

110TH CONGRESS
2D SESSION

S. _____

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

IN THE SENATE OF THE UNITED STATES

Mr. GRASSLEY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

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 “Physician Payments
5 Sunshine Act of 2008”.

1 **SEC. 2. TRANSPARENCY REPORTS AND REPORTING OF**
2 **PHYSICIAN OWNERSHIP OR INVESTMENT IN-**
3 **TERESTS.**

4 Part A of title XI of the Social Security Act (42
5 U.S.C. 1301 et seq.) is amended by inserting after section
6 1128F the following new section:

7 **“SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING**
8 **OF PHYSICIAN OWNERSHIP OR INVESTMENT**
9 **INTERESTS.**

10 “(a) TRANSPARENCY REPORTS.—

11 “(1) PAYMENTS OR OTHER TRANSFERS OF
12 VALUE.—Except as provided in subsection (e), on
13 March 31, 2011, and the 90th day of each calendar
14 year beginning thereafter, each applicable manufac-
15 turer that provides a payment or other transfer of
16 value to a covered recipient (or to an entity or indi-
17 vidual at the request of or designated on behalf of
18 a covered recipient), shall submit to the Secretary,
19 in such electronic form as the Secretary shall re-
20 quire, the following information with respect to the
21 preceding calendar year:

22 “(A) The name of the covered recipient.

23 “(B) The city and State in which the cov-
24 ered recipient is located.

25 “(C) The value of the payment or other
26 transfer of value.

1 “(D) The date on which the payment or
2 other transfer of value was provided to the cov-
3 ered recipient.

4 “(E) A description of the form of the pay-
5 ment or other transfer of value, indicated (as
6 appropriate for all that apply) as—

7 “(i) cash or a cash equivalent;

8 “(ii) in-kind items or services;

9 “(iii) stock, a stock option, or any
10 other ownership interest, dividend, profit,
11 or other return on investment; or

12 “(iv) any other form of payment or
13 other transfer of value (as defined by the
14 Secretary).

15 “(F) A description of the reason for the
16 payment or other transfer of value, indicated
17 (as appropriate for all that apply) as—

18 “(i) consulting fees;

19 “(ii) compensation for services other
20 than consulting;

21 “(iii) honoraria;

22 “(iv) gift;

23 “(v) entertainment;

24 “(vi) food;

25 “(vii) travel;

1 “(viii) education;

2 “(ix) research;

3 “(x) charitable contribution;

4 “(xi) royalty or license;

5 “(xii) ownership; or

6 “(xiii) any other reason for the pay-

7 ment or other transfer of value (as defined

8 by the Secretary).

9 “(G) Any other categories of information
10 regarding the payment or other transfer of
11 value the Secretary determines appropriate.

12 “(2) PHYSICIAN OWNERSHIP.—In addition to
13 the requirement under paragraph (1), on March 31,
14 2011, and the 90th day of each calendar year begin-
15 ning thereafter, each applicable manufacturer, appli-
16 cable distributor, and applicable group purchasing
17 organization, shall submit to the Secretary, in such
18 electronic form as the Secretary shall require, the
19 following information regarding any ownership or in-
20 vestment interest (other than an ownership or in-
21 vestment interest in a publicly traded security and
22 mutual fund, as described in section 1877(c)) held
23 by a physician in the applicable manufacturer, appli-
24 cable distributor, or applicable group purchasing or-
25 ganization during the preceding year:

1 “(A) The dollar amount invested by each
2 physician holding such an ownership or invest-
3 ment interest.

4 “(B) The value and terms of each such
5 ownership or investment interest.

6 “(C) Any payment or other transfer of
7 value provided to a physician holding such an
8 ownership or investment interest (or to an enti-
9 ty or individual at the request of or designated
10 on behalf of a physician holding such an owner-
11 ship or investment interest), including the infor-
12 mation described in subparagraphs (A) through
13 (G) of paragraph (1), except that in applying
14 such subparagraphs, ‘physician’ shall be sub-
15 stituted for ‘covered recipient’ each place it ap-
16 pears.

17 “(D) Any other information regarding the
18 ownership or investment interest the Secretary
19 determines appropriate.

