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'Short' Sighted: FDA's 2020 Budget Aims To Avoid Medical Device Shortages

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The US agency doesn't want to be blindsided by a shortage of medical devices in the marketplace, so it's proposing in its 2020 budget request that manufacturers notify FDA if they're anticipating a shortage. And firms that make "essential" devices would have to periodically inform the agency of their manufacturing capacity under the legislative proposal.

Manufacturers would have to notify US FDA if they're expecting a shortage of devices under a legislative proposal found in the agency's 2020 budget request.

Currently, "no law requires medical device manufacturers to notify FDA when they become aware of a circumstance that could lead to a device shortage," FDA says in its [fiscal year '20 budget](#), posted online March 18.

"Such circumstances may include, for example: discontinuation of a device; interruption of the manufacture of the device, e.g., due to scarcity of a raw material or unavailability of a component part; or loss of or damage to a manufacturing facility," the agency notes.

By being notified more quickly about an anticipated device shortage, FDA says it can take steps to ensure that devices "of public health importance" will be available to those who need them.

FDA also wants to require makers of "essential" devices to periodically inform the agency of their manufacturing capacity. The agency does not define which products would be considered "essential."

Further, FDA wants to "authorize the temporary importation of devices whose risks presented when patients and health-care providers lack access to critically important medical devices outweigh compliance with US regulatory standards," it says.

The agency's focus on medical device availability came mere days before it announced that the closing of at least two sterilization facilities due to environmental hazard concerns could lead to a device shortage. (Also see "[*Sterilization Facility Shutdowns Could Spell Medical Device Shortage; FDA Urges Firms To Assess 'Downstream Impacts'*](#)" - Medtech Insight, 26 Mar, 2019.)