities to reduce administrative burdens while ensuring the provision of safe and high-quality patient care. In an effort to support healthcare providers, asset and strategic management programs have evolved. These programs are often offered through independent third-party service providers and focus on the procurement, utilization, maintenance, servicing, repair and disposal of medical equipment with the aim to reduce healthcare provider costs and improve efficiency. These medical equipment management programs 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.

The National Healthcare Expenditure Accounts estimates the cost of healthcare in the United States accounted for 17.5% of the nation's Gross Domestic Product in 2014. 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 the financial resources needed to deliver better patient care and serve those who are poor

and vulnerable. By providing alternative and additional service options to OEM services, third-party service providers in the clinical engineering industry not only increase market competition by supplementing some existing OEM service providers, but also push other OEMs to maintain quality and cost-effective programs for healthcare providers. As a result, third-party service providers can and do play a vital role in the management, procurement and maintenance of medical equipment throughout the healthcare industry. They are in a unique position to continue offering tailored services to healthcare providers and OEMs as the clinical engineering industry continues to evolve.

Quality and Safety – The Pillars of the Service Model

The Alliance has confidence that the current system, under the watchful eye of the FDA, accrediting agencies and CMS, is proven sufficient and effective in ensuring that Equipment is maintained in a manner that results in safe and high-quality patient care. To ensure the highest quality of service for Equipment management and ongoing patient safety, ISOs have developed Equipment and patient safety programs that work seamlessly with the regulatory framework currently in place. Below are just a few examples of quality and safety programs, illustrating the types of guardrails that ISOs deploy.

a. **Medical Equipment Alert and Recall Program.** As an in-house Equipment service provider, an ISO may be audited in conjunction with their clients by the FDA for management of alerts and recalls if an adverse event involving the Equipment it manages occurs. To ensure that both the ISO and its customers comply with such FDA audits and the regulatory requirements applicable to their customers, ISOs have developed effective alert and recall processes. ISOs actively obtain alert and recall notices through a systematic process of tracking OEM alerts, the FDA's alert notices and websites, and notifications from its customer base and help complete the prompt completion of safety fixes. Due to the large customer base, alert notifications are often provided to ISOs (and therefore to ISO customers), several days before the official OEM notices arrive at a hospital location. Ultimately, this is designed to augment the customer's alert and recall management process and provide timely and accurate information regarding Equipment hazards, alerts and recalls across a multitude of facilities, thereby permitting ISO customers to continue in their delivery of safe patient care.

b. **Safe Medical Device Review Program.** ISOs actively maintain policies which require that any Equipment or use error which may have caused or contributed to the death, serious injury or serious illness of a patient ("Incident") will undergo a quality and safety investigation ("Medical Device Review Program") in accordance with the Safe Medical Devices Act of 1990. This Medical Device Review Program includes documentation, reporting and communications both internal to the ISO and between the ISO and OEMs. Communication regarding Incidents focuses on gathering all relevant facts regarding the Incident related

to the Equipment and reporting it in a clear and concise manner. The ITSP assists the Incident site in carrying out best practices in an adverse event response, including sequestering Equipment, incident investigation and providing instructions for filing Medical Device Reports.

c. **Supplier Quality Management Program.** Many aftermarket suppliers are self-regulating through International Standards Organization certification or are building quality management systems using these standards as guidelines. To ensure patient safety and parts and service quality, and to eliminate suppliers that do not meet expectations, some ISOs have created internal supplier quality management programs ("Supplier Quality Management Program").

d. **Medical Equipment Management Program (MEMP).** All providers of comprehensive clinical engineering programs are governed by a required MEMP that sets policy for all aspects of the program. The MEMP must be approved by the hospital/system Environment of Care Committee or Safety Committee. This provides a tight connection to overall hospital leadership, both administratively as well as clinically.

