

111TH CONGRESS
1ST SESSION

S. 301

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

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 2009

Mr. GRASSLEY (for himself, Mr. KOHL, and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Finance

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, biologicals, 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 2009”.

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.—

13 “(A) IN GENERAL.—Except as provided in
14 subsection (e), on March 31, 2011, and on the
15 90th day of each calendar year beginning there-
16 after, any applicable manufacturer that pro-
17 vides a payment or other transfer of value to a
18 covered recipient (or to an entity or individual
19 at the request of or designated on behalf of a
20 covered recipient), shall submit to the Sec-
21 retary, in such electronic form as the Secretary
22 shall require, the following information with re-
23 spect to the preceding calendar year:

24 “(i) The name of the covered recipi-
25 ent.

1 “(ii) The business address of the cov-
2 ered recipient and, in the case of a covered
3 recipient who is a physician, the specialty
4 and Medicare billing number of the covered
5 recipient.

6 “(iii) The value of the payment or
7 other transfer of value.

8 “(iv) The dates on which the payment
9 or other transfer of value was provided to
10 the covered recipient.

11 “(v) A description of the form of the
12 payment or other transfer of value, indi-
13 cated (as appropriate for all that apply)
14 as—

15 “(I) cash or a cash equivalent;

16 “(II) in-kind items or services;

17 “(III) stock, a stock option, or
18 any other ownership interest, divi-
19 dend, profit, or other return on invest-
20 ment; or

21 “(IV) any other form of payment
22 or other transfer of value (as defined
23 by the Secretary).

24 “(vi) A description of the nature of
25 the payment or other transfer of value, in-

1 dicated (as appropriate for all that apply)

2 as—

3 “(I) consulting fees;

4 “(II) compensation for services
5 other than consulting;

6 “(III) honoraria;

7 “(IV) gift;

8 “(V) entertainment;

9 “(VI) food;

10 “(VII) travel;

11 “(VIII) education;

12 “(IX) research;

13 “(X) charitable contribution;

14 “(XI) royalty or license;

15 “(XII) current or prospective
16 ownership or investment interest;

17 “(XIII) compensation for serving
18 as faculty or as a speaker for a con-
19 tinuing medical education program;

20 “(XIV) grant; or

21 “(XV) any other nature of the
22 payment or other transfer of value (as
23 defined by the Secretary).

24 “(vii) If the payment or other transfer
25 of value is related to marketing, education,

1 or research specific to a covered drug, de-
2 vice, biological, or medical supply, the
3 name of that covered drug, device, biologi-
4 cal, or medical supply.

5 “(viii) Any other categories of infor-
6 mation regarding the payment or other
7 transfer of value the Secretary determines
8 appropriate.

9 “(B) AGGREGATE REPORTING.—Informa-
10 tion submitted by an applicable manufacturer
11 under subparagraph (A) shall include the ag-
12 gregate amount of all payments or other trans-
13 fers of value provided by the applicable manu-
14 facturer to covered recipients (and to entities or
15 individuals at the request of or designated on
16 behalf of a covered recipient) during the pre-
17 ceeding year.

18 “(C) SPECIAL RULE FOR CERTAIN PAY-
19 MENTS OR OTHER TRANSFERS OF VALUE.—In
20 the case where an applicable manufacturer pro-
21 vides a payment or other transfer of value to an
22 entity or individual at the request of or des-
23 ignated on behalf of a covered recipient, the ap-
24 plicable manufacturer shall disclose that pay-

1 ment or other transfer of value under the name
2 of the covered recipient.

3 “(2) PHYSICIAN OWNERSHIP.—In addition to
4 the requirement under paragraph (1)(A), on March
5 31, 2011, and on the 90th day of each calendar year
6 beginning thereafter, any applicable manufacturer or
7 applicable group purchasing organization shall sub-
8 mit to the Secretary, in such electronic form as the
9 Secretary shall require, the following information re-
10 garding any ownership or investment interest (other
11 than an ownership or investment interest in a pub-
12 licly traded security and mutual fund, as described
13 in section 1877(e)) held by a physician (or an imme-
14 diate family member of such physician (as defined
15 for purposes of section 1877(a))) in the applicable
16 manufacturer or applicable group purchasing organi-
17 zation during the preceding year:

18 “(A) The dollar amount invested by each
19 physician holding such an ownership or invest-
20 ment interest.

