

111TH CONGRESS  
1ST SESSION

# H. R. 2813

To establish a national knee and hip replacement registry.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 10, 2009

Mr. PASCRELL (for himself and Mr. DOGGETT) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To establish a national knee and hip replacement registry.

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. SHORT TITLE.**

4       This Act may be cited as the “National Knee and  
5       Hip Replacement Registry Act of 2009”.

6       **SEC. 2. ESTABLISHMENT.**

7       (a) IN GENERAL.—Not later than 3 years after the  
8       date of the enactment of this Act, the Secretary of Health  
9       and Human Services shall establish within the Agency for  
10      Healthcare Research and Quality a national knee and hip

1 replacement registry (referred to in this Act as the “reg-  
2 istry”) for the purpose of identifying predictors (including  
3 patient co-morbidities, conditions, and characteristics; fea-  
4 tures of the prostheses; and surgical technique) that may  
5 lead to poor outcomes in knee and hip replacement sur-  
6 geries in order to assist health care providers in medical  
7 and surgical decision-making, improve patient care and  
8 outcomes generally, detect poorly performing prostheses  
9 and surgical techniques, and reduce the number of knee  
10 and hip replacement revision surgeries required nation-  
11 wide.

12 (b) POLICIES AND PROCEDURES.—Such registry  
13 shall be subject to the policies and procedures developed  
14 under section 3(a).

15 **SEC. 3. KNEE AND HIP REPLACEMENT REGISTRY POLICIES**  
16 **AND PROCEDURES.**

17 (a) POLICIES AND PROCEDURES.—Not later than 3  
18 years after the date of the enactment of this Act, the Ad-  
19 ministrator of the Centers for Medicare and Medicaid  
20 Services, in coordination with the Director of the Agency  
21 for Healthcare Research and Quality, shall develop policies  
22 and procedures for the development and maintenance of  
23 the registry under section 2. The policies and procedures  
24 shall address—

- 1           (1) the scope of data collection to be conducted
- 2           by the registry to conform with the purpose of the
- 3           registry as defined in section 2;
- 4           (2) the core data set to be used by the registry;
- 5           (3) policies to be used by the registry to—
- 6                 (A) ensure scientific rigor in data collec-
- 7                 tion and analysis;
- 8                 (B) avoid bias in the analysis of data;
- 9                 (C) ensure that analysis of the data col-
- 10                lected can be generalizable to the population of
- 11                people getting knee and hip replacements;
- 12                (D) protect, to the extent practicable,
- 13                trade secrets of manufacturers of knee and hip
- 14                replacement prostheses and related products;
- 15                and
- 16                (E) protect patient privacy; and
- 17           (4) guidelines for data collection that—
- 18                 (A) incorporate, to the extent practicable,
- 19                 the recommendations and feedback of stake-
- 20                 holders, including—
- 21                         (i) orthopedic practitioners and pro-
- 22                         viders, such as hospitals, surgeons, nurses,
- 23                         and other practitioners and providers;

1 (ii) manufacturers of knee and hip re-  
2 placement prostheses and related products;  
3 and

4 (iii) patient and consumer groups;

5 (B) balance the importance and usefulness  
6 of potential findings resulting from the collec-  
7 tion of data by the registry with the feasibility  
8 and administrative burden on collecting such  
9 data;

10 (C) allow the registry to use, to the extent  
11 practicable, data that is collected through exist-  
12 ing Federal reporting requirements; and

13 (D) rely, to the extent practicable, on the  
14 voluntary submission of data on both Medicare  
15 and non-Medicare patients by practitioners and  
16 providers.

17 (b) INTERAGENCY COOPERATION.—In developing of  
18 the policies and procedures under subsection (a), the Ad-  
19 ministrator of the Centers for Medicare and Medicaid  
20 Services shall consult with the heads of the Agency for  
21 Healthcare Research and Quality, the Food and Drug Ad-  
22 ministration, the National Institutes of Health, and the  
23 Office of the National Coordinator for Health Information  
24 Technology.

1 **SEC. 4. ACTIVITIES OF THE REGISTRY.**

2 (a) DATA COLLECTION AND STORAGE.—Beginning  
3 not later than 5 years after the date of the enactment of  
4 this Act, the head of the registry shall collect and store  
5 data related to knee and hip replacements (including in-  
6 formation related to prosthetic devices and surgical proce-  
7 dures consistent with the policies and procedures under  
8 section 3(a) in the registry established under subsection  
9 (a) of section 2).

10 (b) DATA ANALYSIS.—The head of the registry shall  
11 conduct data analysis to fulfil the purpose of the registry  
12 under section 2.

13 (c) ACCESS TO DATA.—

14 (1) PROVISION OF DATA TO PROVIDERS.—At  
15 least one time per year, beginning not later than 6  
16 years after the date of enactment of this Act, the  
17 head of the registry shall provide data to health care  
18 providers to allow them to evaluate their perform-  
19 ance, relative to their peers, in—

20 (A) conducting knee and hip replacement  
21 surgeries; and

22 (B) providing care related to such sur-  
23 geries.

24 (2) PROVISION OF DATA TO MANUFACTUR-  
25 ERS.—At least one time per year, beginning not  
26 later than 7 years after the date of the enactment

1 of this Act, the head of the registry shall provide  
2 data to manufacturers of knee and hip replacement  
3 prostheses and related products to allow such manu-  
4 facturers to evaluate the safety and performance of  
5 their products relative to similar products available  
6 on the market.

7 (3) USE OF REGISTRY BY RESEARCHERS.—The  
8 head of the registry shall develop a process to allow  
9 outside researchers to apply to use individually iden-  
10 tifiable data that is contained in the registry to con-  
11 duct longitudinal studies consistent with the purpose  
12 of the registry under section 2.

