

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.

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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

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## 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).”.

○