

113TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.

IN THE SENATE OF THE UNITED STATES

Mr. BENNET (for himself and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.

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 “Medical Electronic
5 Data Technology Enhancement for Consumers’ Health
6 Act” or the “MEDTECH Act”.

7 **SEC. 2. REGULATION OF MEDICAL SOFTWARE.**

8 Section 520 of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 360j) is amended by adding at the end
10 the following:

1 “(o) REGULATION OF PATIENT RECORDS AND CER-
2 TAIN DECISION SUPPORT SOFTWARE.—

3 “(1) IN GENERAL.—The following are not de-
4 vices within the meaning of section 201(h):

5 “(A) Software that is intended solely for
6 administrative or operational support of a
7 health care facility or the processing and main-
8 tenance of financial records within a health care
9 setting.

10 “(B) Products that are intended for use in
11 activities unrelated to the clinical treatment of
12 a disease or disorder and that are for the pur-
13 pose of maintaining health and conditioning.

14 “(C) Electronic patient records created,
15 stored, transferred, or reviewed by health care
16 professionals or individuals working under su-
17 pervision of such professionals that functionally
18 represent a medical chart, including patient his-
19 tory records, but excluding diagnostic image
20 data, provided that software designed for use in
21 maintaining such patient records is validated
22 prior to marketing, consistent with the stand-
23 ards for software validation relied upon by the
24 Secretary in reviewing premarket submissions
25 for devices.

1 accessory, of a device subject to regulation
2 under this Act; or

3 “(ii) as of the date of enactment of
4 this subsection, is regulated or subject to
5 regulation as a device classified as a class
6 II or class III device or has the same func-
7 tion as a component or accessory of a de-
8 vice subject to regulation under this Act.

9 “(2) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed as limiting the au-
11 thority of the Secretary to exercise enforcement dis-
12 cretion as to any device subject to regulation under
13 this Act.”.