



S.L.C.

AMENDMENT NO. Bennet Amendment #2 Calendar No. _____

Purpose: To provide for the development of a strategy and implementation plan with respect to appropriate interactions between medical device regulations and health information technology hardware and software, including medical mobile applications.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Bennet + Mr. Hatch

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . MOBILE MEDICAL APPLICATIONS.**

3 (a) **LIMITATION.**—Notwithstanding any other provi-
4 sion of law, the Food and Drug Administration Medical
5 Mobile Applications Draft Guidance shall not have effect
6 until September 30, 2013.

7 (b) **STRATEGY AND PLAN.**—Not later than March 1,
8 2013, the Secretary of Health and Human Services (re-

1 ferred to in this section as the “Secretary”), in coordina-
2 tion with the Commissioner of Food and Drugs and the
3 National Coordinator of Health Information Technology,
4 shall develop and submit to the appropriate committees
5 of Congress, a strategy and implementation plan on the
6 appropriate interaction between medical device regulation
7 and health information technology hardware and software,
8 including medical mobile applications.

9 (c) WORKING GROUP FOR STAKEHOLDER INPUT.—

10 In carrying out subsection (b), the Secretary shall—

11 (1) convene a working group of external stake-
12 holders and experts, as determined appropriate by
13 the Secretary, to provide appropriate input in the
14 strategy and implementation plan required in this
15 section; and

16 (2) conduct no fewer than 3 public meetings in
17 diverse geographical areas of the United States to
18 provide individuals in different regions an oppor-
19 tunity to comment.