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CDRH's Voluntary Malfunction Summary Reporting Program

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On August 17, 2018, the Food and Drug Administration (FDA) released the Medical Device Voluntary Malfunction Summary Reporting Program (VMSRP) agreed between industry and the FDA as a part of the Medical Device User Fee Amendments (MDUFA IV) commitment letter. A summary reporting system for malfunctions was first contemplated in the FDA Amendments Act (FDAAA) in 2007. Congress directed the agency to enable summary reporting for all class I devices and for those class II devices that were not life-supporting, life sustaining, or permanent implants. Until now, the agency has not implemented the FDAAA provision and provided alternatives, including summary reporting, only following an application by a specific company and the FDA agreement that summary reporting was appropriate for the device and in the situations outlined in the application.

The Voluntary Malfunction Summary Reporting Program allows participating companies to submit certain medical device malfunction reports in summary form on a quarterly basis. The program applies to reportable malfunctions that are not associated with a death or serious injury. The program applies to eligible devices regulated by the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), including device-led combination products. Summary reporting does not include all devices and does not include the following conditions.

- Reportable malfunctions associated with a five-day report
- Reportable malfunctions that are the subject of certain device recalls
- FDA determinations that individual reporting is necessary
- FDA determinations that a device manufacturer may not report in summary fashion
- New types of device malfunctions

The definition of a reportable malfunction remains the same. Only product codes that have been in existence for two years or more are included in the list of eligible product codes, unless the new product code was created solely for administrative reasons. The FDA indicates in the announcement that it will periodically review and update the list of eligible product codes.

Eligible devices

The MDUFA IV commitment letter states that "[f]or most, if not all device procodes, FDA will permit manufacturers of such devices in these procodes to report malfunctions on a quarterly basis and in a summary MDR format. FDA will publish the list of eligible procodes[...]" At this

point in time, the way to determine whether a specific product procode is eligible for the VMSRP is to refer to the Product Classification Database.

As noted above, procodes established within the past two years may not be included in the list of eligible devices. In addition, if a new type of malfunction occurs that the manufacturer has not previously reported to the FDA, the manufacturer must submit an individual report for the first report of its kind. Subsequent reports for the same malfunction may be submitted in quarterly summaries, unless it meets one of the conditions of ineligibility.

Devices being recalled

The FDA continues to require individual reports for reportable malfunctions that are the subject of a recall involving a correction or removal that must be reported to the FDA under 21 C.F.R. Part 806 (meaning class I and II recalls). The individual medical device reporting (MDRs) that have accrued since the last summary report and that are related to the recall event are due on the same day that the company submits a report of correction or removal. The requirement for individual reports (within five or 30 days) continues until the FDA terminates the recall; after the recall is terminated, the company may resume quarterly summary reports for the eligible device. The individual report requirement applies only to the type of malfunction that gave rise to the recall, not to all malfunctions for the device. [1]/

For malfunction events identified for inclusion in a summary report but subsequently identified as the subject of a reportable correction or removal prior to the end of the relevant summary reporting period, a summary MDR must be submitted for those reportable malfunctions that occurred from the time of the last summary report until the beginning of the individual reports that are required when the recall is initiated. This summary report is due within 30 calendar days of the report of correction or removal. [2]/

Five-day reports

The VMSRP does not change the requirement for five-day reports. If a five-day report is submitted for an event that requires remedial action to prevent an unreasonable risk of substantial harm to public health, all subsequent reportable malfunctions of the same type that involve substantially similar devices also must be submitted as individual MDRs as five-day reports. [3]/

Specific determinations by the FDA

The FDA may determine and communicate to a manufacturer that more rapid reporting is required due to an identified public health issue. Written notification will be provided to the manufacturer at the time individual reports are determined to be appropriate and if the agency determines individual reports are no longer required.

The FDA may also decide that a specific manufacturer may no longer participate in the program. The manufacturer will be notified in writing and the requirement for individual malfunction reports is triggered as of the date of receipt of written notification.