13 (d) COORDINATION WITH FDA, NIH, AND OTHER  
14 HHS ENTITIES.—To avoid duplication in data collection  
15 and analysis, the head of the registry shall coordinate ac-  
16 tivities of the registry with—

17 (1) comparative effectiveness research con-  
18 ducted by—

19 (A) the Agency for Healthcare Research  
20 and Quality;

21 (B) the National Institutes of Health; and

22 (C) the Office of the Secretary of Health  
23 and Human Services; and

24 (2) postmarket surveillance activities conducted  
25 by the Food and Drug Administration.

1 (e) COLLECTION OF REGISTRY INFORMATION FROM  
2 FEDERAL DEPARTMENTS AND AGENCIES.—

3 (1) REQUESTS BY THE REGISTRY.—The head  
4 of the registry may request data from Federal de-  
5 partments and agencies if the collection of such data  
6 by the entity established under section 2 conforms  
7 with the policies and procedures under section 3.

8 (2) AGENCY OBLIGATIONS.—Federal depart-  
9 ments and agencies shall provide relevant data to  
10 the registry at the request of the head of the reg-  
11 istry under paragraph (1).

12 (f) PUBLIC FEEDBACK.—Not later than 2 years after  
13 beginning to collect data under subsection (a) and at the  
14 end of each subsequent 2-year period, in order to enhance  
15 the registry’s ability to achieve the purpose of the registry  
16 under section 2 and update policies and procedures under  
17 section 3, the head of the registry, in consultation with  
18 the Center for Medicare and Medicaid Services, the Food  
19 and Drug Administration, the Agency for Healthcare Re-  
20 search and Quality, the Office of the National Coordinator  
21 of Health Information Technology, and the National Insti-  
22 tutes of Health shall seek feedback from—

23 (1) orthopedic providers, such as hospitals, sur-  
24 geons, nurses, and other practitioners;

- 1           (2) manufacturers of knee and hip replacement
- 2       prostheses and related products;
- 3           (3) patient and consumer groups; and
- 4           (4) public health experts and epidemiologist.

5       (g) PUBLIC REPORT.—Beginning not later than six  
6 years after enactment, the head of the registry shall pub-  
7 lish and make publically available an annual report that  
8 contains—

- 9           (1) an overview of the data collected by under
- 10       subsection (a);
- 11           (2) the findings resulting from any analysis of
- 12       such data conducted by the registry; and
- 13           (3) any other information that the head of the
- 14       registry determines is appropriate.

15 **SEC. 5. SAFETY MONITORING AND REPORTING.**

16       (a) SAFETY MONITORING.—The Agency for  
17 Healthcare Research and Quality and the Food and Drug  
18 Administration shall use the data in the registry and any  
19 analysis of such data conducted by the registry or by other  
20 entities to monitor and evaluate the safety of knee and  
21 hip replacement procedures and devices.

22       (b) REPORT.—Not later than 6 years after the date  
23 of the enactment of this Act and annually thereafter, the  
24 Agency for Healthcare Research and Quality, in consulta-  
25 tion with Food and Drug Administration, shall submit a

1 report to the Secretary of Health and Human Services and  
 2 Congress containing recommendations on changes in pol-  
 3 icy and health care provider practices that could enhance  
 4 the safety of knee and hip replacements.

5 **SEC. 6. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
 6 **COLLECTION OF INFORMATION FROM PRO-**  
 7 **VIDERS AND OTHER ENTITIES.**

8 (a) MODIFICATION OF REQUIRED DATA.—The Sec-  
 9 retary of Health and Human Services may modify the in-  
 10 formation required to be reported under administrative  
 11 data sets under title XVIII of the Social Security Act (42  
 12 U.S.C. 1395 et seq.) (including data that is required to  
 13 be submitted by Medicare Advantage organizations and  
 14 quality improvement organizations) to the extent the Sec-  
 15 retary, in consultation with the head of the registry, deter-  
 16 mines that the modification would result in the reporting  
 17 of information that would be useful in carrying out the  
 18 purpose of the registry under section 2.

19 (b) CONDITION OF PARTICIPATION.—In the case that  
 20 two consecutive reports submitted under section 7(a) con-  
 21 clude that the level of provider participation in the registry  
 22 is insufficient to achieve the purpose of the registry under  
 23 section 2, the Secretary of Health and Human Services  
 24 may require providers of services (as defined under section  
 25 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)))

1 and physicians and other suppliers (as defined in sub-  
2 sections (r) and (d) of section 1861 of the Social Security  
3 Act (42 U.S.C. 1395x(r) and (d)), respectively) to report  
4 relevant information directly to the registry as a condition  
5 of participation in the Medicare program under section  
6 1866 and 1842(h) of the Social Security Act (42 U.S.C.  
7 1395cc and 42 U.S.C. 1395u(h)), respectively.

8 **SEC. 7. OVERSIGHT OF THE REGISTRY.**

9 (a) IN GENERAL.—Not later than 1 year after the  
10 date the registry begins collecting data under section 4(a)  
11 and the end of each subsequent 2-year period, the Comp-  
12 troller General of the United States shall submit to Con-  
13 gress a report on the progress of the registry in achieving  
14 the purposes of the registry under section 2.

15 (b) INFORMATION ON PROVIDER PARTICIPATION.—  
16 The report under subsection (a) shall include information  
17 on the number of providers participating in the registry  
18 and an analysis of whether that level of provider participa-  
19 tion is sufficient to achieve the purposes of the registry  
20 under section 2.

21 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS.**

22 There is authorized to be appropriated to carry out  
23 this Act, such sums as are necessary for fiscal years 2010  
24 through 2019.

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