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

23 “(C) Any payment or other transfer of
24 value provided to a physician holding such an
25 ownership or investment interest (or to an enti-

1 ty or individual at the request of or designated
2 on behalf of a physician holding such an owner-
3 ship or investment interest), including the infor-
4 mation described in clauses (i) through (viii) of
5 paragraph (1)(A), except that in applying such
6 clauses, ‘physician’ shall be substituted for ‘cov-
7 ered recipient’ each place it appears.

8 “(D) Any other information regarding the
9 ownership or investment interest the Secretary
10 determines appropriate.

11 “(b) PENALTIES FOR NONCOMPLIANCE.—

12 “(1) FAILURE TO REPORT.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B), except as provided in paragraph (2),
15 any applicable manufacturer or applicable
16 group purchasing organization that fails to sub-
17 mit information required under subsection (a)
18 in a timely manner in accordance with rules or
19 regulations promulgated to carry out such sub-
20 section, shall be subject to a civil money penalty
21 of not less than \$1,000, but not more than
22 \$10,000, for each payment or other transfer of
23 value or ownership or investment interest not
24 reported as required under such subsection.
25 Such penalty shall be imposed and collected in

1 the same manner as civil money penalties under
2 subsection (a) of section 1128A are imposed
3 and collected under that section.

4 “(B) LIMITATION.—The total amount of
5 civil money penalties imposed under subpara-
6 graph (A) with respect to each annual submis-
7 sion of information under subsection (a) by an
8 applicable manufacturer or applicable group
9 purchasing organization shall not exceed
10 \$150,000.

11 “(2) KNOWING FAILURE TO REPORT.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), any applicable manufacturer or ap-
14 plicable group purchasing organization that
15 knowingly fails to submit information required
16 under subsection (a) in a timely manner in ac-
17 cordance with rules or regulations promulgated
18 to carry out such subsection, shall be subject to
19 a civil money penalty of not less than \$10,000,
20 but not more than \$100,000, for each payment
21 or other transfer of value or ownership or in-
22 vestment interest not reported as required
23 under such subsection. Such penalty shall be
24 imposed and collected in the same manner as
25 civil money penalties under subsection (a) of

1 section 1128A are imposed and collected under
2 that section.

3 “(B) LIMITATION.—The total amount of
4 civil money penalties imposed under subpara-
5 graph (A) with respect to each annual submis-
6 sion of information under subsection (a) by an
7 applicable manufacturer or applicable group
8 purchasing organization shall not exceed
9 \$1,000,000.

10 “(3) USE OF FUNDS.—Funds collected by the
11 Secretary as a result of the imposition of a civil
12 money penalty under this subsection shall be used to
13 carry out this section.

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

16 “(1) IN GENERAL.—

17 “(A) ESTABLISHMENT.—Not later than
18 November 1, 2009, the Secretary shall establish
19 procedures—

20 “(i) for applicable manufacturers and
21 applicable group purchasing organizations
22 to submit information to the Secretary
23 under subsection (a); and

1 “(ii) for the Secretary to make such
2 information submitted available to the pub-
3 lic.

4 “(B) DEFINITION OF TERMS.—The proce-
5 dures established under subparagraph (A) shall
6 provide for the definition of terms (other than
7 those terms defined in subsection (g)), as ap-
8 propriate, for purposes of this section.