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[1]/ The text of the program states "[…]all reportable malfunction events of the same nature that involve the same device or a similar device marketed by the manufacturer must be submitted as individual MDRs[…]until the date that the recall is terminated."
In its responses to comments, FDA also states that "[…]manufacturer must submit reportable malfunction events related to that correction or removal as individual MDRs[…]"

[2]/ So, for example, a company submits a summary malfunction report for device malfunction A on July 31 (covering events through June 30.) From June 30 through August 29, the company receives an additional five malfunction reports. On August 30, the company receives a malfunction report alleging serious injury and on September 15, reports its decision to initiate a class I recall to the FDA. As of September 15, individual MDRs are required for the device and malfunction associated with the recall. The company must also submit a summary report for the five malfunction reports received from June 30 to August 29, within 30 days of September 15.

[3]/ 82 FR 246 60925 (December 26, 2017).

Reporting format

For the VMSRP, the same form 3500A used for individual reports will be used. Specific instructions for completion of this form include the following.

- Each unique combination of brand name, device, model, and problem code will be reported on a single summary report.
- The first sentence of the device event narrative must read: "This report summarizes # malfunction events."
- The XML tags "<NOE>" and "<NOE/>" are placed on both sides of the number of events to make the number extractable from the report.
- Event narrative must include a detailed description of the nature of the events and, if relevant and available, include a range of patient age and weight and a breakdown of patient gender, race, and ethnicity.
- Include the device identifier (DI) portion of the unique device identification (UDI) for device version or model.
- Indicate whether this is a combination product.
- Include all appropriate device problem codes.
- Include additional narrative, with numeric breakdowns of devices return, labeled for single use, and reprocessed and reused, where applicable.

Reporting schedule

Reportable malfunctions or supplemental information that you become aware of during these timeframes:	Must be submitted to FDA by:
January 1-March 31	April 30
April 1-June 30	July 31
July 1-September 30	October 31
October 1-December 31	January 31

Supplemental reports

Supplemental reports will be required when they will provide additional information that would have been required in the initial summary report had it been known to the manufacturer at the time of the initial summary report. Supplemental reports, when required, are due at the next scheduled time for summary reporting. There are also rules that apply if a malfunction was initially included in a summary report and is later determined to have been associated with a death or serious injury.

Exemptions, variances, or alternatives

Notwithstanding this program, a manufacturer may still request a different exemption, variance, or alternative under 21 CFR 803.19, including for devices in product codes eligible for the VMSRP. If a company has already been approved for summary reporting pursuant to a specific request, you may continue to report under your exemption, variance, or alternative.

Public access to MDR summary information

The FDA will make summary reports submitted under the program available in the Manufacturer and User Facility Device Experience (MAUDE) database. Any attachments to the report that are incompatible with the MAUDE interface will not be included.

Potential impact of the voluntary MDR summary reporting on companies

If your company currently reports MDRs, it will be important to assess the potential benefits of this new program versus continuing to report individual malfunctions. For companies that submit a low number of MDR malfunction reports, the resources required to modify internal processes to enable summary reporting, including assuring that triggers are in place to detect any condition that might make a malfunction or a device ineligible for summary reporting after it has begun, may outweigh the relief provided by summary reporting.

For companies that submit a large number of malfunction reports, the same assessment should be performed to determine the value of summary reporting. If, for example, a company submits a large number of malfunction reports on a particular device and there are some types of malfunctions that occur more frequently or that account for a high percentage of these reports, there may be value in utilizing the voluntary program that will offset the changes that must be made to accommodate the program.

Because medical device reporting is a frequent subject of inspections, companies will want to assure that they are correctly interpreting and applying the program, including any limitations, before switching to the VMSRP.

We also encourage manufacturers to keep apprised of developments in this area as the FDA may issue additional guidance or tools regarding the implementation of this voluntary program.

For more information, or for assistance with program participation, please contact:

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