

**Amendment to the Amendment in the Nature of a Substitute to H.R. 3
Offered by Mr. Schweikert**

The amendment creates a medication adherence pilot program.

AMENDMENT

OFFERED BY MR. SCHWEIKERT OF ARIZONA

Add at the end the following (and conform the table of contents accordingly):

1 **TITLE _____—MISCELLANEOUS**

2 **SEC. ____ . MEDICATION ADHERENCE TASK FORCE.**

3 (a) IN GENERAL.—Not later than 90 days after the
4 date of the enactment of this Act, the Secretary of Health
5 and Human Services shall establish a medication adher-
6 ence task force for purposes of evaluating the use of medi-
7 cation adherence devices and the impact of the use of such
8 devices on medication adherence rates of individuals diag-
9 nosed with conditions identified by the Director of the
10 Centers for Disease Control and Prevention as having im-
11 proved health outcomes for such individuals who adhere
12 to prescribed treatments.

13 (b) COMPOSITION.—The task force described in sub-
14 section (a) shall consist of the following members:

15 (1) 1 representative from the Food and Drug
16 Administration.

17 (2) 1 representative from the National Insti-
18 tutes of Health.

1 (3) 1 representative from the Centers for Medi-
2 care & Medicaid Services.

3 (4) 1 representative from a self-insured group
4 health plan.

5 (5) 1 representative from the Centers for Dis-
6 ease Control and Prevention.

7 (6) 10 representatives with expertise on such
8 devices appointed by the Secretary.

9 (c) REPORT.—Not later than 180 days after the date
10 of the enactment of this Act, the task force shall submit
11 to the Secretary a report containing an evaluation of the
12 use of medication adherence devices and the impact of the
13 use of such devices on medication adherence rates of indi-
14 viduals.

15 **SEC. ____ . MEDICAL DEVICE INNOVATION PILOT PRO-**
16 **GRAM.**

17 (a) IN GENERAL.—Not later than 180 days after the
18 date of the enactment of this Act, the Secretary of Health
19 and Human Services shall establish a medical device inno-
20 vation pilot program to monitor prescription drug treat-
21 ment adherence through use of such devices for individuals
22 with 1 or more of up to 5 chronic conditions identified
23 by the Director of the Centers for Disease Control and
24 Prevention as having improved health outcomes linked to
25 the adherence of such individuals with such treatments.

1 (b) GOALS.—The goals of the program established
2 under subsection (a) are—

3 (1) to demonstrate—

4 (A) potential benefits of medication adher-
5 ence technology that is repeatable and scalable
6 across disease states of different sizes and com-
7 plexity; and

8 (B) the safety, reliability, and effectiveness
9 of physician remote monitoring;

10 (2) to facilitate the adoption of advanced medi-
11 cation adherence technology; and

12 (3) to demonstrate protocols and standards that
13 allow for increased medication adherence, moni-
14 toring, and adjustment technologies and validation
15 of the cost savings and health outcomes improve-
16 ments.

17 (c) DEVICE CRITERIA.—The medical devices de-
18 scribed in subsection (a), in accordance with Federal Food
19 and Drug Administration regulations, shall include the fol-
20 lowing features:

21 (1) A tamper-proof and lockable design which
22 contains—

23 (C) tamper-evident sensors that report to a
24 patient's physician or pharmacy in the event of

1 a breach in order to prevent untimely and un-
2 authorized access to medication; and

3 (D) shut down capability in the event of
4 patient non-compliance.

5 (2) A medication distribution capability only ac-
6 cessible through a proprietary identification method
7 in order to—

8 (A) track the chain of custody and inven-
9 tory of each prescription;

10 (B) identify medications within the device
11 using a weight sensing mechanism;

12 (C) initiate follow-up protocol if medication
13 is not dispensed within predetermined time pe-
14 riod of dose notification; and

15 (D) ensure end to end encryption to secure
16 sensitive information.

17 (3) A system that collects data from patients
18 and providers and includes the following features:

19 (A) Patient alerting including response,
20 dispense, and medication removal time.

21 (B) Information relating to potential con-
22 tributing factors such as demographics and dis-
23 ease.

24 (C) Device diagnostics for both individual
25 and population data including patient medica-

1 tion refill reports in compliance with applicable
2 regulations.

3 (D) Medication information such as the
4 brand, manufacturer, batch number, and expi-
5 ration date of medication.

6 (E) Prescription information such as the
7 duration of treatment and dosage.

8 (F) Inventory and preferred pharmacy con-
9 tact information.

10 (4) A remote physician portal access and con-
11 trol system to enable variable control and prescrip-
12 tion creation.

13 (d) GRANTS UNDER PROGRAM.—The Secretary, not
14 later than 1 year after the date of enactment of this Act,
15 shall begin to award grants from the Centers for Medicare
16 & Medicaid Services Program Management Account on a
17 competitive basis for purposes of monitoring the effective-
18 ness of medication adherence devices described in sub-
19 section (a). Applicants for such a grant shall—

20 (1) submit to the Secretary an application for
21 a grant such time and containing such information
22 as the Secretary may require; and

23 (2) agree to follow applicable best practices
24 identified by the Secretary, in consultation with in-
25 dustry entities and institutions of higher education,

1 to evaluate the effectiveness of such devices and to
2 ensure that—

3 (A) best practices relating to use of such
4 devices are made public; and

5 (B) nonidentifying data relating to the use
6 of such devices is made public in a transparent
7 format.

8 (e) REPORT.—Not later than 2 years after the date
9 of the enactment of this Act, and annually thereafter
10 through the duration of the pilot program, the Secretary
11 shall submit to Congress a report describing the progress
12 of the program and recommendations relating to the use
13 of devices described in subsection (a).