20 “(b) PENALTIES FOR NONCOMPLIANCE.—

21 “(1) FAILURE TO REPORT.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), except as provided in paragraph (2),
24 any applicable manufacturer, applicable dis-
25 tributor, or applicable group purchasing organi-

1 zation that fails to submit information required
2 under subsection (a) in a timely manner in ac-
3 cordance with regulations promulgated to carry
4 out such subsection, shall be subject to a civil
5 money penalty of not less than \$1,000, but not
6 more than \$5,000, for each payment or other
7 transfer of value or ownership or investment in-
8 terest not reported as required under such sub-
9 section. Such penalty shall be imposed and col-
10 lected in the same manner as civil money pen-
11 alties under subsection (a) of section 1128A are
12 imposed and collected under that section.

13 “(B) LIMITATION.—The total amount of
14 civil money penalties imposed under subpara-
15 graph (A) with respect to each annual submis-
16 sion of information under subsection (a) by an
17 applicable manufacturer, applicable distributor,
18 or applicable group purchasing organization
19 shall not exceed \$50,000.

20 “(2) KNOWING FAILURE TO REPORT.—

21 “(A) IN GENERAL.—Subject to subpara-
22 graph (B), any applicable manufacturer, appli-
23 cable distributor, or applicable group pur-
24 chasing organization that knowingly fails to
25 submit information required under subsection

1 (a) in a timely manner in accordance with regu-
2 lations promulgated to carry out such sub-
3 section, shall be subject to a civil money penalty
4 of not less than \$5,000, but not more than
5 \$50,000, for each payment or other transfer of
6 value or ownership or investment interest not
7 reported as required under such subsection.
8 Such penalty shall be imposed and collected in
9 the same manner as civil money penalties under
10 subsection (a) of section 1128A are imposed
11 and collected under that section.

12 “(B) LIMITATION.—The total amount of
13 civil money penalties imposed under subpara-
14 graph (A) with respect to each annual submis-
15 sion of information under subsection (a) by an
16 applicable manufacturer, applicable distributor,
17 or applicable group purchasing organization
18 shall not exceed \$250,000.

19 “(3) USE OF FUNDS.—Funds collected by the
20 Secretary as a result of the imposition of a civil
21 money penalty under this subsection shall be used to
22 maintain the Internet website through which infor-
23 mation submitted under subsection (a) is made
24 available to the public under subsection
25 (c)(1)(C)(iii).

1 “(c) PROCEDURES FOR SUBMISSION OF INFORMA-
2 TION AND PUBLIC AVAILABILITY.—

3 “(1) IN GENERAL.—

4 “(A) ESTABLISHMENT.—Not later than
5 November 1, 2009, the Secretary shall establish
6 procedures—

7 “(i) for applicable manufacturers, ap-
8 plicable distributors, and applicable group
9 purchasing organizations to submit infor-
10 mation to the Secretary under subsection
11 (a); and

12 “(ii) for the Secretary to make such
13 information submitted available to the pub-
14 lic.

15 “(B) DEFINITION OF TERMS.—The proce-
16 dures established under subparagraph (A) shall
17 provide for the definition of terms (other than
18 those terms defined in subsection (g)), as ap-
19 propriate, for purposes of this section.

20 “(C) PUBLIC AVAILABILITY.—The proce-
21 dures established under subparagraph (A)(ii)
22 shall ensure that—

23 “(i) an applicable manufacturer, ap-
24 plicable distributor, applicable group pur-
25 chasing organization, or a covered recipient

1 (as applicable) has the opportunity to re-
2 view the information that is to be made
3 public with respect to the applicable manu-
4 facturer, applicable distributor, applicable
5 group purchasing organization, or covered
6 recipient prior to such information being
7 made public;

8 “(ii) the information may be corrected
9 as appropriate; and

10 “(iii) not later than September 30,
11 2011, and on June 30 of each calendar
12 year beginning thereafter, the information
13 submitted under subsection (a) with re-
14 spect to the preceding calendar year is
15 made available through an Internet website
16 that—

17 “(I) is searchable and is in a for-
18 mat that is clear and understandable;

19 “(II) contains information that is
20 presented by the name of the covered
21 recipient, the city and State in which
22 the covered recipient is located, the
23 value of payment or other transfer of
24 value, the date on which the payment
25 or other transfer of value was pro-

