The Alliance for Quality Medical Device Servicing **opposes H.R. 7253**. The bill is an attempt by original equipment manufacturer trade groups to broadly define remanufacturing in a manner that serves their own competitive interests while potentially undermining patient safety and increasing healthcare costs.

H.R. 7253 is Unsupported by Data

- There is no evidence that an inadequate definition of remanufacturing is a threat to patient safety. The FDA's 2018 report on third-party servicing examined all "complaints and allegations of regulatory misconduct" made between 2009 and 2018. Of the 68 relevant complaints identified, only 28 were found over a nine-year period related to remanufacturing, which represents .0014 percent of over two million complaints. This is far from sufficient data to support the proponents' claims of significant safety issues caused by the lack of a clear definition of remanufacturing.

H.R. 7253 is Vague and Overly Broad

- The bill's definition of remanufacturing includes the phrase "…could significantly change the performance…" of a device. The proposed addition of "could" to the FDA's existing definition makes this phrase very subjective and vague. In fact, it could be interpreted to mean that anything done to a device constitutes remanufacturing.
- Similarly, the bill requires the FDA to inspect establishments that are "…*otherwise believed to be* engaged in remanufacturing…" This too is subjective and vague because the bill doesn't make clear who makes this determination and how it should be made.
- It is overly broad because it expands the definition of remanufacturing to include activities, such as changing the "anatomical location of use" and "design.''
- All told, the bill does not clarify the definition of remanufacturing, but rather makes the definition less precise, more open to interpretation and with little ability to apply a consistent standard. Moreover, it ignores the input from hospitals, independent medical device service organizations, some original equipment manufacturers, as well as independent patient safety organizations, like ECRI, who provided public comments to the FDA's draft guidance document.

H.R. 7253 is Unduly Burdensome

- The bill unfairly places the burden on the third-party service providers and hospitals' in-house service departments to prove they are not engaged in remanufacturing and then for reporting that information to the FDA.
- Moreover, doing so will make hiring a third-party service provider or deploying a hospital's in-house servicing department a more expensive and less attractive option, which is why this measure is anti-competitive and likely to increase healthcare costs.
- Finally, as clearly demonstrated during the COVID-19 pandemic, manufacturers are unable to promptly send their service representatives to the healthcare delivery organizations (HDOs) to repair and provide planned maintenance. If HDOs are forced to depend solely on the manufacturers for service, the care of patients is likely to be undermined due to the lack of devices in safe and reliable conditions (and HDOs are unable to acquire additional backup devices to compensate for the service delays).

H.R. 7253 Fails to Allow Access to the Materials Needed to Comply with Its Provisions

- In order to determine whether its activities meet the bill's definition of remanufacturing, a third-party service provider or hospital must have access to the information needed to make that determination, such as device material and performance specifications.
- The bill fails to require manufacturers to provide access to the service materials and diagnostic and calibration software necessary to diagnose malfunctions, maintain, calibrate the medical devices they produced. This material is essential for service providers to restore devices to their original specifications.
- By not including such disclosure requirements, H.R. 7253 contradicts President Biden's July 2021 Executive Order promoting competition in the economy. The language also collides with the FTC May 2021 Report to Congress on anticompetitive practices related to repair markets.

In sum, the Alliance urges Congress to set aside this bill and allow the FDA to complete its guidance on remanufacturing, considering input from all stakeholders.

The Alliance for Quality Medical Device Servicing is an informal coalition of five leading independent medical device service organizations which support health care providers across the United States. The members of the Alliance are TRIMEDX, Sodexo, Crothall, Agiliti, and the InterMed Group.

The Alliance represents some of the largest participants in the Independent Service Organization ("ISO") segment of the U.S. medical device service industry. Alliance members collectively employ tens of thousands of associates across all fifty states and actively service and maintain millions of medical devices.