

110TH CONGRESS
1ST SESSION

S. _____

To amend title XVIII of the Social Security Act to provide for the reporting of sales price data for implantable medical devices.

IN THE SENATE OF THE UNITED STATES

Mr. GRASSLEY (for himself and Mr. SPECTER) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend title XVIII of the Social Security Act to provide for the reporting of sales price data for implantable medical devices.

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 “Transparency in Med-
5 ical Device Pricing Act of 2007”.

1 **SEC. 2. REPORTING OF SALES PRICE DATA FOR**
2 **IMPLANTABLE MEDICAL DEVICES.**

3 Title XVIII of the Social Security Act (42 U.S.C.
4 1395 et seq.) is amended by adding at the end the fol-
5 lowing new section:

6 **“SEC. 1898. REPORTING OF SALES PRICE DATA FOR**
7 **IMPLANTABLE MEDICAL DEVICES.**

8 **“(a) COLLECTION OF SALES PRICE DATA.—**

9 **“(1) QUARTERLY REPORTS FROM MANUFAC-**
10 **TURERS OF COVERED MEDICAL DEVICES.—**Not later
11 than the date that is 30 days after the last day of
12 each fiscal year quarter beginning on or after Janu-
13 ary 1, 2009, in the case of a covered medical device
14 that is used in a procedure identified under sub-
15 section (b), each manufacturer of such device shall
16 submit to the Secretary, in such form as the Sec-
17 retary shall require, the following:

18 **“(A) The name of the manufacturer of the**
19 **covered medical device.**

20 **“(B) The name of the covered medical de-**
21 **vice.**

22 **“(C) The category type of the covered**
23 **medical device (using a nomenclature specified**
24 **by the Secretary for categorizing medical de-**
25 **vices in order to ensure consistent reporting).**

1 “(D) The hospital inpatient procedure or
2 hospital outpatient procedure identified under
3 subsection (b) with respect to which the medical
4 device was used during the quarter.

5 “(E) The average and median sales price
6 of the covered medical device.

7 “(F) Such other information as the Sec-
8 retary requires, including the unit of measure
9 used to determine the number of medical de-
10 vices sold by the manufacturer.

11 “(2) PENALTIES FOR NONCOMPLIANCE.—

12 “(A) FAILURE TO SUBMIT INFORMA-
13 TION.—Any manufacturer of a covered medical
14 device that fails to submit information required
15 under paragraph (1) in accordance with regula-
16 tions promulgated to carry out such paragraph,
17 shall be subject to a civil money penalty of not
18 less than \$10,000, but not more than
19 \$100,000, for each such failure.

20 “(B) MISREPRESENTATION.—Any manu-
21 facturer of a covered medical device that mis-
22 represents the average or median sales price of
23 such device in information submitted under
24 paragraph (1) shall be subject to a civil money
25 penalty of not less than \$10,000, but not more

1 than \$100,000, for each such misrepresentation
2 and for each day in which such misrepresented
3 average or median sales price is made publicly
4 available under subsection (c).

5 “(C) IMPOSITION AND COLLECTION.—A
6 penalty under subparagraph (A) or (B) shall be
7 imposed and collected in the same manner as
8 civil money penalties under subsection (a) of
9 section 1128A are imposed and collected under
10 that section.

11 “(3) DEFINITIONS.—In this section:

12 “(A) AVERAGE SALES PRICE.—

13 “(i) IN GENERAL.—Subject to clauses
14 (ii) and (iii), the term ‘average sales price’
15 means, of a covered medical device for a
16 fiscal year quarter for a manufacturer for
17 a unit—

18 “(I) the manufacturer’s sales to
19 all purchasers (excluding sales ex-
20 empted in clause (ii)) in the United
21 States for such covered medical device
22 in the quarter; divided by

23 “(II) the total number of such
24 units of such covered medical device

1 sold by the manufacturer in such
2 quarter.

3 “(ii) CERTAIN SALES EXEMPTED
4 FROM COMPUTATION.—In calculating the
5 manufacturer’s average sales price under
6 this subparagraph, certain sales may be ex-
7 cluded in the case where the Secretary de-
8 termines such exclusion is appropriate.

9 “(iii) SALE PRICE NET OF DIS-
10 COUNTS.—In calculating the manufactur-
11 er’s average sales price under this subpara-
12 graph, such price shall include volume dis-
13 counts, cash discounts, free goods and
14 services that are contingent on any pur-
15 chase requirement, chargebacks, and re-
16 bates, and any other discounts or price
17 concessions the Secretary determines to be
18 appropriate (using a methodology devel-
19 oped by the Secretary to estimate costs
20 during the quarter that are attributable to
21 discounts and price concessions).

22 “(B) COVERED MEDICAL DEVICE.—The
23 term ‘covered medical device’ means any device
24 for which payment is available under title

1 XVIII or a State plan under title XIX or XXI
2 (or a waiver of such a plan).

3 “(C) MEDIAN SALES PRICE.—

4 “(i) IN GENERAL.—Subject to clauses
5 (ii) and (iii), the term ‘median sales price’
6 means, of a covered medical device for a
7 fiscal year quarter for a manufacturer for
8 a unit, the median of all sales by the man-
9 ufacturer to purchasers (excluding sales
10 exempted in clause (ii)) in the United
11 States for such covered medical device in
12 the quarter.

13 “(ii) CERTAIN SALES EXEMPTED
14 FROM COMPUTATION.—In calculating the
15 manufacturer’s median sales price under
16 this subparagraph, certain sales may be ex-
17 cluded in the case where the Secretary de-
18 termines such exclusion is appropriate.

19 “(iii) SALE PRICE NET OF DIS-
20 COUNTS.—In calculating the manufactur-
21 er’s median sales price under this subpara-
22 graph, such price shall include volume dis-
23 counts, cash discounts, free goods and
24 services that are contingent on any pur-
25 chase requirement, chargebacks, and re-

1 bates, and any other discounts or price
2 concessions the Secretary determines to be
3 appropriate (using a methodology devel-
4 oped by the Secretary to estimate costs
5 during the quarter that are attributable to
6 discounts and price concessions).

7 “(b) IDENTIFICATION OF PROCEDURES.—For pur-
8 poses of subsection (a), the Secretary shall identify—

9 “(1) all hospital inpatient procedures for which
10 payment is provided under section 1886(d) that in-
11 volve the implantation of a medical device; and

12 “(2) all hospital outpatient procedures for
13 which payment is provided under section 1833(t)
14 that involve the implantation of a medical device.

15 “(c) PUBLIC AVAILABILITY.—Not later than April
16 30, 2009, the Secretary shall establish procedures to en-
17 sure that the information reported under subsection (a)
18 is readily accessible to the public through the Internet
19 website of the Centers for Medicare & Medicaid Services
20 in a manner that is easily searchable, downloadable, and
21 understandable. Such procedures shall ensure that the
22 website is updated each quarter as new information is re-
23 ported under such subsection.”.