1 vided to the covered recipient, the
2 form of the payment or other transfer
3 of value, indicated (as appropriate)
4 under subsection (a)(1)(E), and the
5 reason for the payment or other
6 transfer of value, indicated (as appro-
7 priate) under subsection (a)(1)(F);

8 “(III) contains information that
9 is able to be easily aggregated;

10 “(IV) contains a description of
11 any enforcement actions taken to
12 carry out this section, including any
13 penalties imposed under subsection
14 (b), during the preceding year;

15 “(V) contains information that is
16 presented in the appropriate overall
17 context, which may include back-
18 ground information on industry-physi-
19 cian relationships;

20 “(VI) in the case of information
21 submitted with respect to a payment
22 or other transfer of value described in
23 subsection (e), lists such information
24 separately from the other information
25 submitted under subsection (a) and

1 designates such separately listed in-
2 formation as funding for clinical re-
3 search; and

4 “(VII) contains any other infor-
5 mation the Secretary determines
6 would be helpful to the average con-
7 sumer.

8 “(2) CONSULTATION.—In establishing the pro-
9 cedures under paragraph (1), the Secretary shall
10 consult with the Inspector General of the Depart-
11 ment of Health and Human Services, affected indus-
12 try, consumers, and other interested parties in order
13 to ensure that the information made available to the
14 public under such paragraph is presented in the ap-
15 propriate overall context.

16 “(d) RELATION TO STATE LAWS.—The provisions of
17 this section shall preempt any law or regulation of a State
18 or of a political subdivision of a State relating to the dis-
19 closure or reporting of information regarding payments or
20 other transfers of value provided to covered recipients by
21 applicable manufacturers to the State or to any other gov-
22 ernmental entity for purposes of including such informa-
23 tion in any State-sponsored database or other repository
24 of information.

1 “(e) DELAYED REPORTING FOR PAYMENTS MADE
2 PURSUANT TO PRODUCT DEVELOPMENT AGREEMENTS
3 AND CLINICAL INVESTIGATIONS.—In the case of a pay-
4 ment or other transfer of value made to a covered recipient
5 by an applicable manufacturer pursuant to a product de-
6 velopment agreement for services furnished in connection
7 with the development of a new drug, device, or medical
8 supply, or by an applicable manufacturer in connection
9 with a clinical investigation, the applicable manufacturer
10 may report the value of such payment or other transfer
11 of value in the first reporting period under subsection (a)
12 after the earlier of the following:

13 “(1) The date of the approval or clearance of
14 the covered drug, device, or medical supply by the
15 Food and Drug Administration.

16 “(2) Two calendar years after the date such
17 payment or other transfer of value was made.

18 “(f) IMPLEMENTATION.—

19 “(1) CONSULTATION.—The Secretary shall con-
20 sult with the Inspector General of the Department
21 of Health and Human Services on the implementa-
22 tion of this section.

23 “(2) LIMITATION ON REVIEW.—There shall be
24 no judicial review of the implementation of this sec-
25 tion.

1 “(g) DEFINITIONS.—In this section:

2 “(1) APPLICABLE DISTRIBUTOR.—The term
3 ‘applicable distributor’ means a distributor of a cov-
4 ered drug, device, or medical supply.

5 “(2) APPLICABLE GROUP PURCHASING ORGANI-
6 ZATION.—The term ‘applicable group purchasing or-
7 ganization’ means a group purchasing organization
8 that purchases, arranges for, or negotiates the pur-
9 chase of a covered drug, device, or medical supply.

10 “(3) APPLICABLE MANUFACTURER.—The term
11 ‘applicable manufacturer’ means a manufacturer of
12 a covered drug, device, or medical supply.

13 “(4) CLINICAL INVESTIGATION.—The term
14 ‘clinical investigation’ means any experiment involv-
15 ing 1 or more human subjects in which a drug or
16 device is administered, dispensed, or used.

17 “(5) COVERED DEVICE.—The term ‘covered de-
18 vice’ means any device for which payment is avail-
19 able under title XVIII or a State plan under title
20 XIX or XXI (or a waiver of such a plan).

21 “(6) COVERED DRUG, DEVICE, OR MEDICAL
22 SUPPLY.—The term ‘covered drug, device, or med-
23 ical supply’ means any drug, biological product, de-
24 vice, or medical supply for which payment is avail-

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

3 “(7) COVERED RECIPIENT.—

4 “(A) IN GENERAL.—The term ‘covered re-
5 cipient’ means—

6 “(i) a physician; and

7 “(ii) a physician medical practice.

