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September 22, 2021

Janet Woodcock M.D.
Acting Commissioner of Food and Drugs - Food and Drug Administration
Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring Maryland 20993

RE: Docket No. FDA-2018-N-3741, Remanufacturing of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff

Dear Acting Commissioner Dr. Woodcock:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit comments on the Remanufacturing of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff.

Within the draft guidance the FDA bases remanufacturing around the following definitions:

• Recondition/Refurbish/Rebuild: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair of components, installation of OEM provided updates and upgrades, and replacement of worn parts.

• Remanufacture: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

• Repair: A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

• Service: Repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that significantly change the finished device's safety or performance specifications, or intended use.

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These definitions have an impact on what an organization or third party servicer can do to a medical device, thus influencing the organization's right to repair. While the AHA agrees with the FDA that changing a finished device's performance, or intended use would constitute remanufacturing, the AHA feels that the use of the word "significant[ly]" within several of these definitions adds ambiguity to the guidance. While the FDA attempts to define what "significant[ly] changing" is under Section VI to be:

> "For purposes of this draft guidance, FDA generally considers a ***significant*** change to device performance or safety specifications to be one that, based on verification and validation testing and/or a risk-based assessment, results in a finished device that is outside the OEM's performance or safety specifications or introduces new risks or ***significantly*** modifies existing risks."

The AHA feels that the general consideration of this definition is subjective to interpretation as to what constitutes significantly changing the finished device's safety or performance specifications or intended use and thus creates ambiguity to what is truly intended within the guidance.

Based on this understanding and in consultation with several of our health care leaders in the biomedical field the AHA recommends that the FDA change the definitions language to:

• Recondition/Refurbish/Rebuild: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not change the finished device's performance or degrade the devices safety specifications, or intended use. These activities include repair of components, installation of OEM provided updates and upgrades, and replacement of worn parts.

• Remanufacture: Process, condition, renovate, repackage, restore, or any other act done to a finished device that changes the finished device's performance or degrades the devices safety specifications, or intended use.

• Repair: A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

• Service: Repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that change the finished device's performance specifications, or degrade the devices safety specifications or intended use.

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These changes along with coordinated changes throughout the remainder of the guidance language will help to clarify the difference between service, repair, and reconditioning/refurbishing/rebuilding and remanufacturing and will eliminate any ambiguity from the guidance language.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Jonathan Flannery, AHA's senior associate director, advocacy, ASHE, at jflannery@aha.org.

Sincerely,

Chad Beebe,
Deputy Executive Director
American Society for Health Care Engineering
(ASHE) of the American Hospital Association