III. Current Regulatory and Accreditation Landscape

Under the Federal Food, Drug, and Cosmetic Act, except for very limited and specific circumstances, the FDA has rightfully exercised little authority related to the manner in which End Users service and maintain their own Equipment. Likewise, FDA regulations do not currently apply to independent service providers when the ISO contracts directly with the End User. However, FDA regulations do apply to certain service, repair and maintenance activities performed by the OEM or its third-party agents. Either due to a misunderstanding of the law or in an effort to weigh down competitors with duplicate, overlapping regulation, many OEMs have incorrectly asserted that FDA's regulations apply to the service, repair and maintenance activities performed by ISOs on behalf of the End Users. We believe, and the regulations support, that ISOs are governed by the same regulatory framework as End Users. Additionally, most ISO contracts contain language explaining that they are agents of the hospital, which means they are acting on behalf of the hospital.

An End User’s service, repair and maintenance of Equipment is subject to various statutory and regulatory schemes and accreditation conditions, including the Clinical Laboratory Improvement Act, the Safe Medical Devices Act of 1990, CMS Conditions of Participation, conditions of accrediting bodies such as The Joint Commission and Det Norske Veritas, as well as multiple state laws and regulations. CMS explicitly allows End Users to diverge from OEM recommended maintenance intervals, except when forbidden by other federal laws, state laws or Conditions of Participation requirements. End Users that choose to employ alternate maintenance activities and/or schedules must develop, implement and maintain a

documented Alternative Equipment Management ("AEM") program to minimize risks to patients and others in connection with use of certain Equipment.

Imaging and other radiological equipment are examples of Equipment for which End Users may not deviate from the OEM's maintenance recommendations as required by CMS's own interpretive guidelines relative to the conditions for participation for radiologic services in 42 C.F.R. 482.26(b)(2). As a result, in providing services to End Users, ISOs are obligated to abide by the rules and regulations applicable to its customers in addition to those further discussed below. The fact that CMS has distinguished between Equipment that may be managed via an AEM program and Equipment that requires adherence to an OEM's recommendation demonstrates that CMS is constructively engaged in the regulation of this area and acknowledges the importance of risk stratification based on Equipment type and key service actors.

The regulatory framework applicable to healthcare providers guides the actions of the Alliance's members. The Alliance is deeply committed to abiding by all relevant regulations and standards that apply to our customers, the End Users. By way of example, our members actively ensure their customers adhere to the Safe Medical Devices Act of 1990, and when acting as a customer's agent, will develop and submit requisite reports in the event a medical device or user error may have caused or contributed to the death, serious injury, or serious illness of a patient. These programs, and other ISO programs like it, are ultimately subject to continued review by government authorities, including CMS and State Departments of Health as well as accreditation surveyors.

In addition, our members actively monitor and participate in relevant trade organizations, standards development and publications to ensure that their practices are tracking with evolving industry standards and best practices related to patient safety and Equipment efficacy. Our members apply standards and recommended practices to further ensure safety, quality and effective delivery of service. Examples of standards include ANSI/AAMI EQ56:2013 "Recommended practice for a medical equipment management program" and the ANSI/AAMI EQ89:2015 standard "Guidance for the use of medical equipment maintenance strategies and procedures."

Organized programs, like those of Alliance members, have policies and procedures that align with the federal, state and hospital required regulations and standards pertaining to medical Equipment management and record retention to ensure compliance, and Equipment efficacy and safety. These regulations and the resulting policies govern procedures such as inventory management, preventative maintenance scheduling, manufacturer alert and recall management, reporting, incident investigations and emergency back-up needs. The Alliance's members believe strongly that the programs they maintain achieve the aims of ensuring that Equipment is maintained in a manner that results in high quality, safe, patient care. However, we also recognize that there is always value in examining existing standards and programs to consider possible improvements. As such, the Alliance welcomes the opportunity to work with an industry organization, like AAMI, to further develop and promulgate industry best practices.

