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):

TITLE _____—MISCELLANEOUS

SEC. _____. MEDICATION ADHERENCE TASK FORCE.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish a medication adherence task force for purposes of evaluating the use of medication adherence devices and the impact of the use of such devices on medication adherence rates of individuals diagnosed with conditions identified by the Director of the Centers for Disease Control and Prevention as having improved health outcomes for such individuals who adhere to prescribed treatments.

(b) COMPOSITION.—The task force described in subsection (a) shall consist of the following members:

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

(2) 1 representative from the National Institutes of Health.

(3) 1 representative from the Centers for Medicare & Medicaid Services.

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

(5) 1 representative from the Centers for Disease Control and Prevention.

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

(c) REPORT.—Not later than 180 days after the date of the enactment of this Act, the task force shall submit to the Secretary a report containing an evaluation of the use of medication adherence devices and the impact of the use of such devices on medication adherence rates of individuals.

SEC. ____. MEDICAL DEVICE INNOVATION PILOT PROGRAM.

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

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

(1) to demonstrate—

(A) potential benefits of medication adherence technology that is repeatable and scalable across disease states of different sizes and complexity; and

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

(2) to facilitate the adoption of advanced medication adherence technology; and

(3) to demonstrate protocols and standards that allow for increased medication adherence, monitoring, and adjustment technologies and validation of the cost savings and health outcomes improvements.

(c) DEVICE CRITERIA.—The medical devices described in subsection (a), in accordance with Federal Food and Drug Administration regulations, shall include the following features:

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

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

a breach in order to prevent untimely and unauthorized access to medication; and

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

(2) A medication distribution capability only accessible through a proprietary identification method in order to—

(A) track the chain of custody and inventory of each prescription;

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

(C) initiate follow-up protocol if medication is not dispensed within predetermined time period of dose notification; and

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

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

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

(B) Information relating to potential contributing factors such as demographics and disease.

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

tion refill reports in compliance with applicable regulations.

(D) Medication information such as the brand, manufacturer, batch number, and expiration date of medication.

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

(F) Inventory and preferred pharmacy contact information.

(4) A remote physician portal access and control system to enable variable control and prescription creation.

(d) GRANTS UNDER PROGRAM.—The Secretary, not later than 1 year after the date of enactment of this Act, shall begin to award grants from the Centers for Medicare & Medicaid Services Program Management Account on a competitive basis for purposes of monitoring the effectiveness of medication adherence devices described in subsection (a). Applicants for such a grant shall—

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

(2) agree to follow applicable best practices identified by the Secretary, in consultation with industry entities and institutions of higher education,

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

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

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

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

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