To amend the Federal Food, Drug, and Cosmetic Act to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 15, 2022

Mr. BURGESS introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, and for other purposes.

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

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Protecting and Transforming Cyber Health Care Act of 2022” or the “PATCH Act of 2022”.

5
SEC. 2. ENSURING CYBERSECURITY OF MEDICAL DEVICES.

(a) In General.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

“SEC. 524B. ENSURING CYBERSECURITY OF DEVICES.

“(a) In General.—For purposes of ensuring cybersecurity throughout the lifecycle of a cyber device, any person who submits a premarket submission for the cyber device shall include such information as the Secretary may require to ensure that the cyber device meets such cybersecurity requirements as the Secretary determines to be appropriate to demonstrate a reasonable assurance of safety and effectiveness, including at a minimum the cybersecurity requirements under subsection (b). The Secretary may establish exemptions to the requirements under this subsection.

“(b) Cybersecurity Requirements.—At a minimum, the manufacturer of a cyber device shall meet the following cybersecurity requirements:

“(1) The manufacturer shall have a plan to appropriately monitor, identify, and address in a reasonable time postmarket cybersecurity vulnerabilities and exploits.

“(2) The manufacturer shall—

“(A) have a plan and procedures for a Coordinated Vulnerability Disclosure to be part of
submissions to the Food and Drug Administra-
tion; and

“(B) collect and maintain such other infor-
information as the Secretary may (by order pub-
lished in the Federal Register or by other proc-
ess) require to demonstrate a reasonable assurance of the safety and effectiveness of the cyber
device.

“(3) The manufacturer shall design, develop,
and maintain processes and procedures to make
available updates and patches to the cyber device
and related systems throughout the lifecycle of the
cyber device to address—

“(A) on a reasonably justified regular
cycle, known unacceptable vulnerabilities; and

“(B) as soon as possible out of cycle, crit-
ical vulnerabilities that could cause uncontrolled
risks.

“(4) The manufacturer shall furnish to the Sec-
retary a software bill of materials, including com-
cmercial, open-sourced, and off-the-shelf software
components that will be provided to users.

“(e) SUBSTANTIAL EQUIVALENCE.—In making a de-
termination of substantial equivalence under section
513(i) for a cyber device, the Secretary may—
“(1) find that cybersecurity information for the 
cyber device described in the relevant premarket 
submission in the cyber device’s use environment is 
inadequate; and

“(2) issue a nonsubstantial equivalence deter-
mination based on this finding.

“(d) DEFINITION.—In this section:

“(1) The term ‘cyber device’ means a device 
that—

“(A) includes software; or

“(B) is intended to connect to the internet.

“(2) The term ‘lifecycle of the cyber device’ in-
cludes the postmarket lifecycle of the cyber device.

“(3) The term ‘premarket submission’ means 
any submission under section 510(k), 513, 515(e), 
515(f), or 520(m).”.

(b) PROHIBITED ACT.—Section 301(q) of the Fed-
eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)) 
is amended by adding at the end the following:

“(3) The failure to comply with any requirement 
under section 524B (relating to ensuring the cybersecu-
ritiy).”.

(e) ADULTERATION.—Section 501 of the Federal 
Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
ed by inserting after paragraph (j) the following:
“(k) If it is a device with respect to which the sponsor
is in violation of section 524B (relating to ensuring cyber-
security).”.

(d) MISBRANDING.—Section 502(t) of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is
amended—

(1) by striking “or (3)” and inserting “(3)”;

and

(2) by inserting before the period at the end the
following: “, or (4) to furnish a software bill of ma-
terials as required under section 524B (relating to
ensuring the cybersecurity)”.

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