9 “(C) PUBLIC AVAILABILITY.—The proce-
10 dures established under subparagraph (A)(ii)
11 shall ensure that, not later than September 30,
12 2011, and on June 30 of each calendar year be-
13 ginning thereafter, the information submitted
14 under subsection (a) with respect to the pre-
15 ceding calendar year is made available through
16 an Internet website that—

17 “(i) is searchable and is in a format
18 that is clear and understandable;

19 “(ii) contains information that is pre-
20 sented by the name of the applicable man-
21 ufacturer or applicable group purchasing
22 organization, the name of the covered re-
23 cipient, the business address of the covered
24 recipient, the specialty of the covered re-
25 cipient, the value of the payment or other

1 transfer of value, the date on which the
2 payment or other transfer of value was
3 provided to the covered recipient, the form
4 of the payment or other transfer of value,
5 indicated (as appropriate) under subsection
6 (a)(1)(A)(v), the nature of the payment or
7 other transfer of value, indicated (as ap-
8 propriate) under subsection (a)(1)(A)(vi),
9 and the name of the covered drug, device,
10 biological, or medical supply, as applicable;

11 “(iii) contains information that is able
12 to be easily aggregated and downloaded;

13 “(iv) contains a description of any en-
14 forcement actions taken to carry out this
15 section, including any penalties imposed
16 under subsection (b), during the preceding
17 year;

18 “(v) contains background information
19 on industry-physician relationships;

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

1 rately listed information as funding for
2 clinical research;

3 “(vii) contains any other information
4 the Secretary determines would be helpful
5 to the average consumer; and

6 “(viii) provides the covered recipient
7 an opportunity to submit corrections to the
8 information made available to the public
9 with respect to the covered recipient.

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

18 “(d) ANNUAL REPORTS AND RELATION TO STATE
19 LAWS.—

20 “(1) ANNUAL REPORT TO CONGRESS.—Not
21 later than April 1 of each year beginning with 2011,
22 the Secretary shall submit to Congress a report that
23 includes the following:

24 “(A) The information submitted under
25 subsection (a) during the preceding year, aggre-

1 gated for each applicable manufacturer and ap-
2 plicable group purchasing organization that
3 submitted such information during such year.

4 “(B) A description of any enforcement ac-
5 tions taken to carry out this section, including
6 any penalties imposed under subsection (b),
7 during the preceding year.

8 “(2) ANNUAL REPORTS TO STATES.—Not later
9 than April 1 of each year beginning with 2011, the
10 Secretary shall submit to States a report that in-
11 cludes a summary of the information submitted
12 under subsection (a) during the preceding year with
13 respect to covered recipients in the State.

14 “(3) RELATION TO STATE LAWS.—

15 “(A) IN GENERAL.—Effective on January
16 1, 2010, subject to subparagraph (B), the pro-
17 visions of this section shall preempt any law or
18 regulation of a State or of a political subdivi-
19 sion of a State that requires an applicable man-
20 ufacturer (as defined in subsection (g)) to dis-
21 close or report information (as described in sub-
22 section (a)) regarding a payment or other
23 transfer of value provided by the applicable
24 manufacturer to a covered recipient (as so de-
25 scribed).

1 “(B) NO PREEMPTION OF ADDITIONAL RE-
2 QUIREMENTS.—Subparagraph (A) shall not
3 preempt any law or regulation of a State or of
4 a political subdivision of a State that requires
5 the disclosure or reporting of information not
6 required to be disclosed or reported under this
7 section.

8 “(e) DELAYED REPORTING FOR PAYMENTS MADE
9 PURSUANT TO PRODUCT DEVELOPMENT AGREEMENTS
10 AND CLINICAL INVESTIGATIONS.—In the case of a pay-
11 ment or other transfer of value made to a covered recipient
12 by an applicable manufacturer pursuant to a product de-
13 velopment agreement for services furnished in connection
14 with the development of a new drug, device, biological, or
15 medical supply, or by an applicable manufacturer in con-
16 nection with a clinical investigation, the applicable manu-
17 facturer may report the value of such payment or other
18 transfer of value in the first reporting period under sub-
19 section (a) after the earlier of the following:

20 “(1) The date of the approval or clearance of
21 the covered drug, device, biological, or medical sup-
22 ply by the Food and Drug Administration.

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

25 “(f) IMPLEMENTATION.—

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

5 “(2) LIMITATION ON REVIEW.—There shall be
6 no judicial review of the implementation of this sec-
7 tion.

8 “(g) DEFINITIONS.—In this section:

9 “(1) APPLICABLE GROUP PURCHASING ORGANI-
10 ZATION.—The term ‘applicable group purchasing or-
11 ganization’ means a group purchasing organization
12 (as defined by the Secretary) that purchases, ar-
13 ranges for, or negotiates the purchase of a covered
14 drug, device, biological, or medical supply.

