

[DISCUSSION DRAFT]113TH CONGRESS
2^D SESSION**H. R.** _____

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

Mr. OLSON introduced the following bill; which was referred to the Committee on _____

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

1 development and use of clinical data registries that are
2 integrated with clinical practice guidelines and best prac-
3 tices or standards of care for the improvement of patient
4 care. The Secretary shall make such recommendations
5 available to the public by posting them on a public Website
6 of the Department of Health and Human Services.

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

10 (1) Recommendations for a set of standards
11 that, if adopted, would allow for the bidirectional,
12 interoperable exchange of information between the
13 electronic health records of the reporting clinicians
14 and such registries.

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

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

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

21 (5) Recommendations for how registries can be
22 used to track utilization of preventive health benefits
23 and their impact, such as screenings and the Medi-
24 care annual wellness visits that may reduce the risk
25 of chronic diseases, such as obesity, osteoporosis,

1 cardiovascular disease, cancer, diabetes and their
2 complications.

3 (c) CONSULTATION WITH CLINICAL EXPERTS.—The
4 Secretary shall consult with national medical specialty so-
5 cieties in the development of such recommendations as
6 they relate to the diseases that they manage and treat
7 (such as with the American Association of Clinical
8 Endocrinologists with respect to recommendations relating
9 to diabetes and pre-diabetes conditions).