

113TH CONGRESS
2^D SESSION

H. R. 5214

To require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2014

Mr. OLSON introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

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. RECOMMENDATIONS FOR DEVELOPMENT AND**
4 **USE OF CLINICAL DATA REGISTRIES.**

5 (a) IN GENERAL.—Not later than one year after the
6 date of the enactment of this Act, the Secretary of Health
7 and Human Services shall make recommendations for the
8 development and use, when appropriate, of clinical data

1 registries that are integrated with clinical practice guide-
2 lines and best practices or standards of care, including
3 registries designed to minimize duplication and burden on
4 those operating or reporting to such registries, for the im-
5 provement of patient care. The Secretary shall make such
6 recommendations available to the public by posting them
7 on a public Website of the Department of Health and
8 Human Services.

9 (b) SPECIFIC RECOMMENDATIONS.—Such rec-
10 ommendations, with respect to such registries, shall in-
11 clude the following:

12 (1) Recommendations for a set of standards
13 that, if adopted by such registries, would allow for
14 the bidirectional, interoperable exchange of informa-
15 tion between the electronic health records of the re-
16 porting clinicians and such registries.

17 (2) Recommendations on how clinical registries,
18 including outcomes-based registries, may be devel-
19 oped and then used to evaluate various care models
20 and methods, including improved clinical care co-
21 ordination, and the impact of such models and meth-
22 ods on the management of diseases as measured by
23 appropriate care parameters based on clinical prac-
24 tice guidelines and best practices (such as A1C,

1 blood pressure, and cholesterol levels in the case of
2 diabetes).

3 (3) Recommendations on how such registries
4 should be structured to facilitate the recording and
5 reporting of post-market data for the purposes of
6 monitoring safety and efficacy of FDA-approved de-
7 vices and drugs, reporting relevant clinical data to
8 satisfy attestation requirements for coverage of pre-
9 scribed devices and drugs, and better defining appro-
10 priate clinical use in support of evidence develop-
11 ment for the Medicare program (such as improving
12 patient access to safe and effective glucose moni-
13 toring systems and future glucose monitoring tech-
14 nologies).

15 (4) Recommendations on how data from such
16 registries may be used to inform physicians and
17 other health care professionals regarding clinical
18 practices for the prevention of diseases (such as dia-
19 betes and the precursor conditions of diabetes) and
20 appropriate methods for the dissemination of clinical
21 practice support tools and other educational re-
22 sources that may be derived from registry data.

23 (5) Recommendations for how registries can be
24 used to promote preventive health benefits such as
25 screenings and the Medicare annual wellness visits

1 that may reduce the risk of chronic diseases (such
2 as obesity, osteoporosis, cardiovascular disease, can-
3 cer, diabetes and their complications).

4 (c) CONSULTATION WITH CLINICAL EXPERTS.—The
5 Secretary shall consult with national medical specialty so-
6 cieties and with manufacturers of drugs and medical de-
7 vices in the development of such recommendations as they
8 relate to the diseases that they (or their manufactured
9 drugs or devices) manage and treat (such as with
10 endocrinologists with respect to recommendations relating
11 to diabetes and pre-diabetes conditions).

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