



Voluntary Malfunction Summary Reporting One Year Out

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The US FDA launched a voluntary summary reporting program last year to streamline reports for qualifying product malfunctions. It's a positive step forward for the agency, but companies should weigh the pros and cons before deciding to participate.

When the US Food and Drug Administration finalized its Voluntary Malfunction Summary Reporting Program (VMSR) last year, it intended to promote efficiency in the medical device malfunction reporting process, while ensuring it gathers enough information effectively monitor devices.

As its one-year anniversary approaches in September, the voluntary program, which was developed based on results of a two-year pilot, is gaining traction. Additionally, FDA recently announced that it has ended the Alternative Summary Reporting program for all medical devices, emphasizing the use of the VMSR program instead.

But the newer program might only provide limited benefits to participating manufacturers, as it forces them to accommodate various methods of reporting. Manufacturers debating whether to join the program must weigh the pros and cons, and, in either case, set themselves up for reporting success.

How the Program Works

The voluntary summary program was created as an alternative method of complying with the Medical Device Reporting (MDR) requirements in section 519 of the

Federal Food, Drug, and Cosmetic Act (21 USC § 360i) and the regulations in 21 CFR Part 803. Only manufacturers qualify for the program, not importers or user facilities.

Under the program, manufacturers of eligible Class I and Class II medical devices can elect to voluntarily submit malfunction reports in a summary format quarterly, rather than utilizing the electronic format of form FDA 3500A as is currently required for reporting upon becoming aware of a malfunction occurring. More than 5,600 device types are eligible, and FDA makes the reports publicly available in MAUDE, its online database of reported adverse events.

Quarterly summary reports utilize the same electronic submission system used to submit individual MDRs. They should include a “similar level of detail” as individual reports to allow for sufficient understanding of the malfunction, any circumstances that led to the malfunction, and any follow-up steps taken to investigate, correct, and prevent it from happening again, according to an August 17, 2018 rule finalizing the program. Quarterly summary reports require additional information that identifies the number of reportable malfunctions that each report incorporates.

Manufacturers must also submit separate quarterly summary reports for each unique combination of brand name, device model, and problem codes. The final rule provides additional guidance on specific formatting requirements.

Expectations also exist for manufacturers to submit supplemental reports to previously submitted quarterly summary reports in the event that new information is obtained on the device malfunction after its initial report. Supplemental information must be submitted to FDA pursuant to 21 CFR 803.12(a). The manufacturer does not need to submit separate reports, unless the new information causes the event to no longer qualify for summary reporting.

Reporting Malfunctions, Not Adverse Events

The new summary reporting program focuses only on device malfunctions, so adverse events are not applicable for reporting under the new quarterly program. As an example, if a manufacturer received 50 complaint reports about an infusion pump model experiencing false alarms that interrupted delivery but did not involve patients or result in injury or death and were deemed to be a device malfunction, then the manufacturer may accumulate these received reports and report them in the quarterly summary form. If, however, the interrupted service led to an adverse event of patient injury or death, then the manufacturer must report the reported adverse event within the 30-day or five-day requirements of 21 CFR 803, depending on the severity of the issue.

Additional Exclusions from Quarterly Summary Reporting

Several additional instances may exclude manufacturers from submitting eligible Class I and Class II medical device reports via the new quarterly summary reporting method.

If it is identified that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, then the manufacturer must submit reports according an original five-day report under 21 CFR 803.53(a). After a manufacturer submits a five-day report, any quarterly summary reporting is temporarily suspended pending FDA review. Until cleared by FDA, the manufacturer must submit all subsequent reportable malfunctions of the same nature involving substantially similar devices as individual MDRs pursuant to 21 CFR 803.50 and 803.52.

Furthermore, when a company learns of a new type of reportable malfunction, i.e. one that has never been reported to FDA during the life of the device, it must submit an individual report to FDA within the standard 30-day timeframe. The manufacturer may subsequently submit

malfunctions of this type in summary form after the initial individual 30-day report.

FDA can provide written notification when it determines that individual malfunction reports are necessary to provide additional information and more rapid reporting for an identified public health issue involving certain devices. FDA also can restrict summary reporting if it needs to monitor a potential public health issue. Finally, FDA can bar a manufacturer from the summary reporting program if the manufacturer failed to comply with MDR requirements or failed to follow conditions of the program.

