ALLIANCE
FOR QUALITY MEDICAL DEVICE SERVICING

February 22nd, 2019

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: White Paper: Evaluating Whether Activities are Servicing or Remanufacturing
Food and Drug Administration Docket No. FDA-2018-N-3741

I. Introduction

On behalf of the Alliance for Quality Medical Device Servicing, consisting of TRIMEDX (which now also includes the former Aramark Healthcare Technologies business unit), Sodexo, Crothall, ABM and The InterMed Group (the "Alliance"), we are pleased to submit comments in response to the FDA's White Paper: Evaluating Whether Activities are Servicing or Remanufacturing ("White Paper"). In this response, we have addressed certain key topics that the Alliance believes should be considered by FDA when developing draft guidance as noted in FDA's May 2018 Report on the Quality, Safety, and Effectiveness of Servicing Medical Devices. Specifically, this response highlights the need for fair competition and increased access to information and materials, the pros and cons of a risk-based approach, and considerations that should be taken into account with respect to software. With respect to data that could be used to identify potential issues, we support the establishment of a baseline from which improvement can be measured. In addition, we highlight in our response areas where we believe more specificity is needed before ultimate guidance is issued. The Alliance welcomes the opportunity to elaborate on any of these points in further discussion with FDA and interested stakeholders.

II. Assessing Specifications and the Pros and Cons of a Risk-Based Approach

To assess component, part and material specifications during servicing or remanufacturing the Alliance believes that full access to the intended use, all performance and safety specifications as well as the "Service Materials" (i.e. instructions, training, manuals, tests, measurements, tools, information, processes, software keys, parts etc.) for a medical device and its components, parts and materials should be required. Access to these items will not only ensure an efficient and effective assessment for all participants in the market, but also ensure the advancement of safety and effectiveness.

The proposed guiding principles, flowchart and risk assessment can be useful in establishing or adjusting an organization's general policies and procedures for performing assessments on devices, components, parts and materials when not provided by an Original Equipment Manufacturer ("OEM"). However, the Alliance believes that the suggested assessment after each service activity is unnecessary, excessively burdensome and will not produce improved safety or quality. Service organizations already perform

assessments consistent with recommendations by the OEMs to determine if performance, intended use or safety has been changed. So, these activities should instead be used as a guide to assist organizations in developing policies and procedures as well as when sourcing parts, but not a required activity for routine service. It should be further stated that the details of what is required by "assessment," "evaluation," and "adequate documentation" are not clear and would benefit from a more detailed explanation. Similarly, the definition of "significantly change" is vague and should be clarified. Although the vagueness of the terms may be intentional to allow for discretion, it does become problematic as it allows for substantial variance from one practitioner's interpretation to another.

The benefit of the risk-based approach discussed in this white paper is that it is consistent with what most participants in the industry already do as part of running their business and ensuring safety and effectiveness. Participants in the medical device service market already comply with numerous laws, regulations and quality requirements and standards. Given this, the Alliance would suggest that FDA carefully consider what additional guidance is necessary for servicers. If more guidance is created, that guidance should not be redundant but rather clearly focused on addressing a well-defined issue or gap. Finally, to perform the most effective risk assessments, OEM's should be required to provide access to the intended use, all performance and safety specifications, and Service Materials.

III. Additional Considerations for Software

The Alliance believes there are several considerations that should be considered and addressed in the upcoming guidance specific to software. Given the nature of software on medical devices, it is most often not possible to edit or directly manipulate the software. In addition, contractual and licensing terms typically prevent users or servicers from making changes. Accordingly, the Alliance agrees with FDA that changes to integral software, that are not validated by OEMs, should be excluded from servicing. We also agree that the common activities performed on software listed in the White Paper should be considered within the realm of servicing, and not in violation of FDA regulations. However, we suggest expanding the list of acceptable software servicing activities to include the following:

- Accessing repair, performance, diagnostic or other information through software keys or other means, which OEMs should be compelled to provide.
- Collecting data from the device, whether self-generated via operating and/or diagnostic software or resident on the device for analysis, interpretation and prediction to help improve safety and effectiveness of servicing the device.
- Executing diagnostic and cybersecurity software on the device.
- Performing software patches, upgrades, installs and changes validated by the OEM, system backups, and accessing keys and data.

IV. Data Measurements, Definition and Examples

Clearly defining what constitutes the difference between service and remanufacturing is a necessary first step to effectively address the subject. In order to be effective, the guidance should include more examples that are illustrative of not only what each activity is, but maybe even more importantly what it is not. While this may appear to be a simple task, there are many complexities. To begin with, are we evaluating a system, a device, a subassembly, a board, or a component? If we confine the evaluation to what is covered by the 510(k) process (e.g., a medical device), the discussion is seemingly simplified. For example, if a circuit board is remanufactured and installed in a medical device, has the device been serviced or remanufactured? If we propose that servicing never goes beyond restoring a device to original manufacturer conditions, whereas remanufacturing results in a change to original specifications, this seems to remove some of the subjectivity. In the example given, if the remanufactured circuit board did not in any way change the original specifications or functionality of the device, then its replacement is considered service. It will be useful to incorporate clarification such as this, as well as meaningful "edge cases" that illustrate examples where it is difficult to decide how the activity should be classified due to reliance on interpretation, multiple dependencies and assumptions. Providing such examples and expounding upon the decision logic necessary and the significance of specific assumptions to the ultimate determination of whether an activity is service, remanufacturing or neither is essential to the guidance.

