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FDA Asks For More Summary Adverse Event Reports Under Proposed MDR Program

by Shawn M. Schmitt

The US agency has proposed a Voluntary Malfunction Summary Reporting Program that will allow makers of an array of devices to submit Medical Device Reports in a summary, rather than individual, format to FDA. The program aims to make the MDR-reporting process more effective and give the agency clearer post-market visibility.

Makers of an array of devices will soon be able to submit Medical Device Reports in a summary format to US FDA thanks to an upcoming program that aims to make the MDR-reporting process more effective and give the agency clearer post-market visibility of problem products.

Submitting reports under the Voluntary Malfunction Summary Reporting Program "would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively," the agency says in a *Dec. 26 Federal Register notice*.

The proposed program – which does not extend to importers or user facilities – addresses goals outlined in a 2016 MDUFA IV *commitment letter*. That letter directs the agency to allow makers of a majority of devices to report adverse events quarterly under FDA's *Alternative Summary Reporting Program* rather than individually on full MedWatch reporting forms. Summary reporting allows device firms to submit abbreviated reports in a summarized, line-item format.

In any given year, more MDRs are reported to FDA individually than in summaries. For example, 871,654 MDRs were sent to the agency individually in 2016, while only 465,624 were sent as part of the Alternative Summary Reporting Program. (Also see "*Adverse Events Dip Slightly In 2016; MDR Summary Reporting To US FDA Ticks Up*" - Medtech Insight, 8 Feb, 2017.)

"While manufacturers must report certain device malfunctions to the FDA, these individual reports often describe the same problem, creating a process where the FDA conducts duplicate

reviews of common malfunctions," said Jeff Shuren, director of the agency's Center for Devices and Radiological Health.

"We're proposing to streamline this process through a summary reporting system that would enable us to more efficiently detect potential safety issues and free up agency resources to better focus on addressing them," he said.

Despite FDA's desire to receive more adverse event reports in summaries, the agency "will still be requiring manufacturers to file individual reports on deaths and serious injuries associated with devices, so there will be no change in reporting those events," Shuren added.

The program also will not "change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers," the agency stresses in its FR notice.

> *"For many manufacturers, this approach would greatly reduce the volume of reports that they would need to submit to FDA," the agency says.*

Per the commitment letter, the agency will publish a list of eligible device product codes within a year of receiving proposed procodes from industry. FDA is accepting procode recommendations during the comment period for the program under docket No. FDA-2017-N-6730, which closes in 60 days (Feb. 23).

"An important part of this proposed voluntary program is providing clarification to manufacturers regarding the product codes eligible for the program," the agency says. "When this proposed voluntary program is finalized ... FDA will identify on its website a list of device product codes that are eligible."

The list of qualified devices will include high-risk class II and class III products, as directed by the commitment letter.

Meanwhile, adverse events linked to devices that fall under a procode that has been in existence for fewer than two years cannot be reported in summaries.

And "FDA recognizes that new product codes will be created" over time, the agency says, noting

that it will "evaluate new product codes after they have been in existence for two years to determine whether they should be added to the list."

The agency is considering how to incorporate combination device/drug products into its list of eligible procodes, and invites comments from industry about which combo products to include.

Not All Events Can Be Reported In Summaries

Although "the agency believes that for many types of reportable malfunctions, submission of summary reports on a quarterly basis would allow FDA to collect sufficient detail to monitor devices effectively," FDA says, "there are still situations in which submission of individual malfunction reports on a more prompt basis than quarterly is necessary to protect the public health. Those situations may involve class I devices and class II devices that are not implantable, life-supporting, or life-sustaining."

Events involving deaths or serious injuries cannot be filed in summaries, the agency notes. Those events must still be reported to FDA within 30 days (or within five days if a problem with a device is particularly egregious).

In addition, "if FDA determines that individual malfunction reports are necessary from a specific manufacturer or for specific devices, FDA would notify relevant manufacturers that they must submit individual reports and provide an explanation for that decision, and the steps necessary to return to summary, quarterly reporting," the agency says.

The agency may also "revoke or modify in writing an exemption, variance or alternative reporting requirement if it determines that revocation or modification is necessary to protect the public health."

Further, companies can't report in summaries if a new type of reportable malfunction occurs for a device, or if a reportable malfunction is the subject of an ongoing device recall.

"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 to FDA until 90 days past the date the recall is terminated," the agency says.

Successful FDA Pilot Leads To Program

The proposed summary reporting program is the result of a successful *2015 FDA pilot program* that allowed enrolled device-makers to submit MDRs in a summary format on a quarterly basis for class I and class II products that aren't permanently implantable, life-supporting or life-sustaining.

That pilot revealed several notable findings, FDA says.

"First, participants were able to reduce the volume of reports by over 87% ... while preserving the essential information regarding the context around malfunction events. This increased efficiency in reporting, and in the agency review and processing of malfunction reports," the agency says in its FR notice.

"The format also allowed for simple, transparent and cost-effective reporting through existing electronic reporting processes for submission of electronic MDRs (eMDRs)," FDA says. "Lastly, summary reports collected in this format could be more easily shared publicly, facilitating transparency of malfunction reporting."

Through the pilot, the agency also learned that the summary format could be used by large and small firms alike, with varying numbers of marketed products.

"FDA believes that bundling 'like events' together into a single summary report description would have benefits for manufacturers, FDA and the public," the agency concludes.

"For many manufacturers, this approach would greatly reduce the volume of reports that they would need to submit to FDA. For FDA, information would be received in a streamlined manner that would facilitate more efficient understanding of malfunction issues. For the public, summary reports could make malfunction event trends for a particular device more readily transparent."

From the editors of The Gray Sheet