113TH CONGRESS
*2d Session*
HOUSE OF REPRESENTATIVES
REPORT
113–683

# 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

DECEMBER 22, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

# R E P O R T

[To accompany H.R. 5214]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5214) to require the Secretary of Health and Human Services to provide for recommendations for the development of patient care, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

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 recommendations 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.

## PURPOSE AND SUMMARY

H.R. 5214, a bill to streamline government recommendations related to the development of clinical data registries, was introduced

on July 28, 2014, by Representative Pete Olson (R–TX) and subsequently referred to the Committee on Energy and Commerce.

The legislation would require the Secretary of Health and Human Services (HHS) to provide for recommendations for the development and use of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care.

## BACKGROUND AND NEED FOR LEGISLATION

Clinical data registries present opportunities for the collection and dissemination of clinical data that can be used to improve the quality of care delivered, increase research and surveillance opportunities for treatments and services, and ease the burden of government and other payer requirements on developers and providers.

Many sub-agencies within HHS have rules that relate to the ways in which data registries can be used to facilitate reporting and other administrative requirements. Qualified clinical data registries (QCDR) are just one example and were included as an authorized reporting mechanism available for the Physician Quality Reporting System (PQRS) under the Medicare Physician Fee Schedule beginning in 2014.[1] A QCDR is a Centers for Medicare and Medicaid Services (CMS)-approved entity that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Unfortunately, these various sub-agencies do not always use the same requirements related to the collection, dissemination, and administration of registry data. Various payment rules and agency publications oftentimes can offer contradictory statements that needlessly increase the burden on those seeking to operate and employ registries. The Committee believes such duplication in many instances is unnecessary.

The legislation would seek to engage the Secretary in a process of disseminating information on a set of recommendations related to the form and function of registries. Such a process would force HHS and its sub-agencies to rethink the current piece-meal approach to registry requirements and facilitate greater transparency for policymakers to ensure government requirements are streamlined and efficient.

The Committee recognizes, however, that registries have various users, audiences, and purposes (as is evidenced by the multi-stakeholder developed Agency for Healthcare Research and Quality User Guide and the American Medical Association's National Quality Registry Network process). The Committee does not intend for this new requirement in the legislation to limit flexibility or stymie development of registries by forcing current innovation into a one-size-fits all registry approach. The Committee expects the Secretary will work to improve coordination without sacrificing innovation.

## HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

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[1] CMS, Physician Quality Reporting System *www.cms.gov*.

## COMMITTEE CONSIDERATION

On July 29 and 30, 2014, the full Committee met in open mark-up session and approved H.R. 5214, as amended, by a record vote of 25 yeas and 18 nays.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 5214, reported to the House, as amended, by a record vote of 25 yeas and 18 nays. The following reflects the record votes taken during the Committee consideration:

### COMMITTEE ON ENERGY AND COMMERCE—113TH CONGRESS

### ROLL CALL VOTE #47

*Bill: H.R. 5214, 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*

Amendment: A motion by Mr. Upton to order H.R. 5214 favorably reported to the House, as amended. (Final Passage), Disposition: Agreed to, by a roll call vote of 25 yeas and 18 nays

| REPRESENTATIVE | YEAS | NAYS | PRESENT | REPRESENTATIVE | YEAS | NAYS | PRESENT |
|---|---|---|---|---|---|---|---|
| Mr. Upton | X | | | Mr. Waxman | | X | |
| Mr. Hall | X | | | Mr. Dingell | | | |
| Mr. Barton | X | | | Mr. Pallone | | X | |
| Mr. Whitfield | | | | Mr. Rush | | | |
| Mr. Shimkus | X | | | Ms. Eshoo | | X | |
| Mr. Pitts | X | | | Mr. Engel | | X | |
| Mr. Walden | X | | | Mr. Green | | X | |
| Mr. Terry | X | | | Ms. DeGette | | X | |
| Mr. Rogers | | | | Mrs. Capps | | X | |
| Mr. Murphy | X | | | Mr. Doyle | | X | |
| Mr. Burgess | X | | | Ms. Schakowsky | | | |
| Mrs. Blackburn | X | | | Mr. Matheson | | X | |
| Mr. Gingrey | X | | | Mr. Butterfield | | X | |
| Mr. Scalise | | | | Mr. Barrow | | X | |
| Mr. Latta | X | | | Ms. Matsui | | | |
| Mrs. McMorris Rodgers | | | | Ms. Christensen | | | |
| Mr. Harper | X | | | Ms. Castor | | X | |
| Mr. Lance | X | | | Mr. Sarbanes | | X | |
| Mr. Cassidy | X | | | Mr. McNerney | | X | |
| Mr. Guthrie | X | | | Mr. Braley | X | | |
| Mr. Olson | X | | | Mr. Welch | | X | |
| Mr. McKinley | X | | | Mr. Lujan | | X | |
| Mr. Gardner | X | | | Mr. Tonko | | X | |
| Mr. Pompeo | | | | Mr. Yarmuth | | X | |
| Mr. Kinzinger | X | | | | | | |
| Mr. Griffith | X | | | | | | |
| Mr. Bilirakis | X | | | | | | |
| Mr. Johnson | X | | | | | | |
| Mr. Long | X | | | | | | |
| Mrs. Ellmers | | | | | | | |

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of the legislation is to streamline the various governmental reporting requirements related to clinical data registries for the purpose of supporting registry development and use by requiring the Secretary to publish one set of recommendations.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 5214 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the House of Representatives, the Committee finds that H.R. 5214 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
*Washington, DC, September 10, 2014.*

Hon. FRED UPTON,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

DEAR CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5214, 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.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Amber G. Marcellino.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

*H.R. 5214—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*

H.R. 5214 would require the Secretary of Health and Human Services to make recommendations for the development and use of clinical data registries for the improvement of patient care. The legislation would direct the Secretary to post such recommendations on the agency's website.

CBO estimates that implementing the bill would have no significant effect on spending subject to appropriation. Enacting H.R. 5214 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 5214 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budget of state, local, or tribal governments.

The CBO staff contact for this estimate is Amber G. Marcellino. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 5214 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program.

## DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 5214 would not direct specific rule making within the meaning of 5 U.S.C. 551.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Recommendations for development and use of clinical data registries*

Section 1 would require the Secretary of HHS to consult with clinical experts and make recommendations for the use of clinical data registries to improve patient care. Specifically, the bill directs the Secretary to include in the recommendations: (1) standards to allow exchange of information between electronic health records and registries, (2) how registries can be used to evaluate models

and methods of care, (3) how registries can be used to monitor the safety and efficacy of products approved by the Food and Drug Administration, (4) how registry data can inform health care professionals on the prevention of disease and how educational resources derived from registry data can be disseminated, and (5) how registries can promote preventive health care.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

This legislation does not amend any existing Federal statute.

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