8 “(B) SPECIAL RULE FOR CERTAIN PAY-
9 MENTS OR OTHER TRANSFERS OF VALUE.—In
10 the case where an applicable manufacturer, ap-
11 plicable distributor, or applicable group pur-
12 chasing organization provides a payment or
13 other transfer of value to an entity or individual
14 at the request of or designated on behalf of a
15 covered recipient or a physician (as applicable),
16 the applicable manufacturer, applicable dis-
17 tributor, or applicable group purchasing organi-
18 zation shall disclose that payment or other
19 transfer of value under the name of the covered
20 recipient or physician.

21 “(8) KNOWINGLY.—The term ‘knowingly’ has
22 the meaning given such term in section 3729(b) of
23 title 31, United States Code.

24 “(9) MANUFACTURER OF A COVERED DRUG,
25 DEVICE, OR MEDICAL SUPPLY.—The term ‘manufac-

1 turer of a covered drug, device, or medical supply’
2 means any entity which is engaged in the produc-
3 tion, preparation, propagation, compounding, conver-
4 sion, or processing of a covered drug, device, or med-
5 ical supply.

6 “(10) PAYMENT OR OTHER TRANSFER OF
7 VALUE.—

8 “(A) IN GENERAL.—The term ‘payment or
9 other transfer of value’ means a transfer of
10 anything of value and includes, subject to sub-
11 paragraph (B), without limitation, any com-
12 pensation, gift, honorarium, speaking fee, con-
13 sulting fee, travel, services, or dividend, profit
14 distribution, stock or stock option grant, or any
15 ownership or investment interest held by a phy-
16 sician in an applicable manufacturer (excluding
17 a dividend or other profit distribution from, or
18 ownership or investment interest in, a publicly
19 traded security and mutual fund (as described
20 in section 1877(c)).

21 “(B) EXCLUSIONS.—An applicable manu-
22 facturer, applicable distributor, or applicable
23 group purchasing organization shall not be re-
24 quired to submit information under subsection
25 (a) with respect to the following:

1 “(i) Any payment or other transfer of
2 value provided by an applicable manufac-
3 turer, applicable distributor, or applicable
4 group purchasing organization to a covered
5 recipient or a physician (as applicable)
6 where the aggregate amount transferred
7 to, requested by, or designated on behalf of
8 the covered recipient or physician does not
9 exceed \$500 during the calendar year.
10 Such aggregate amount shall be deter-
11 mined without taking into account any
12 payment or other transfer of value de-
13 scribed in clauses (ii) through (x).

14 “(ii) Product samples that are not in-
15 tended to be sold and are intended for pa-
16 tient use.

17 “(iii) Educational materials that are
18 intended for patient use or to benefit pa-
19 tients.

20 “(iv) The qualitative value of any
21 training or education related to a payment
22 or other transfer of value reported under
23 subsection (a) that is indicated as being
24 for the reason described in subsection
25 (a)(1)(F)(viii).

1 “(v) The loan of a covered device for
2 a short-term trial period, not to exceed 90
3 days, to permit evaluation of the covered
4 device by the covered recipient.

5 “(vi) Items or services provided under
6 a contractual warranty, including the re-
7 placement of a covered device, where the
8 terms of the warranty are set forth in the
9 purchase or lease agreement for the cov-
10 ered device.

11 “(vii) A transfer of anything of value
12 to a physician when the physician is a pa-
13 tient and not acting in the professional ca-
14 pacity of a physician.

15 “(viii) Discounts (including rebates).

16 “(ix) Anything below \$25 in value, in-
17 creased, for calendar years after 2010, by
18 the percentage increase in the consumer
19 price index for all urban consumers (all
20 items; United States city average) for the
21 12-month period ending with June of the
22 previous year.

23 “(x) In-kind items used for the provi-
24 sion of charity care.

1 “(11) PHYSICIAN.—The term ‘physician’ has
2 the meaning given that term in section 1861(r). For
3 purposes of this section, such term does not include
4 a physician who is a full-time employee of the appli-
5 cable manufacturer that is required to submit infor-
6 mation under subsection (a).”.