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IV. Industry Data and Evidence of Medical Device Service Safety

Members of the Alliance have taken great care to ensure they are not only complying with applicable laws and regulations, but that they are also working to play their part as End Users aim to deliver high-quality and safe care in a cost challenged environment. As part of this goal ISOs have collected and analyzed safety data from their operations and from industry and regulatory sources. Industry leaders, such as the ECRI Institute, have utilized industry data to conduct studies on service safety. The data analysis in each case has failed to support OEM claims that there are safety issues specifically attributed to ISO service of medical devices. To the contrary, and as discussed herein, evidence reflects that there is no correlation between safety issues and the provider of the maintenance and/or service.

The ECRI Institute, an independent nonprofit organization with a mission focused on improving patient safety, has conducted multiple evidence-based studies over the past few decades. Most recently, as part of the response to FDA's 2016 notice and request for comments, ECRI Institute provided a 109-page document[3] detailing the extensive research conducted on this topic. The Institute reviewed the following data sources to arrive at their conclusion:

- FDA's Manufacturer and User Facility Device Experience (MAUDE) database;
- ECRI Institute's Health Devices Alerts Tracker;
- ECRI Institute's confidential contracted accident investigations of medical device accidents involving serious and fatal injuries; and
- The National Library of Medicine PubMed database.

The results of the ECRI Institute's analysis identified only 96 reports out of +2.1M records related to service between 2006-2015, or .005% of the population. This is a relatively insignificant contributing root cause to the population of safety issues when compared to causes like software, design, cybersecurity and others. It is also important to note that this same conclusion was arrived at via the results of an earlier ECRI Institute review of the MAUDE database from 1977-1998. Additionally, similar data substantiating these findings has been collected, analyzed and published in Biomedical Instrumentation & Technology in 2013, was referenced by The Joint Commission (TJC) response to FDA's Request for Comments, and was supported by the results of an AAMI survey. All conclude that medical device service is not a cause for safety issues, reinforcing the Alliance's position.

The study published in Biomedical Instrumentation & Technology in 2013 entitled, "An Estimate of Patient Incidents Caused by Medical Equipment Maintenance Omissions," estimates the magnitude of safety incidents due to maintenance omissions to be between .00011 - .0006 occurrences per million opportunities based on a worst-case scenario analysis of the sentinel events database collected by TJC. To put this into perspective, this is

[3] This report, submitted in June of 2016 to FDA request for comments on docket FDA-2016-N-0436 and is titled, "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments"

between 5,000 and 30,000 times fewer defects than the Six Sigma performance quality excellence goal of 3.4 defects per million opportunities. In addition to the estimated low contribution medical device service plays in safety events, the same sentinel event data clearly identifies that there are multiple higher risk causes for safety risks. These findings were also supported by the results of a survey conducted by AAMI in 2012 of 1,526 participants who reported no known patient incidents traceable to service. The analysis of the combination of data from these sources fails to identify evidence of significant safety issues related to service that would warrant application of expanded regulatory requirements.

In addition to the low contribution medical device service plays in safety events, the same data clearly identifies that there are numerous other higher risk causes for safety hazards. For example, software represents the largest single root cause for safety issues and for Q4 2017 represented 26% of all safety recalls and when combined with the following common root causes: design, use error, human factors, non-conforming material, labeling and manufacturing, represent the majority of the safety issue root causes for medical devices.

Data supports that the majority of medical equipment safety issues are tied to matters strictly within the OEMs' realm of control. Many issues are tied to service specifications, maintenance processes and procedures, all of which are design outputs required to be produced by the OEM. These significant root causes for safety issues are rightfully the responsibility of the OEM product design owner under the current regulatory requirements and with improved rigor and effectiveness of both FDA enforcement and OEM Quality Management System (QMS) implementations, safety of existing and future devices should improve. An important point of consideration is that if a safety issue were to occur with service of a medical device, the probable root cause would either be insufficient or ineffective design and therefore the correction, corrective action and preventive action would be appropriately required of the OEM per the current regulation. One more important item supporting this position is the fact that the FDA recall database does not identify service as a root cause, supporting the conclusion that service is not a significant safety issue.

