

114TH CONGRESS
1ST SESSION

H. R. 4292

To provide for research and the testing of innovative health care delivery models to improve medication adherence, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2015

Mrs. NOEM (for herself and Mr. PASCRELL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for research and the testing of innovative health care delivery models to improve medication adherence, and for other purposes.

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 “Synchronization &
5 Nonadherence Correction (SYNC) Act of 2015”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Between one-half and two-thirds of patients
2 with chronic diseases in the United States do not
3 take medications as prescribed.

4 (2) Low rates of medication adherence result in
5 higher health care costs, reduced effectiveness of
6 health care treatments and regimens, negative health
7 effects for patients, and tens of thousands of deaths
8 on an annual basis.

9 (3) Medication adherence may be lowest among
10 patients with chronic diseases.

11 (4) Improving medication adherence would re-
12 duce unnecessary hospital admissions and emergency
13 room visits.

14 (5) Nonadherence is estimated to cost the
15 United States health care system over
16 \$100,000,000,000 each year.

17 (6) Improving medication adherence could im-
18 prove patient health outcomes, reduce health care
19 costs, and lead to productivity gains.

20 **SEC. 3. DEFINITIONS.**

21 In this Act:

22 (1) The term “applicable individual” means an
23 applicable individual (as defined in section
24 1115A(a)(4)(A) of the Social Security Act, 42

1 U.S.C. 1315(a)(4)(A)) who has been prescribed 2 or
2 more chronic care medications.

3 (2) The term “medication adherence” means a
4 patient taking medications according to the pre-
5 scribed dosage, time, frequency, and direction.

6 (3) The term “medication wastage” means,
7 with respect to a medication, a switch of the medica-
8 tion or strength of the medication within the same
9 therapeutic class that occurs before the expected re-
10 fill date.

11 (4) The term “persistence” means the act of
12 continuing treatment with a medication for the pre-
13 scribed duration.

14 (5) The term “primary nonadherence” means
15 the failure to pickup a newly prescribed medication
16 from a pharmacy.

17 (6) The term “Secretary” means the Secretary
18 of Health and Human Services.

19 (7) The term “synchronization” means the co-
20 ordination of medication refills for a patient taking
21 two or more chronic medications such that the pa-
22 tient’s medications are refilled on the same schedule
23 for a given time period.

1 **SEC. 4. NATIONAL RESEARCH AND REPORTING STRATEGY**
2 **FOR IMPROVED MEDICATION ADHERENCE.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services, acting through the Agency for
5 Healthcare Research and Quality, the Centers for Medi-
6 care & Medicaid Services, the Health Resources and Serv-
7 ices Administration, the Director of the National Insti-
8 tutes of Health, and the Director of the Centers for Dis-
9 ease Control and Prevention, and in coordination with the
10 Patient-Centered Outcomes Research Institute, shall con-
11 duct research and develop information to better inform de-
12 cisionmakers regarding medication adherence and medica-
13 tion persistence, and methods to improve medication ad-
14 herence and persistence in Federal health programs.

15 (b) ACTIVITIES INCLUDED.—The activities described
16 in subsection (a) shall include development of annual sta-
17 tistics on recommended medications, the rate of medica-
18 tion adherence, the rate of primary nonadherence, and the
19 rate of medication persistence for patients with chronic
20 diseases such as cardiovascular disease, hypertension, dia-
21 betes, autoimmune diseases, chronic obstructive pul-
22 monary disease (COPD), and mental health conditions
23 treated under the following health care programs:

24 (1) MEDICARE.—The Medicare program under
25 title XVIII of the Social Security Act.

1 (2) MEDICAID.—The Medicaid program under
2 title XIX of such Act.

3 (3) FEHBP.—The Federal Employees Health
4 Benefit Program under chapter 89 of title 5, United
5 States Code.

6 (c) BIENNIAL REPORT ON MEDICATION ADHERENCE
7 AND MEDICATION PERSISTENCE.—Not later than 2 years
8 after the date of enactment of this Act (and annually
9 thereafter), the Secretary shall submit to Congress a re-
10 port on the statistics collected under subsection (a), to-
11 gether with recommendations for such legislation and ad-
12 ministrative action to address problems and improve medi-
13 cation adherence and medication persistence as the Sec-
14 retary determines appropriate.

15 **SEC. 5. TESTING MODELS FOR IMPROVING MEDICATION**
16 **ADHERENCE.**

17 (a) IN GENERAL.—The Secretary shall test innova-
18 tive health care delivery models, as described in sub-
19 sections (b) and (c), to improve medication adherence and
20 medication persistence, with the goal of improving health
21 outcomes and decreasing health costs for chronic care con-
22 ditions.