Establishing a meaningful way to quantify the problem being addressed by the guidance with data is a necessary component to measure the effectiveness of the guidance and any attempt to improve. As such, it is the Alliance's suggestion that some attention be given to defining an algorithm utilizing existing safety and performance data that can both establish a baseline for current performance and measure variance to the baseline. Doing this will establish key performance indicators, that can be used to guide decision making and actions surrounding both servicing and remanufacturing to improve safety and effectiveness. This should include details on what data should be used and by whom and how it is collected and utilized in order to perform meaningful analysis to facilitate consistent decision making and repeatability in measuring performance.

V. Access to Information, Materials and Fair Competition

The Alliance, in response to the question of which device technical, performance or other product specifications should be included in the device labeling to facilitate high quality, safe and effective servicing, has several points to make and which it hopes FDA will consider carefully when drafting the forthcoming guidance. First, the intended use, all performance and safety specifications for the device and its components, parts and materials, as well as the Service Materials should be required to be provided by an OEM at a reasonable commercial price to assist in verifying that the performance and safety specifications and intended use have not significantly changed. Access to the Service Materials is not only a prerequisite to abide by the guidance and answer the question of "significant change" to the device, but it also serves to harmonize with the European Union's requirement that has been in

existence as part of the Medical Devices Directive since 1993[1]. The Alliance also strongly recommends that FDA include in the labeling requirement that all OEMs provide the details of the type and frequency of the maintenance and calibration needed to ensure the safety and effectiveness of the medical device.

The forthcoming guidance is an opportunity for improvement in the regulatory landscape as it pertains to collaboration between OEMs and independent service organizations. Guidance that promotes collaboration and information sharing between OEMs and Independent Third-Party Service Providers (ITSP) would benefit end users, patients and the industry. A concern that has existed since the Quality System Regulation rule was proposed in 1993 is that many OEMs have been unwilling to share servicing and maintenance procedures, methodologies, tools, training, parts and documentation (collectively, the "Service Materials"). 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?". Current CMS requirements include the need to follow OEM guidelines, which of course is not possible for a service provider, including OEM multi-vendor service organizations, if these Service Materials are not made available. It is clear the industry would greatly benefit from increased collaboration which will be driven by this guidance if it requires OEMs to provide access to Service Materials.

To be clear, access to Service Materials does not mean a lack of protections for OEMs. OEMs have raised concerns that some ITSPs 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 ITSP 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, 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. It is the experience of the Alliance that such arrangements are feasible, exist and have proven beneficial for all parties involved.

End Users and their agents need to be free to purchase Service Materials 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. To preserve a competitive

[1] 1 Medical Devices Directive 93/42/EEC 13.6 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

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 result is an unreasonable and unnecessary increase in the costs associated with maintaining and repairing a device.

ITSPs in the clinical engineering industry not only increase market competition by supplementing existing OEM service providers, but also push 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 ITSPs. Independent third-party service providers deliver quality service, often at lower costs and provide no conflict of interest about 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 and would make compliance with guidance difficult if not impossible.

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 ITSPs. The 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 Alliance understands that FDA may consider exclusionary behavior to be outside of its general purview. However, restricting these practices not only allows an open and competitive market, but also ensures the highest levels of safety and effectiveness by ensuring that any entity providing service has access to the training and tools needed to meet the highest standards of quality service. As was highlighted by the Federal Trade Commission at a previous FDA Public Workshop, any expansion of regulation that has the effect of reducing competition should be scrutinized.

VI. Conclusions and Recommendations

The Alliance appreciates the opportunity to provide comments to the docket on Medical Device Servicing and Remanufacturing Activities. As the industry matures, healthy discussion on these matters is important and the Alliance looks forward to continued discussion and collaboration.

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The summary below should not diminish the detail and explanation provided by the Alliance in its response above, but instead provide a simplified recommendation of actions to be taken in response to the White Paper and Workshop discussion.

- Provide Guidance on Collaboration and Information Sharing between OEMS and ITSPs.
- Require OEMs to make available Service Materials for independent purchase at a commercially reasonable price.
- Require maintenance and calibration information as part of labeling.
- Do not require a risk assessment after each service event.
- Expand the list of acceptable software serving activities.
- Improve the definition of service and remanufacturing using detailed cases including “edge cases”.
- Establish a quantifiable measure of the problem being addressed with this guidance to establish a baseline and measure change.

Thank you for the opportunity to provide feedback on Medical Device Servicing and Remanufacturing Activities.

Submitted by the Alliance for Quality Medical Device Servicing