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USFDA to increase transparency in medical device reporting

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FDA has formally ended the Alternative Summary Reporting (ASR) Program.

In the spirit of promoting public transparency, the U.S. Food and Drug Administration's Center for Devices and Radiological Health is taking a number of important steps to update its Medical Device Reporting (MDR) Program, one of the tools the FDA uses to monitor device performance, detect potential device-related safety concerns or signals and contribute to the benefit-risk assessment of these products.

FDA has formally ended the Alternative Summary Reporting (ASR) Program. Under this program, manufacturers of certain devices could request an exemption from the requirement to file individual medical device reports for certain events that were well-known and well-established risks associated with a particular device and to instead submit quarterly summary reports of such events.

Since the program's inception in 1997, the FDA granted 108 such exemptions to individual manufacturers for certain well-known events associated with specific devices, which were often already described in the product labeling available to health care professionals and patients. The ASR Program allowed the FDA to more efficiently review reports of well-known, well-understood adverse events, so we could focus on identifying and taking action on new safety signals and less understood risks.

Since 2017, steps have been taken to gradually sunset the ASR Program and to streamline medical device reporting as FDA implemented the Voluntary Malfunction Summary Reporting (VMSR) Program. The VMSR Program reflects a pilot program conducted in response to changes made in the Food and Drug Administration Amendments Act of 2007 and goals agreed to as part of the Medical Device User Fee Amendments of 2017 (MDUFA IV) process. The FDA implemented the VMSR Program after conducting the pilot study that demonstrated the value of the program to public health.