15 “(2) APPLICABLE MANUFACTURER.—The term
16 ‘applicable manufacturer’ means a manufacturer of
17 a covered drug, device, biological, or medical supply.

18 “(3) CLINICAL INVESTIGATION.—The term
19 ‘clinical investigation’ means any experiment involv-
20 ing 1 or more human subjects in which a drug or
21 device is administered, dispensed, or used.

22 “(4) COVERED DEVICE.—The term ‘covered de-
23 vice’ means any device for which payment is avail-
24 able under title XVIII or a State plan under title
25 XIX or XXI (or a waiver of such a plan).

1 “(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR
2 MEDICAL SUPPLY.—The term ‘covered drug, device,
3 biological, or medical supply’ means any drug, bio-
4 logical product, device, or medical supply for which
5 payment is available under title XVIII or a State
6 plan under title XIX or XXI (or a waiver of such
7 a plan).

8 “(6) COVERED RECIPIENT.—The term ‘covered
9 recipient’ means the following:

10 “(A) A physician.

11 “(B) A physician medical practice.

12 “(C) A physician group practice.

13 “(7) EMPLOYEE.—The term ‘employee’ has the
14 meaning given such term in section 1877(h)(2).

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

18 “(9) MANUFACTURER OF A COVERED DRUG,
19 DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The
20 term ‘manufacturer of a covered drug, device, bio-
21 logical, or medical supply’ means any entity which is
22 engaged in the production, preparation, propagation,
23 compounding, conversion, processing, marketing, or
24 distribution of a covered drug, device, biological, or

1 medical supply (or any subsidiary of or entity affili-
2 ated with such entity).

3 “(10) PAYMENT OR OTHER TRANSFER OF
4 VALUE.—

5 “(A) IN GENERAL.—The term ‘payment or
6 other transfer of value’ means a transfer of
7 anything of value and includes, subject to sub-
8 paragraph (B), without limitation, any com-
9 pensation, gift, honorarium, speaking fee, con-
10 sulting fee, travel, services, dividend, profit dis-
11 tribution, stock or stock option grant, or owner-
12 ship or investment interest.

13 “(B) EXCLUSIONS.—An applicable manu-
14 facturer shall not be required to submit infor-
15 mation under subsection (a) with respect to the
16 following:

17 “(i) Any payment or other transfer of
18 value provided by an applicable manufac-
19 turer to a covered recipient where the ag-
20 gregate amount transferred to, requested
21 by, or designated on behalf of the covered
22 recipient does not exceed \$100 during the
23 calendar year. Such aggregate amount
24 shall be determined without taking into ac-

1 count any payment or other transfer of
2 value described in clauses (ii) through (ix).

3 “(ii) Product samples that are not in-
4 tended to be sold and are intended for pa-
5 tient use.

6 “(iii) Educational materials that di-
7 rectly benefit patients or are intended for
8 patient use.

9 “(iv) The loan of a covered device for
10 a short-term trial period, not to exceed 90
11 days, to permit evaluation of the covered
12 device by the covered recipient.

13 “(v) Items or services provided under
14 a contractual warranty, including the re-
15 placement of a covered device, where the
16 terms of the warranty are set forth in the
17 purchase or lease agreement for the cov-
18 ered device.

19 “(vi) A transfer of anything of value
20 to a covered recipient when the covered re-
21 cipient is a patient and not acting in the
22 professional capacity of a covered recipient.

23 “(vii) Discounts (including rebates).

24 “(viii) In-kind items used for the pro-
25 vision of charity care.

1 “(ix) A dividend or other profit dis-
2 tribution from, or ownership or investment
3 interest in, a publicly traded security and
4 mutual fund (as described in section
5 1877(c)).

6 “(11) PHYSICIAN.—The term ‘physician’ has
7 the meaning given that term in section 1861(r). For
8 purposes of this section, such term does not include
9 a physician who is an employee of the applicable
10 manufacturer that is required to submit information
11 under subsection (a).”.

○