

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 5214
OFFERED BY MR. OLSON OF TEXAS**

Strike all after the enacting clause and insert the following:

1 **SECTION 1. RECOMMENDATIONS FOR DEVELOPMENT AND**
2 **USE OF CLINICAL DATA REGISTRIES.**

3 (a) **IN GENERAL.**—Not later than one year after the
4 date of the enactment of this Act, the Secretary of Health
5 and Human Services shall make recommendations for the
6 development and use, when appropriate, of clinical data
7 registries that are integrated with clinical practice guide-
8 lines and best practices or standards of care, including
9 recommendations designed to minimize duplication and
10 burden on those operating or reporting to such registries,
11 for the improvement of patient care. The Secretary shall
12 make such recommendations available to the public by
13 posting them on a public Website of the Department of
14 Health and Human Services.

15 (b) **SPECIFIC RECOMMENDATIONS.**—Such rec-
16 ommendations, with respect to such registries, shall in-
17 clude the following:

1 (1) Recommendations for a set of standards
2 that, if adopted by such registries, would allow for
3 the bidirectional, interoperable exchange of informa-
4 tion between the electronic health records of the re-
5 porting clinicians and such registries.

6 (2) Recommendations on how clinical registries,
7 including outcomes-based registries, may be devel-
8 oped and then used to evaluate various care models
9 and methods, including improved clinical care co-
10 ordination, and the impact of such models and meth-
11 ods on the management of diseases as measured by
12 appropriate care parameters based on clinical prac-
13 tice guidelines and best practices (such as A1C,
14 blood pressure, and cholesterol levels in the case of
15 diabetes).

16 (3) Recommendations on how such registries
17 should be structured to facilitate—

18 (A) the recording and reporting of post-
19 market data for the purposes of monitoring
20 safety and efficacy of FDA-approved devices
21 and drugs;

22 (B) the reporting of relevant clinical data
23 to satisfy attestation requirements for coverage
24 of prescribed devices; and

1 (C) coverage with evidence development
2 policies for devices under the Medicare program
3 (such as improving patient access to safe and
4 effective glucose monitoring systems).

5 (4) Recommendations on how data from such
6 registries may be used to inform physicians and
7 other health care professionals regarding clinical
8 practices for the prevention of diseases (such as dia-
9 betes and the precursor conditions of diabetes) and
10 appropriate methods for the dissemination of clinical
11 practice support tools and other educational re-
12 sources that may be derived from registry data.

13 (5) Recommendations for how registries can be
14 used to promote preventive health benefits such as
15 screenings and the Medicare annual wellness visits
16 that may reduce the risk of chronic diseases (such
17 as obesity, osteoporosis, cardiovascular disease, can-
18 cer, diabetes and their complications).

19 (c) CONSULTATION WITH CLINICAL EXPERTS.—The
20 Secretary shall consult with national medical specialty so-
21 cieties, patient groups, technology vendors, and developers
22 and manufacturers of drugs and medical devices in the
23 development of such recommendations as they relate to
24 the diseases that members of such societies manage and
25 treat (such as with endocrinologists with respect to rec-

1 ommendations relating to diabetes and pre-diabetes condi-
2 tions).

3 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion may be construed as—

5 (1) authorizing the Secretary of Health and
6 Human Services to take any action with regard to
7 the recommendations made under this section (other
8 than making such recommendations available to the
9 public in the manner described in subsection (a));

10 (2) limiting or interfering with the authority of
11 a health care practitioner to practice medicine or to
12 prescribe or administer a drug or device to an indi-
13 vidual for a condition or disease; or

14 (3) providing the Centers for Medicare & Med-
15 icaid Services with authority to limit (or to encour-
16 age other individuals or entities to limit) coverage
17 under the Medicare program under title XVIII of
18 the Social Security Act for an item or service fur-
19 nished to an individual on account of the participa-
20 tion, or lack of participation, of the individual in a
21 registry or other data collection system.

