GAO Highlights

MEDICAL DEVICES

FDA Should Strengthen Policies Guiding Audits of Third Party Review Organizations

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A report to congressional committees

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What GAO Found

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) administers the Third Party Review Program, a voluntary alternative review process for selected low-to-moderate risk medical devices, such as diagnostic ultrasound systems and surgical lasers. Under this program, which is intended to facilitate faster reviews, device sponsors can contract with FDA-accredited entities. These entities, known as Third Party Review Organizations (third parties), conduct the initial review of certain premarket applications, known as 510(k) submissions. These third party reviews occur prior to agency officials making the final decision about whether the device can be marketed.

According to FDA officials, the agency received approximately $8 million for Third Party Review Program operations in fiscal years 2023 through 2027. FDA's administration of the program includes overseeing third parties' accreditation and reaccreditation applications to ensure participation standards are met, and reviewing third parties' recommendations on 510(k) submissions and making final decisions. From fiscal years 2018 through 2025, third parties provided FDA with 617 510(k) submission reviews and recommendations, which accounted for about 2 percent of CDRH's 510(k) submission reviews annually.

Center for Devices and Radiological Health (CDRH) and Third Party 510(k) Medical Device Submission Reviews, Fiscal Years 2018–2025, as of November 2025

	Fiscal Year							
	2018	2019	2020	2021	2022	2023	2024	2025
Number of 510(k) submissions reviewed by CDRH only	3,276	3,464	3,504	3,731	3,554	3,684	3,461	3,476
Number of 510(k) submissions reviewed by Third Party Review Organizations and CDRH	75	78	85	90	77	77	68	67

Source: GAO analysis of Food and Drug Administration data. | GAO-26-108499

FDA is required to audit third parties periodically to ensure they remain in compliance with the standards for program participation. The agency conducted 25 periodic audits of third parties from 2000 to 2026, according to FDA officials. These audits were conducted in four phases: 13 audits from 2000 through 2003, five audits from 2011 through 2013, two audits in 2022, and five audits from 2025 to 2026. Results of these audits varied in terms of the deficiencies identified.

GAO found that FDA's audit policies have gaps and are missing key details. For example, FDA has not established time frames specifying how long it should take the agency to complete an audit and communicate results to third parties. As a result, GAO identified several recent audits with findings of deficiencies, such as language in standard operating procedures being too vague, that took FDA more than 6 months to close. Ensuring the agency has detailed policies, such as time frames for completing audits and communicating results, would strengthen FDA's efforts to ensure third parties meet program requirements and are therefore eligible to continue reviewing 510(k) submissions, which provide recommendations to FDA as to whether devices should be allowed on the market and thus available for patient use.

Why GAO Did This Study

FDA, within the Department of Health and Human Services (HHS), is responsible for ensuring that medical devices sold in the U.S. are regulated to provide reasonable assurance of safety and effectiveness. The review process FDA uses to make this determination represents a substantial investment of time and resources for both the agency and the device sponsor. The Food and Drug Administration Modernization Act of 1997 created the Third Party Review Program, which FDA oversees. Since program inception, FDA said it accredited 32 third parties to participate in the program; as of May 2026, there were nine third parties with active accreditations.

The Consolidated Appropriations Act, 2023, includes a provision for GAO to report on the Third Party Review Program. This report (1) describes FDA's roles and responsibilities in administering the Third Party Review Program; and (2) examines the extent to which FDA audits third parties' performance.

GAO reviewed the statute authorizing the Third Party Review Program and FDA's related policy and guidance documents. GAO analyzed FDA third party performance metrics from fiscal years 2018 through 2025. GAO also reviewed documentation and internal communications from completed third party audits. GAO interviewed FDA officials and representatives from six third parties.

What GAO Recommends

GAO is making one recommendation to FDA to update its policies for the Third Party Review Program audit process to include, for example, target time frames for completing audits and communicating findings to third parties. HHS concurred with GAO's recommendation.