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Re: Docket No. FDA-2026-N-7129 — Adverse Event Program for Medical Devices; Medical Product Safety Network (MedSun) (OMB Control No. 0910-0471)

Dear Dockets Management Staff:

I am writing in response to FDA's July 17, 2026, notice (91 FR 44863) requesting comment on the extension of the information collection that supports the Medical Product Safety Network (MedSun). These comments are my own, submitted in my individual capacity.

Some quick background so the Agency knows where my perspective comes from. I have spent over a decade in regulated quality engineering; in my current role I serve as the quality subject matter expert for Urology implantable product lines, providing day-to-day production support and owning the CAPA and nonconformance programs. My work sits on the manufacturer side of the adverse event data that MedSun produces complaint investigations, MDR decisions, and root cause analysis. I also write on quality topics; my article "Why Do Most CAPAs Fail?" appeared in Quality Digest in May 2026. I have organized my comments around the four questions in the notice.

1. Is the collection necessary, and does it have practical utility?

Yes, and I would like to explain why from the receiving end. When an adverse event report lands on a manufacturer's desk, the problem is never that we have too few reports. The problem is that most reports do not tell us enough to figure out what happened. Was it the device? A use error? A maintenance issue at the facility? A report that just says, "device failed during procedure" can eat weeks of investigation time and still end in "unable to determine."

MedSun reports are different because the reporters are trained and the program follows up with additional questions. A smaller network of three hundred facilities producing complete, clinically detailed reports is worth more for signal detection than a much larger volume of thin ones. I support extending this collection.

2. Are the burden estimates accurate?

Thirty minutes per report is right for a simple malfunction report. I doubt it holds for the harder cases, and the notice says FDA is specifically promoting reporting from pediatric intensive care units, electrophysiology laboratories, and hospital laboratories, which is where the harder cases live. These events tend to involve implanted or life-sustaining devices, multiple products interacting, and someone hunting through several hospital systems for serial numbers, lot numbers, and chart details.

Two suggestions:

- Check the 30-minute figure against a sample of actual reports, broken out by complexity (simple malfunction vs. serious injury or death vs. multi-device event), instead of using one average for everything.
- Count the supplemental follow-up questions as their own line item. They happen later, often involve a different person, and folding them into the same 30 minutes hides real work.

Getting the burden model right also matters for question 4; it is hard to reduce burden that has not been measured.

3. Can the quality, utility, and clarity of the information be improved?

A few things that would make MedSun data significantly more usable downstream:

- **Use IMDRF adverse event codes.** If the report form captures (or maps to) IMDRF terminology for device problems and clinical outcomes, MedSun data becomes directly comparable to MAUDE and international vigilance data. Free-text narratives are valuable, but structured codes are what make trending possible.
- **Ask for the UDI.** Ambiguous device identification is the single most common gap I see in adverse event data. A prompt to scan or enter the Unique Device Identifier would fix identification and let the system auto-fill model and lot information, which also saves the reporter time.
- **Separate the device problem from the use environment.** A field that distinguishes what the device did from the conditions around it (training, maintenance status, configuration) makes root cause attribution far more reliable. It also helps FDA spot use-related hazards that cut across manufacturers, which no single company's complaint file will ever show.
- **Give the sites feedback.** People who see their reports used write better reports. Even a periodic aggregate summary back to participating facilities would help.

4. Can the burden be reduced, including through automation?

- Let facilities pull data from their electronic health record and materials-management systems instead of retyping it: patient demographics, event date, device identifiers. FHIR-based exchange makes this practical now in ways it was not a decade ago.
- UDI barcode scanning, per above. It serves both data quality and burden reduction.
- Use a short form for simple malfunctions and expand into the full question set only when the event involves death, serious injury, or multiple devices.
- Make sure reporters can save a partial report and come back to it. Clinical details arrive in pieces; the form should tolerate that.

Closing

MedSun is one of the more sensible things in device postmarket surveillance: a small, trained network producing high-quality data rather than a large, untrained one producing noise. I support the extension and offer these suggestions to make the data more usable, and the burden estimates more accurate. Thank you for considering these comments.

Respectfully submitted,

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