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New Legislation Gives More Time for Medical Device Reporting

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Under the recently enacted FDA Reauthorization Act of 2017, drug and device manufacturers will have more time to report device malfunctions to the U.S. Food and Drug Administration (FDA).

Current standards require medical device malfunction reports to the FDA within 30 days. The 2017 Act maintains the 30-day deadline for reporting events that have already resulted in serious medical consequences to users—"adverse events." But the Act expands the quarterly reporting function, allowing 90 days to report issues that may cause harm in the future but have not yet resulted in patient complications, injuries, or deaths—"malfunctions." The Act also allows companies to submit summary malfunction reports when the incident reported is already known and understood by the FDA, rather than reporting incidents individually.

Do the New Reporting Requirements Impact Patients?

FDA officials and lawmakers who support the new reporting requirements commented publicly and made statements to lawmakers that the changes in reporting will not increase patient risk. The new regulations do not automatically extend quarterly reporting to all medical devices. Devices on the market less than two years still must report malfunctions within 30 days, and the FDA has the discretion to determine whether the new rules extend to higher-risk Class II and Class III devices. Further, the FDA still can require individual malfunction reports from specific manufacturers or specific devices "if necessary to protect public health." Additionally, industry leaders note that it is still in companies' interest to "report adverse events as quickly and as clearly as they can."

The more flexible reporting requirements come at a time when the FDA has been criticized for lax oversight, including by lawmakers in a series of congressional hearings in recent years. The FDA's system is one of "passive surveillance," meaning the agency relies on manufacturers to report incidents, says Dr. Jeffrey E. Shuren, the director of the agency's Center for Devices and Radiological Health. Dr. Shuren said that failure to report is "likely common" but neither the FDA nor the Government Accountability Office could quantify non-reporting.

Critics of the new requirements fear that delayed reporting will keep healthcare providers and patients from learning about problems. Detractors note that past issues with medical devices, including last year's reports of premature battery depletion in defibrillators, were reported as

malfunctions. Under the new rules, a similar incident could be reported three times later.

Changing Regulations: Medical Devices and Other Consumer Products

The FDA is one of several agencies that regulate the products and devices that people use every day, and reporting requirements vary widely. For instance, the Consumer Product Safety Commission (CPSC), which regulates items from toys and clothing to off-road vehicles and home appliances, requires companies to report product defects posing the risk of injury within 24 hours. The contrast between the CPSC's 24-hour requirement and the FDA's expanded quarterly reporting program has raised questions about which reporting timeline better promotes consumer safety.

Both the CPSC and the FDA still rely on "passive surveillance" through industry reports to evaluate risks in their respective industries. Some stakeholders, including Dr. Shuren of the FDA, have advocated for agencies to take a more active approach to monitoring. For its part, the FDA has indicated that reporting may become less important over time, as the agency moves to a new data-driven system that will mine electronic health records to detect patterns of issues in medical devices.

But these active monitoring systems are not in place yet, and may not be for several years. In the interim, the medical device industry awaits the FDA's publication of a list of devices eligible to move from 30-day to quarterly reporting. The effects, if any, of the change in reporting timeline, will not be known until the FDA has the opportunity to evaluate reporting after it publicizes the list, which it is expected to do within the next year.

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