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:

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

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall make recommendations for the development and use, when appropriate, of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care, including recommendations designed to minimize duplication and burden on those operating or reporting to such registries, for the improvement of patient care. The Secretary shall make such recommendations available to the public by posting them on a public Website of the Department of Health and Human Services.

(b) SPECIFIC RECOMMENDATIONS.—Such recommendations, with respect to such registries, shall include the following:

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

(2) Recommendations on how clinical registries, including outcomes-based registries, may be developed and then used to evaluate various care models and methods, including improved clinical care coordination, and the impact of such models and methods on the management of diseases as measured by appropriate care parameters based on clinical practice guidelines and best practices (such as A1C, blood pressure, and cholesterol levels in the case of diabetes).

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

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

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

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

(4) Recommendations on how data from such registries may be used to inform physicians and other health care professionals regarding clinical practices for the prevention of diseases (such as diabetes and the precursor conditions of diabetes) and appropriate methods for the dissemination of clinical practice support tools and other educational resources that may be derived from registry data.

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

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

ommendations relating to diabetes and pre-diabetes conditions).

(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed as—

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

(2) limiting or interfering with the authority of a health care practitioner to practice medicine or to prescribe or administer a drug or device to an individual for a condition or disease; or

(3) providing the Centers for Medicare & Medicaid Services with authority to limit (or to encourage other individuals or entities to limit) coverage under the Medicare program under title XVIII of the Social Security Act for an item or service furnished to an individual on account of the participation, or lack of participation, of the individual in a registry or other data collection system.