This data, as well as much of the content herein were provided to the FDA, at its request, for consideration and review ahead of its response to Congress. Based on this data and other important elements of the role ISOs play in the medical device servicing industry, the resulting report from the FDA, FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices[4] in May of 2018, concluded the following:

- The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
- Rather, the objective evidence indicates that many OEMs and third-party entities provide high quality, safe, and effective servicing of medical devices;

[4] This report, published in May, 2018, is available at https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/UCM607469.pdf

- A majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing"; and
- The continued availability of third-party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.

Other important industry groups had similar conclusions. AAMI, noting that it takes a neutral and broad view of the entire service industry, reiterated the statistical data showing that the number of technology related adverse events caused by poor maintenance or repairs is very low compared with overall adverse incidents in healthcare. The Joint Commission, a nationally recognized leader in performance measurement, commented that there "seems to be little, if any, evidence of differences in the risks associated with the various maintenance activities performed by the different owners, users and maintainers." The Joint Commission further commented that it did not have "knowledge of any statistically significant level of safety problems resulting from the activities of any kind of maintenance/service provider."

Based on this, the Alliance strongly believes that the current regulations, laws and quality practices have been proven effective in ensuring the intended goal of safe and effective delivery of service and it is the opinion of the Alliance that enacting right to repair legislation is not only warranted, but necessary in the medical device space in order to address anti-competitive actions in the industry and ensure consumers rights to choose and ISO right to compete.

V. Opportunities for Improvement in the Regulatory Landscape – OEM Collaboration

The Alliance believes that a right to repair framework promoting collaboration and information sharing between OEMs and ISOs and hospitals would benefit End Users and patients. A concern that has existed since the Quality System Regulation ("QSR") rule was proposed in 1993 is that OEMs have generally been unwilling to share servicing and maintenance procedures, methodologies, tools, training, parts and documentation (collectively, the "Materials") with End Users. In fact, the 2013 CMS Memorandum on servicing and maintenance acknowledged in part that "Hospitals may find that manufacturer's recommendations for some equipment are not available to them or their contractors." At a meeting in November 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?" As outlined below, the industry would greatly benefit from increased collaboration.

a. ***Service Manuals***. CMS's current position recognizes that OEMs generally do not provide this information to End Users, that it lacks the authority to compel the OEMs to provide such information, and that without such information an End User and its agents (including ISOs) cannot be required to comply with OEM-recommended maintenance schedules, procedures and specifications. Although

the FDA has been aware of this problem since the early 1990's and arguably has authority to require OEMs to provide such information, it has rarely exercised this authority. Given this the Alliance would urge FTC to consider use of its authority to require OEMs to work collaboratively with independent third-party service providers and End Users.

b. **Other Service Information**. The Alliance believes that End Users and their patients would benefit from a system which creates incentives for OEMs to allow ISOs to freely access Materials. We have seen OEMs restrict access to certain materials, providing them only in the event that a technician has received training directly from the OEM. Such restrictions unnecessarily limit ISOs from transferring the knowledge and materials they receive across their customer base, not only resulting in increased costs and reduced efficiencies, but most importantly risking patient safety through delayed execution of service. This is particularly concerning with regard to executing safety recall actions.

c. ***Training Service Providers***. Several OEMs have recognized the value of collaborating with independent third-party service providers by establishing training programs that permit ISOs and/or hospital technicians to become approved trainers on the OEMs' Equipment. This model allows ISOs and/or hospitals to provide training within their respective organizations, using the OEM's training materials and pre- and post-training test requirements. By equipping the personnel on the ground with the knowledge needed to resolve a service issue, equipment uptime is increased, and safety concerns mitigated. This is exactly the type of collaboration the Alliance is requesting from all OEMs.