23 (b) MODELS TO TEST EFFICACY OF SYNCHRONI-
24 ZATION.—

1 (1) IN GENERAL.—The model described in this
2 subsection shall test the efficacy of synchronization
3 of prescription drug medications for applicable en-
4 rollees in improving medication adherence, deter-
5 mining cost avoidance, and improving outcomes for
6 those enrollees.

7 (2) PARTICIPATION.—An applicable enrollee
8 who is eligible to participate in the model testing
9 under this subsection shall participate in the model
10 testing, unless the enrollee elects not to participate
11 in the model.

12 (3) MODELS TESTED.—The following models of
13 synchronization shall be tested under this sub-
14 section:

15 (A) MODEL 1.—Synchronization (synchro-
16 nization of prescription drug medications and
17 medication reconciliation phone calls or elec-
18 tronic communication with enrollees prior to
19 filling prescriptions).

20 (B) MODEL 2.—Synchronization (as de-
21 scribed in subparagraph (A)) and compliance-
22 based packaging.

23 (C) MODEL 3.—Synchronization (as de-
24 scribed in subparagraph (A)) and ongoing phar-
25 macist counseling that shall occur at the pa-

1 tient’s request and include review of the appro-
2 priateness of the medication regimen and any
3 barriers to medication adherence.

4 (4) EVALUATION.—The Secretary shall evaluate
5 the models in paragraph (3) by collecting and ana-
6 lyzing relevant plan and enrollee data, including at
7 least the following:

8 (A) Synchronization enrollment and drop-
9 out rates.

10 (B) Primary medication nonadherence.

11 (C) Medication adherence and persistence
12 rates.

13 (D) Demographic characteristics of appli-
14 cable enrollees.

15 (E) Plan characteristics, such as plan ben-
16 efit design.

17 (F) Impact of the models on applicable en-
18 rollees who are—

19 (i) eligible for benefits under a State
20 plan under title XIX of the Social Secu-
21 rity; or

22 (ii) eligible for premium and cost-
23 sharing subsidies under section 1860D-
24 14(a) of the Social Security Act (42 U.S.C.
25 1395w-114(a)).

1 (G) Prescription drug claims data in com-
2 parison to other medical claims data for appli-
3 cable enrollees in order to examine the effect of
4 synchronization and adherence on overall health
5 spending, including health care costs avoided,
6 and patient outcomes.

7 (c) TESTING 90-DAY FILLS AT RETAIL PHARMACIES
8 FOR THE FIRST PRESCRIPTION.—

9 (1) IN GENERAL.—The Secretary shall conduct
10 a demonstration that compares the use of 90-day
11 first fills of prescriptions at retail pharmacies or
12 using mail-order for maintenance medications
13 against 30-day first fills for applicable enrollees
14 under part D of title XVIII of the Social Security
15 Act, to determine whether there is an impact on
16 medication persistence, cost avoidance, and improv-
17 ing outcomes for those enrollees in subsequent refill
18 periods.

19 (2) DRUGS TESTED.—The model under this
20 subsection shall only pertain to first fills for mainte-
21 nance drugs treating chronic diseases such as car-
22 diovascular disease, hypertension, diabetes, auto-
23 immune diseases, chronic obstructive pulmonary dis-
24 ease (COPD), and mental health conditions.

1 (3) EVALUATION OF DEMONSTRATION BY
2 GAO.—

3 (A) PROVISION OF DATA FOR EVALUA-
4 TION.—The Secretary shall make available to
5 the Comptroller General of the United States
6 relevant plan and enrollee data in order to en-
7 able an evaluation of the demonstration under
8 this subsection under subparagraph (B).

9 (B) EVALUATION.—Using data made avail-
10 able under subparagraph (A) and other relevant
11 data, the Comptroller General of the United
12 States shall evaluate the demonstration con-
13 ducted under this subsection. Such evaluation
14 shall examine the effect of long-term fills and
15 adherence on overall health spending, including
16 health care costs avoided, and patient outcome,
17 and shall examine at least the following in rela-
18 tion to part D enrollees using 90-day first fills
19 in comparison with those enrollees using 30-day
20 first fills:

21 (i) Medication adherence and persist-
22 ence rates.

23 (ii) Cost differentials in pharmacy
24 costs.

1 (iii) Prescription drug claims data in
2 comparison to other medical claims.

3 (iv) Medication wastage (as defined in
4 section 3).

5 (C) REPORT.—The Comptroller General
6 shall submit a report to the Secretary and Con-
7 gress on the evaluation conducted under this
8 paragraph.

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