

115TH CONGRESS
1ST SESSION

H. R. 3985

To establish a working group of public and private entities led by the Food and Drug Administration to recommend voluntary frameworks and guidelines to increase the security and resilience of Internet of Medical Things devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 5, 2017

Mr. TROTT (for himself and Mrs. BROOKS of Indiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To establish a working group of public and private entities led by the Food and Drug Administration to recommend voluntary frameworks and guidelines to increase the security and resilience of Internet of Medical Things devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Internet of Medical
5 Things Resilience Partnership Act of 2017”.

1 **SEC. 2. STUDY ON THE SECURITY AND RESILIENCE OF CER-**
2 **TAIN MEDICAL DEVICES.**

3 (a) STUDY.—Not later than 5 months after the date
4 of enactment of this Act, the Commissioner of the Food
5 and Drug Administration, in consultation with the Na-
6 tional Institute of Standards and Technology, shall estab-
7 lish a working group of public and private entities to de-
8 velop recommendations for voluntary frameworks and
9 guidelines to increase the security and resilience of net-
10 worked medical devices sold in the United States that
11 store, receive, access, or transmit information to an exter-
12 nal recipient or system for which unauthorized access,
13 modification, misuse, or denial of use may result in patient
14 harm.

15 (b) WORKING GROUP.—

16 (1) IN GENERAL.—In developing the recommen-
17 dations under subsection (a), the Commissioner shall
18 seek input from a working group representing the
19 Federal Government, industry, and academia.

20 (2) CHAIRPERSON.—The Commissioner of the
21 Food and Drug Administration, or a designee of the
22 Commissioner, shall serve as the chairperson of the
23 working group established under paragraph (1).

24 (3) MEMBERSHIP.—Membership of the working
25 group shall include a representative from each of the
26 following:

1 (A) The Center for Devices and Radio-
2 logical Health of the Food and Drug Adminis-
3 tration.

4 (B) The Office of the National Coordinator
5 for Health Information Technology of the De-
6 partment of Health and Human Services.

7 (C) The Office of Technology Research
8 and Investigation of the Federal Trade Com-
9 mission.

10 (D) The Cybersecurity and Communica-
11 tions Reliability Division of the Federal Com-
12 munications Commission.

13 (E) The National Institute of Standards
14 and Technology of the Department of Com-
15 merce.

16 (F) The National Cyber Security Alliance.

17 (4) APPOINTED MEMBERS.—The chairperson
18 shall appoint to the working group a minimum of 3
19 qualified representatives from each of the following
20 private sector categories:

21 (A) Medical device manufacturers.

22 (B) Health care providers.

23 (C) Health insurance providers.

24 (D) Cloud computing.

25 (E) Wireless network providers.

1 (F) Enterprise security solutions systems.

2 (G) Health information technology.

3 (H) Web-based mobile application devel-
4 opers.

5 (I) Software developers.

6 (J) Hardware developers.

7 (c) REPORT.—Not later than 18 months after the
8 date of enactment of this Act, the Commissioner shall sub-
9 mit to Congress a report on the recommendations devel-
10 oped under subsection (a), including—

11 (1) an identification of existing cybersecurity
12 standards, guidelines, frameworks, and best prac-
13 tices that are applicable to mitigate vulnerabilities in
14 the devices described in subsection (a);

15 (2) an identification of existing and developing
16 international and domestic cybersecurity standards,
17 guidelines, frameworks, and best practices that miti-
18 gate vulnerabilities in such devices;

19 (3) a specification of high-priority gaps for
20 which new or revised standards are needed; and

21 (4) potential action plans by which such gaps
22 can be addressed.

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