Finally, Medical Device Reports associated with recalls are handled in a similar fashion when required to be reported under 21 CFR 806: all reportable malfunction events of the same nature that involve the same or similar device marketed by the manufacturer must be submitted as individual MDRs in accordance with 21 CFR 803.50 and 803.52, until the date the recall is terminated. Individual MDRs are not required if already exempt, such as for a Class III recall.

Other Reporting Requirements: Combination Products

The voluntary program includes only device-led combination products (i.e. where the device is the primary mode of action). Drug and biologic-led combination products are subject to a different reporting system and are not permitted to use this system for their device constituent parts. The device-led combination products complaints remain subject to the same requirements as medical devices for reporting under both 21 CFR 803 and the quarterly summary reporting.

Challenges Participants Face

The key consideration for manufacturers interested in participating in the voluntary program is whether it will actually save them time and resources—or add them. The change from reporting all malfunction MDRs individually to batch reporting on a quarterly basis promotes efficiency in the frequency of the manufacturer's reporting, but it does not modify report content requirements.

Furthermore, even with quarterly reporting, manufacturers must still process complaints immediately upon receiving them to assess the nature of the device malfunction and whether the malfunction would lead to death or serious injury. This assessment will now need to further qualify if the confirmed device malfunction is eligible for quarterly summary reporting, or if there is a scenario in which the device malfunction must be submitted in the 30-day timeframe. Only once the decision on reportability is made, will the manufacturer be able to collect the report

with other device malfunctions that have met the criteria for quarterly reporting.

To determine if participating in the voluntary program makes sense for them, manufacturers should consider the following:

How many of your devices are eligible?

This might seem obvious, but the summary program provides an alternative for only a narrow field of devices with product codes in existence for at least two years, and low-risk malfunction events that have not been found to or have a low likelihood to result in death or serious injury. Furthermore, only manufacturers qualify, not importers or user facilities.

So, if manufacturers of devices that reside in multiple device classification sought to participate in the voluntary program, they would need to evaluate whether they would have to have dual reporting processes in place – one for devices eligible for the voluntary quarterly summary reporting program, and one for devices required to be reported under the standard reporting requirements of 21 CFR 803 (30-day or five-day).

For example, a manufacturer with a broad offering of Class I, Class II, and Class III devices may find it extremely challenging to implement the quarterly malfunction reporting system, because the manufacturer would need to implement multiple MDR reporting processes. As a result, manufacturers need to conduct internal analyses to determine whether the benefits of quarterly summary reporting outweigh the burdens of the needed modifications.

As a result, manufacturers should consider the time and resource necessary to run one program for reporting of MDR events as they do now vs. maintaining a process that allows for both 30-day and quarterly reporting.

Who will monitor the program?

New product codes may be added to the summary reporting program through an FDA periodic evaluation after two years or manufacturer request. Meanwhile, manufacturers must monitor the FDA product code database to determine

whether any new codes have been identified as eligible for the summary reporting program.


How robust is your review process?

In order to ensure that manufacturers are complying with the appropriate timeframes for reporting an event (5-day, 30-day, quarterly), the company's process must have a robust upfront screening process that allows for quick and accurate identification of each type of complaint.

While many organizations' processes currently address reporting for 5- and 30-day reports, the addition of a system that allows quarterly reporting may be seen as a burden for personnel, who will now have to develop processes to ensure the new timeframe is added and honored. In addition, a new format and content for quarterly summary reports will require additional checks and balances to ensure all information is included in summary fashion. Companies utilizing electronic systems that can incorporate timeframe tracking or notification may be more likely to incorporate quarterly summary reporting into their processes.

What it Means in Practice

Utilizing FDA's new voluntary summary reporting program will hopefully promote efficiency for manufacturers, but this will depend on the company's existing complaint assessment processes and the changes needed for successful quarterly summary reporting.

Taking all of these considerations into account, the voluntary quarterly summary reporting program may be seen by some as a "baby step" in streamlining the FDA reporting process. However, even if modest, these changes are positive, because they begin to address the contemporary needs of the agency and manufacturers without compromising public safety. This voluntary program is a critical step in the right direction, and hopefully will expand in the future to include more products and greater reporting efficiencies. 

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