

Medical Product OUTSOURCING

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Is 2008 Finally the Year of eMDR?

By Tamar June

For those medical device companies still on the fence about whether to explore electronic medical device reporting (eMDR), here's some important news: The FDA is going to mandate eMDR. End of sentence.

After sending some mixed signals in the second half of 2007, FDA eMDR experts have said clearly of late that they'll mandate eMDR within two years. The only debate now is how quickly it will happen, and what kind of extension smaller device companies may get.

It will be mandated, but it's at least "18 months away" from being made mandatory, said Stephen Sykes, deputy director of the Office of Surveillance and Biometrics and an agency lead on the eMDR initiative. Speaking in December, Sykes said the agency hopes and expects to release a draft eMDR guidance sometime early in 2008, but the timetable is still a bit slippery, he admitted.

According to Sykes, the approximate timetable goes like this: The agency will issue draft guidance in the first half of 2008, take comments on it for 90 days and then issue a final rule that will mandate eMDR within a year of the final rule coming out. Smaller device companies may get another year or so to comply, but that was still being debated internally at the agency as of January.

But let's back up for a moment and make sure we understand what eMDR is—and isn't.

Background on eMDR

Collection of adverse event information on medical devices is mandated by requirements of the Food Drug and Cosmetics Act and comes primarily from manufacturers, user facilities, importers and voluntary reporters. Data entry contractors currently enter a majority of these reports manually—very slowly and with a great chance for human error.

The FDA's eMDR project provides the capability for electronic data entry and processing of medical device adverse event reports. The project uses the Health Level Seven (HL7) Individual Case Safety Report (ICSR) standard to receive medical device adverse events (MDRs). The eMDR application accepts electronic medical device reports via two options, designed for low- and high-volume reporters.

The low-volume option, which only can be used for fewer than 50 electronic submissions per month, is called CeSub. It's a free downloadable application that will allow submission of MDR reports one at a time. The software contains data elements from the current MedWatch and generates an HL7 ICSR message for each MDR the user generates using the software.

The high-volume option is HL7 ICSR. This option provides automated server-to-server communication, which means that MDRs automatically can be sent to the FDA without having to upload them to an external application. In addition, this option will allow the FDA to send automatic receipts that are used to keep track of the status of each MDR sent. This method is suitable for processing electronic MDR files either individually or in a batch.

eMDR utilizes the FDA Gateway, an agency-wide entry point for all electronic submissions, to receive eMDRs. The Gateway authenticates and validates electronic submissions and routes them to the agency's Center for Devices and Radiological Health (CDRH).

The Value Is Clear

"We're encouraging [bigger] device companies to do it now" rather than wait for a mandate from the agency, the FDA's Sykes said. The agency is working now with an ever-increasing number of device companies and industry vendors on eMDR projects, he added.

The number of MDRs already is about 100,000 per year and rising, Sykes said.

"Most device companies will welcome the change" to eMDR, said device industry attorney John Q. Lewis, a partner with Jones Day, a law firm in Cleveland, OH. "I only hope the FDA doesn't underestimate the concerns of smaller device companies" as they decide on the mandate timetable, Lewis noted, adding that "it makes sense to give them more time and allow private vendors" to prepare software packages to help.

However, the bottom line is that Lewis and most industry experts are applauding the eMDR initiative as a "necessary development" for both the device industry and the FDA.

Indira Konduri, eMDR project leader at the Office of Surveillance and Biometrics, agreed that the "industry has responded very favorably to the idea of electronic MDRs," adding that "larger volume MDR reporters are more involved" so far.

Konduri also is encouraging the industry to leverage the benefits of eMDR. For companies, she cited decreased administrative costs, immediate acknowledgment of receipt and direct entry of the report into the FDA's Manufacturer and User Facility Device Experience Database, also called "MAUDE." And for the agency, Konduri said eMDR will mean decreased administrative costs in processing paper reports, immediate availability of reports for analysis and more timely follow-up.

How It Works

If all is going right, the high-volume Electronic Submissions Gateway (ESG) program should work like this:

- FDA ESG receives an inbound submission
- FDA ESG sends Acknowledgement 1 to the submitter. This confirms that the submission was successfully received by the ESG and contains a Message Integrity Check to validate that the submission was received intact
- The submission is automatically transferred to the FDA center
- Acknowledgement 2 is then sent by ESG to indicate that the submission reached the CDRH
- The center validates and processes the submission
- Acknowledgement 3 is sent by the CDRH and indicates if the submission was successfully loaded into the adverse event database or notes any errors that occurred during validation and loading

The launch of the program has not been without its challenges and setbacks—as FDA personnel will be the first to admit. The agency has missed a few

deadlines, and it has struggled at times to handle different test submissions it thought it could handle.

But the, so far, relatively slow pace of eMDR adoption remains something of a surprise to many in the industry.

Why the Slow Adoption Rate?

"I'm surprised it has taken this long," said attorney Peter Reichertz with Sheppard, Mullin, Richter & Hampton. He's a partner in the California firm's Washington, DC office and is leader of its Food and Drug Law Group.

Leveraging eMDR would be "so much more efficient for device companies, I can't explain why it hasn't happened faster," said Reichertz, who works regularly with FDA-regulated device companies. He also noted that the device industry is made up of smaller companies than its drug industry counterparts. That could be slowing adoption, he said. "Still, device companies are usually ahead of drug companies on the tech side, so it doesn't really make sense" that device companies haven't embraced eMDR faster, he added.

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The reality is that eMDR is coming. The agency will mandate it within two years. It's better for the FDA, and it is better for the device industry. Savvy companies will move ahead now to leverage the many advantages of eMDR as soon as possible.

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