OEM Protections. OEMs have raised concerns that some ISOs may create service quality issues. While there has been no relevant data to suggest that quality issues or patient safety concerns are related to who provides the service, there may be a benefit to providing clarification that the OEMs are not liable for the actions or inactions of an independent third-party service provider. Put differently, the actions or inactions of an ISO cannot extend to an OEM. Also, given the complex nature of certain equipment, it is acknowledged that there is proprietary and confidential information associated with the maintenance and training necessary to maintain such equipment. To protect such information, a regulation requiring the provision of such information may be coupled with the opportunity for OEMs to request that recipients enter into reasonable confidentiality agreements, designed to protect the proprietary and confidential interests of the OEMs. Furthermore, the cost to an OEM can be appropriately mitigated by allowing OEMs to charge a commercially reasonable fee.

Purchasing and Sales Practices. End Users and their agents need to be free to purchase equipment, service contracts, and supplies, independent of one another, and without adverse financial repercussion. Certain OEMs have aimed to restrict the sale of a piece of equipment, tying it to a commitment that the End User also purchase a service contract. Likewise, our members have seen the ability to purchase supplies tied to the purchase of a service

contract. In order to preserve a competitive marketplace and ensure that equipment is being serviced and repaired in an efficient and effective manner, we advise that OEMs be required to parcel out equipment, service contracts and supplies, for independent sales.

The Alliance appreciates that OEMs will want to incentivize their customers to purchase service contracts and supplies from them, and as such may offer a discounted rate for the purchase of a bundle. However, OEMs must make these items available for independent purchase, and at a price that is commercially reasonable. Alliance members have experienced situations where their customers have been charged extraordinary, unreasonable prices for a part or supply when the customer did not have a service contract with the OEM. The end result is an unreasonable, unnecessary increase in the costs associated with maintaining and repairing a device.

Further, we believe the industry would benefit from increased transparency in pricing. We recommend that OEMs be required to provide the End User with upfront pricing of parts and supplies associated with a particular device. One of the keys to achieving these outcomes is ensuring the right level of oversight, while fostering collaboration.

Concerns with Existing Practices. ISOs in the clinical engineering industry not only increase market competition by supplementing existing OEM service providers, but also push other OEMs to maintain high quality cost-effective programs for healthcare purchasers. The Alliance is concerned about certain OEM practices that have the effect of reducing competition for services that are provided by both OEMs and ISOs. As discussed above, independent third-party service providers deliver the same level of quality for those services, often at lower costs and provide no conflict of interest with regard to selling particular brands of equipment; however, the anti-competitive practices of some OEMs have the effect of increasing prices for those services to customers of OEMs.

Further, 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. In short, these practices run contrary to the Quadruple Aim. Market competition is necessary to drive innovation and cost reduction. The exclusionary conduct of certain OEMs includes the following:

- tying agreements for ongoing service and maintenance to the purchase of original Equipment or replacement parts;
- refusing to provide manuals to purchasers and their agents;
- refusing to provide service training to ISOs;
- requiring licensing agreements in order for purchasers to obtain service/repair manuals;
- refusing to provide purchasers with a preventative maintenance schedule;

- refusing to provide purchasers with key codes to access software needed to run necessary reports;
- bundling discounts for purchasing service contracts along with original Equipment or parts that can only be obtained from the OEM;
- requiring that only OEM service personnel, procedures, and parts can be used in servicing Equipment, or conversely, prohibiting the purchaser or its agent from performing maintenance, repair, service or installation of Equipment;
- pressuring purchasers to not use ISOs for maintenance or other servicing under unsubstantiated safety and outcome claims;
- taking advantage of a recall situation to sell unneeded replacement OEM parts, for commercial gain, as part of a safety recall increasing cost and delaying a safety fix; and
- restricting completion of recalls by preventing (inappropriately) qualified ISO from executing the corrective action associated with a recall, delaying a safety fix and increasing cost.

