AMENDMENT TO H.R. 4368, AS REPORTED (AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2024)

OFFERED BY MRS. MILLER-MEEKS OF IOWA

At the end of the bill (before the short title), insert the following:

SEC. _____. REPORT ON THE INTEROPERABILITY OF MEDICAL DEVICES.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Commissioner on Food and Drugs, in consultation with the National Coordinator for Health Information Technology, shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and make publicly available (including through posting on the website of the Food and Drug Administration), a report on the state of interoperability of medical devices and the implications of such state for the safety and effectiveness of such medical devices.

(b) CONTENTS.—The report described in subsection (a) shall include—

(1) a review of existing medical device interoperability standards and the extent to which such standards have been adopted, including—

(A) whether medical device interoperability standards included in the Recognized Consensus Standards Database of the Food and Drug Administration were widely adopted by the medical device industry upon inclusion in the Database;

(B) a discussion of how adoption of interoperability standards for medical devices support patient access to data, home-based care, telemedicine, and data sharing among devices used in the clinical setting;

(C) a comparison of the standards used for device interoperability with the standards used for other aspects of clinical care, such as standards to ensure the security of health information and standards to support interoperability among electronic health record systems;

(D) an assessment of the ability of patients to obtain standard data from the devices they use, and the associated standards used to facilitate access to such data; and

(E) an analysis of the cost burden on health care providers, the medical device industry, and other entities associated with the adoption of medical device interoperability standards;

(2) recommendations to improve adoption of device interoperability standards, including any needed guidance, regulatory or statutory changes, or incentives for such adoption; and

(3) a summary of recommendations or information submitted to the Commissioner by stakeholders under subsection (c).

(c) STAKEHOLDER COMMENT.—Not later than 180 days prior to the submission of the report under subsection (a), the Commissioner shall consult with representatives of regulated industry groups, patient groups, academia, and other interested parties to obtain recommendations or information relevant to the report.