July 6th, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Expansion of the Abbreviated 510(k) Program
Draft Guidance for Industry and Food and Drug Administration

Dear Food and Drug Administration:

The Alliance for Quality Medical Device Servicing (the "Alliance") appreciates the opportunity to provide input on the "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria" draft guidance. The Alliance is comprised of Independent Service Organizations ("ISOs") that deliver clinical asset management, service, and operational expertise across the spectrum of healthcare providers ensuring the safe and effective maintenance, repair and ongoing operation of the medical devices, technologies, products and systems we service. Our membership includes representatives from TriMedx, Crothall, Aramark, ABM, Sodexo, and The InterMed Group.

The Alliance believes that the draft guidance is effective at providing a clear description of this pathway for premarket clearance and the performance criteria necessary to demonstrate substantial equivalence and that a device is safe and effective. The Alliance also believes that the guidance would benefit from the addition of specific language requiring the inclusion of service and maintenance procedures, methodologies, tools, software keys, training, parts and documentation (collectively, the "Materials" needed to maintain, support, service, repair all aspects of medical devices ensuring maximization of safety and quality) and that these Materials be made available to all servicers, including end users and third-party service organizations. The Alliance believes that by doing so the FDA will help address restrictive and anti-competitive practices that are deliberately limiting or preventing access to these Materials. Ensuring such access will help to ensure safety through the total product lifecycle, harmonize FDA thinking with similar global requirements, and help to ensure 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).

A marketplace which encourages medical device owners, operators, their chosen service providers and original equipment manufacturers ("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. The Alliance believes that collaboration between independent service organizations and OEMs is paramount to providing safe, high quality and cost-effective service to healthcare facilities and believes that the FDA should state in this guidance that OEMs submit as part of the Device Description in the 510(k) and make available service and maintenance Materials. This addition does not increase the burden on the OEM, but rather reinforces the need to make available these outputs which are already required as part of existing regulations. This will ensure better collaboration, that standards are met and that the paramount goal and maximization of patient safety remains at the forefront. As such, the Alliance believes that a guidance document that would make service Materials available would benefit end users and patients and would not only improve service safety, effectiveness and cost, but it would also be consistent with similar global requirements of OEMs such as the requirements by the European Union.

Regulatory guidance promoting collaboration and information sharing between OEMs and independent service organizations would benefit end users and patients. A concern that has existed since the Quality System Regulation rule was proposed in 1993 is that OEMs have generally been unwilling to share servicing and maintenance 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, which would be directly facilitated by adding the requirement of access to service and maintenance Materials and, for instance, updates to operations, maintenance, etc., need to be readily available, and pushed to owners, servicers, and maintainers.

a. ***Service Manuals***. CMS's current position recognizes that OEMs often 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 Independent service organizations) 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. The dialogue that took place at the FDA's Public Workshop in October 2016, and the needs of our current healthcare landscape, suggest that FDA should consider use of its regulatory authority to require OEMs to work collaboratively with independent third-party service providers and end users. Establishing such a requirement would be consistent with other global requirements, and address actions by some OEMs to prevent access to required Materials.

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 qualified servicers, including independent service organizations 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 servicers from transferring the knowledge and materials they receive across their customer base, not only resulting in increased costs and reduced efficiencies, but potentially creating patient safety issues. 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 independent service organizations and/or hospital technicians to become approved trainers on the OEMs' Equipment. This model allows independent service organizations and/or hospitals to participate in providing 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 beneficial to all parties as increased product uptime may improve

patient care, efficiency, safety and the perception of value and performance for the product.

OEMs have raised concerns that some independent service organizations may create service quality issues. However, as concluded in the recent FDA Report to Congress, "the currently available objective evidence is not sufficient to conclude that there is a concern whether or not there is a widespread public health concern related to servicing of medical devices, including third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time." The Alliance concurs with this conclusion and 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 independent service organization 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, language in this guidance requiring the provision of service Materials 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.

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. 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 and unnecessary increase in the costs associated with maintaining and repairing a device. Independent service organizations not only increase options, but also market competition by supplementing OEM service providers, and 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 independent service organizations. Independent third-party service providers deliver high levels of quality for those services, often at lower costs with site-based staff, 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. Limiting options results in 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 OEM can include, among other practices: (i) tying agreements for ongoing service and maintenance to the purchase or original equipment or replacement parts, (ii) refusing to provide service training to independent service organizations, (iii) requiring licensing agreements in order for purchasers or their agents to obtain service/repair manuals, (iv) refusing to provide purchasers or their agents with preventative maintenance schedules, (v) refusing to provide purchasers or their agents with key codes to access

software needed to run necessary reports, (vi) bundling discounts for purchasing service contracts along with original equipment or parts that can only be obtained from the OEMs, and (vii) pressuring purchasers to not use independent service organizations for maintenance or other servicing under unsubstantiated safety and outcome claims.

Alliance members understand that the 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. This can create a spirit of competition ensuring quality and allowing customers options when determining which partner/solution best fits their organizations mission and vision.

For the reasons outlined herein, the Alliance is concerned, on behalf of itself and its many hospital customers around the country, that failure to require access to the Materials necessary to service and maintain medical devices will not drive standardization and consistency in regard to quality and safety and add unnecessary financial burden and significant costs to an already overburdened healthcare market, thus undermining the industry goal of innovating to achieve the Quadruple Aim.

It is the position of the Alliance that the FDA should incorporate into this guidance document the requirement that as part of the premarket submission process OEMs submit and make available the Materials necessary to maintain and service the medical device. This will help improve safety, increase collaboration, reduce anti-competitive practices, harmonize U.S. requirements with global requirements, and help achieve the Quadruple Aim.

We appreciate the opportunity to offer comments on the “Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria” draft guidance and it is our hope that the comments and suggestions included in this document help enhance the FDA’s thinking regarding this important topic and improve the final product. The Alliance would welcome the chance to provide additional information to the FDA on this subject.

Respectfully submitted,

The Alliance for Quality Medical Device Servicing