Alliance members face these exclusionary behaviors every day and is asking the FTC to restrict these practices as it will not only allow for a more open and competitive market, but will also ensure the highest levels of safety and effectiveness by requiring that any entity providing service has access to the training and tools needed to meet the highest standards of quality service.

VI. Conclusions and Recommendations

We appreciate the opportunity to offer comments, data and our perspective on right to repair as it relates to the medical device industry. We hope that the comments and suggestions included in this document help address questions and concerns related to this segment of the repair and servicing industry. As noted, the Alliance does believe that medical device repair should be included in any right to repair actions and that there is significant data and evidence supporting the fact that ISOs have been safely and effectively servicing medical devices for decades. Furthermore, we are concerned that growing anti-competitive behaviors from some OEMs are restricting consumer choice, ability to service and repair devices, and ultimately increasing safety risks and costs.

Since we established the Alliance to serve as a voice of the broader ISO industry, in particular those organizations offering a comprehensive on-site service model, we are committed to following up on these issues and recommendations. We welcome the opportunity to collaborate further with the FTC and others in the industry on these topics, including discussion of the issues raised in this document, and to provide additional information.

ALLIANCE
FOR QUALITY MEDICAL DEVICE SERVICING

Appendix A: Terminology Primer for the Medical Device Servicing Industry

In order to minimize confusion, it is important to define the basic classifications of servicing entities. These primary three categories are: Original Equipment Manufacturer (OEM), Internal Hospital Department of Clinical Engineering (Self-op), and Independent Service Organization (ISO).

OEM - most OEMs service only their own equipment. As such, OEMs are governed by FDA 21 CFR. However, for those OEMs that service another OEM's equipment, they are technically an ISO for that equipment service. A few OEMs also provide full comprehensive clinical engineering programs. Thus, OEMs should be divided into two groups with OEM being used for the cases where they are providing service on their own equipment. OEM MVS, for multi-vendor service, should be used when the OEMs are providing clinical engineering programs and servicing another OEM's equipment.

Self-Op - there is a wide variety of self-op programs regarding what services are provided by their own employees and what is provided by ISOs and OEMs, but all have the same regulatory requirements as far as CMS is concerned. As hospital employees, they "are" the hospital when it comes to CMS, TJC, and DNV requirements. A few Self-Op clinical engineering programs have achieved ISO 9001 certification.

ISO - there is a great diversity here, from very small to very large. Some ISOs service only a single type or brand of device and some many types of devices. Others provide full outsourced clinical engineering programs. For those that provide fully outsourced, comprehensive CE programs, they are subject to the same regulations as the self-op programs, with most having legal agreements with the hospitals to operate as their agent. Several ISOs have achieved ISO 9001 or ISO 13485 certification.

Regulatory requirements are identical for anyone providing a full clinical engineering program, as they are all obligated by the hospital in essentially the same way. Since 1990, the Safe Medical Devices Act (21 CFR 803.32 (c)) requires the reporting of all incidents in which a medical device or user error may have caused or contributed to the death, serious injury or serious illness of a patient. If the hospital receives payment from federally funded Medicare or Medicaid programs, they must be accredited, which is typically done under TJC, DNV, or HFAP. All are governed by CMS. Since it is the hospital being regulated, whomever they choose as their service provider must abide by the same rules. This of course includes the self-op programs, but also includes the ISOs and OEMs when they are providing full outsourced clinical engineering programs. In these cases, self-ops, ISOs, and OEM MVSs all contract some of the work to other parties.

Naming Suggestions

Self-Op for a clinical engineering program is run by the healthcare delivery organization (HDO) with its own staff.

ISO Comprehensive, (ISOcomp) covers an independent organization that is providing comprehensive clinical engineering services.

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ISO Limited, (ISO) for an ISO that provides medical equipment service but is not providing a comprehensive clinical engineering program.

Multi-Vendor Service, (OEMmvs) for an OEM that is providing comprehensive clinical engineering services.

OEM or Original Equipment Manufacturer for a company that is providing service on their own equipment.