The FDA concluded in its 2018 Report to Congress on Medical Device Servicing that "[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'..." As evidenced by this report, confusion existed regarding the definition of medical device servicing. In 2021, the FDA issued "Remanufacturing of Medical Devices" draft guidance to provide clarity "regarding the distinction between servicing and remanufacturing of a device."

While we agree with the FDA on the need for the guidance, the Alliance for Quality Medical Device Servicing (Alliance) identified some imperfections and opportunities for improvement that deserve attention, namely: (i) the meaning of **significant change** remains subjective and considerable discretion exists despite the examples provided; (ii) the **service assessment process** is excessively cumbersome and the requirement of supervisory approval may significant delay the return of serviced devices (estimated to be ~26 million/year) to clinical use, thus hampering clinical care and risking patient safety; (iii) limiting the **scope** of the guidance document only to third parties, while exempting servicing staff employed by healthcare delivery organizations (HDOs), manufacturers acting as "multi-vendor service" (MVS) organizations and the government (military and Veteran's Administration), defies logic since the latter groups are likely responsible for the majority of all medical device servicing.

In light of the above, the Alliance makes the following recommendations with the ultimate goal of ensuring safe and effective patient care.

- **Simplified Approach through Organizational Policy on Remanufacturing.** Instead of the complex and cumbersome post-service assessment of whether the servicing exceeded limits, we suggest that the FDA guides each servicing entity to establish a clear pre-service policy whether remanufacturing is allowed and, if allowed, register with the FDA and establish appropriate procedures to ensure compliance with applicable FDA regulations. If remanufacturing is not allowed, the servicing entity should train its servicing staff on how to avoid it, including instructions on when and how to seek guidance and approval before initiating those questionable activities. By adopting this simplified approach, we believe it will reduce device downtime, thus saving HDOs significant additional capital investments (for backups) and reducing patient care delays and possible diversions.
- **Inclusion of Service Information in IFU.** We urge FDA to follow the European Union's example of requiring service information (in addition to the safety and performance specifications) in the instruction for use (IFU) so servicing entities can perform appropriate tests to confirm that the safety and performance specifications have not been unintentionally changed. Without specifications and testing procedures, servicing entities are prevented from knowing the boundaries between servicing and remanufacturing.
- **Scope.** We also strongly urge FDA to reconsider the overly narrow scope of the Draft Guidance and make it applicable to **all** parties involved in servicing.
- **Enforcement and Auditing**. Finally, we suggest that FDA clarify how it will enforce this guidance and audit the servicing organizations so they can be properly prepared.

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The Alliance for Quality Medical Device Servicing was formed in 2018 and is comprised of five leading national medical device service organizations: TRIMEDX, Sodexo, Crothall, Agiliti, and the InterMed Group. Alliance members collectively employ tens of thousands of technicians, clinical engineers and skilled professionals who provide medical device repair and servicing in hospitals and health systems in all 50 states.