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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study to assess the potential for reusing medical devices that are considered to be single-use devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. FOUSHEE introduced the following bill; which was referred to the Committee on _____

A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to conduct a study to assess the potential for reusing medical devices that are considered to be single-use devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REPROCESSING OF SINGLE-USE DEVICES.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, (in this section referred to as the ''Secretary'')

shall conduct a study to assess the potential for reusing medical devices that are considered to be single-use devices.

(b) PRIMARY CRITERIA.—In conducting the study under subsection (a), the Secretary shall ensure that patient safety and infection prevention are the primary criteria used in examining the potential for reusing single-use devices, with stratification by risk category and clinical use.

(c) FOCUS ON THIRD PARTY REPROCESSORS.—In conducting the study under subsection (a), the Secretary shall focus on the enhanced use of third party reprocessors, including reprocessors cleared by the Food and Drug Administration, as opposed to in-house reprocessing, or the acquisition of sterilization technologies, by hospitals.

(d) CONTENTS.—In conducting the study under subsection (a), the Secretary shall examine, at a minimum—

(1) existing pathways of the Food and Drug Administration for the reprocessing of single-use devices, including instances in which current rules are sufficient and instances in which barriers exist;

(2) the role of third-party reprocessors of single-use devices versus in-house hospital reprocessing;

(3) the operational feasibility of reprocessing single-use devices, including sterile processing capacity, staffing, equipment, chain of custody, tracking, and quality assurance;

(4) the financial and environmental return of reprocessing single-use devices, taking into consideration waste reduction, cost savings, and any added labor, capital, or compliance burden; and

(5) issues related to liability and accountability if a reprocessed single-use device fails or contributes to patient harm.

(e) CONSULTATION.—In conducting the study under subsection (a), the Secretary shall seek input from—

(1) non-Federal entities, including hospitals, supply chain leaders, infection prevention organizations, sterile processing organizations, clinicians, and appropriate industry representatives; and

(2) Federal entities, including the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare & Medicaid Services.

(f) DEFINITIONS.—In this section, the terms ''device'' and ''single-use device'' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(g) REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this Act, the Secretary shall transmit to Congress a report on the results of the study, including—

(1) a listing of single-use devices that the Secretary determines have the potential for reuse; and

(2) recommendations for programs and activities to provide for such reuse, including the use of—

(A) reprocessors cleared by the Food and Drug Administration;

(B) appropriate cleaning and sterilization technology;

(C) quality assurance and tracking systems; and

(D) infection prevention controls.