The FDA is preparing for a possible government shutdown after President Donald Trump said he will not sign a continuing resolution to keep the government open through February unless it includes funding for a border wall, which his opposition has stated they will not approve.

Even in a shutdown, essential public-health related employees at the federal watchdog would continue working, alongside activities paid for through the agency’s user fee program. Approximately 60% of FDA staff, more than 10,000 employees, would be able to continue their work during the shutdown, according to a *Politico* report.

The remaining approximate 40% of the FDA’s employees, around 7,000 individuals, would be forced to take leave without pay.

Work at the FDA that would stop in a partial shutdown includes inspections, compliance and enforcement activities, according to *Politico*. Meetings with external bodies, as well as non-urgent research would most likely be frozen during the shutdown as well, according to the report.

For medical device companies with products in the pipeline, a shutdown could mean delays to clearances and could force them to push back panel review meetings, clinical trial launches and other steps along the regulatory pathway.

Other agencies and departments that would face closure include the Dept. of Homeland Security, the Dept. of Commerce, the Dept. of the Interior, the Dept. of Agriculture, the Dept. of Housing and Urban Development, the Dept. of Justice, the Dept. of Transportation and independent agencies including NASA and the Environmental Protection Agency.

The looming shutdown comes just as the FDA has begun to lay out plans for improvements to its regulatory process for medical devices, including the *implementation of a new Safer Technologies Program* and finalized guidelines for its Breakthrough Device Program, and *updates to its 510(k) clearance pathway* including a reduction in older predicate devices and an alternative pathway based on objective safety and performance criteria.
The post FDA braces for partial government shutdown appeared first on MassDevice.