

111TH CONGRESS
1ST SESSION

H. R. 3138

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 HOUSE OF REPRESENTATIVES

JULY 9, 2009

Mr. HILL 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

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), not later than March 31 of each
15 year (beginning with 2012), any applicable
16 manufacturer that provides a payment or other
17 transfer of value to a covered recipient (or to
18 an entity or individual at the request of or des-
19 ignated on behalf of a covered recipient), shall
20 submit to the Secretary, in such electronic form
21 as the Secretary shall require, the following in-
22 formation with respect to the preceding cal-
23 endar 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 National Provider Identifier of the
5 covered 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 Such reports may be submitted at the holding
10 company or divisional level at the manufactur-
11 er’s discretion.

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

21 “(C) SPECIAL RULE FOR CERTAIN PAY-
22 MENTS OR OTHER TRANSFERS OF VALUE.—In
23 the case where an applicable manufacturer pro-
24 vides a payment or other transfer of value to an
25 entity or individual at the request of or des-

1 ignated on behalf of a covered recipient, the ap-
2 plicable manufacturer shall disclose that pay-
3 ment or other transfer of value under the name
4 of the covered recipient.

5 “(2) PHYSICIAN OWNERSHIP.—In addition to
6 the requirement under paragraph (1)(A), not later
7 than March 31 of each year (beginning with 2012)
8 any applicable manufacturer, applicable group pur-
9 chasing organization, or applicable distributor shall
10 submit to the Secretary, in such electronic form as
11 the Secretary shall require, the following information
12 regarding any ownership or investment interest
13 (other than an ownership or investment interest in
14 a publicly traded security and mutual fund, as de-
15 scribed in section 1877(c)) held by a physician (or
16 an immediate family member of such physician (as
17 defined for purposes of section 1877(a))) in the ap-
18 plicable manufacturer, applicable group purchasing
19 organization or applicable distributor during the pre-
20 ceding year:

21 “(A) The dollar amount invested by each
22 physician holding such an ownership or invest-
23 ment interest.

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

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

11 “(D) Any other information regarding the
12 ownership or investment interest the Secretary
13 determines appropriate.

14 “(b) PENALTIES FOR NONCOMPLIANCE.—

15 “(1) FAILURE TO REPORT.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), except as provided in paragraph (2),
18 any applicable manufacturer, applicable group
19 purchasing organization, or applicable dis-
20 tributor that fails to submit information re-
21 quired under subsection (a) in a timely manner
22 in accordance with rules or regulations promul-
23 gated to carry out such subsection, shall be sub-
24 ject to a civil money penalty of not less than
25 \$1,000, but not more than \$10,000, for each

1 payment or other transfer of value or ownership
2 or investment interest not reported as required
3 under such subsection. Such penalty shall be
4 imposed and collected in the same manner as
5 civil money penalties under subsection (a) of
6 section 1128A are imposed and collected under
7 that section.

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

15 “(2) KNOWING FAILURE TO REPORT.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), any applicable manufacturer, appli-
18 cable group purchasing organization, or applica-
19 ble distributor that knowingly fails to submit
20 information required under subsection (a) in a
21 timely manner in accordance with rules or regu-
22 lations promulgated to carry out such sub-
23 section, shall be subject to a civil money penalty
24 of not less than \$10,000, but not more than
25 \$100,000, for each payment or other transfer of

1 value or ownership or investment interest not
2 reported as required under such subsection.
3 Such penalty shall be imposed and collected in
4 the same manner as civil money penalties under
5 subsection (a) of section 1128A are imposed
6 and collected under that section.

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

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

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

20 “(1) IN GENERAL.—

21 “(A) ESTABLISHMENT.—Not later than
22 June 1, 2011, the Secretary shall establish pro-
23 cedures—

24 “(i) for applicable manufacturers, ap-
25 plicable group purchasing organizations,

1 and applicable distributors to submit infor-
2 mation to the Secretary under subsection
3 (a); and

4 “(ii) for the Secretary to make such
5 information submitted available to the pub-
6 lic.

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

12 “(C) PUBLIC AVAILABILITY.—The proce-
13 dures established under subparagraph (A)(ii)
14 shall ensure that, not later than September 30,
15 2012, and on June 30 of each succeeding cal-
16 endar year, the information submitted under
17 subsection (a) with respect to the preceding cal-
18 endar year is made available through an Inter-
19 net website that—

20 “(i) is searchable and is in a format
21 that is clear and understandable;

22 “(ii) contains information that is pre-
23 sented by the name of the applicable man-
24 ufacturer, applicable group purchasing or-
25 ganization, or applicable distributor, the

1 name of the covered recipient, the business
2 address of the covered recipient, the spe-
3 cialty of the covered recipient, the value of
4 the payment or other transfer of value, the
5 date on which the payment or other trans-
6 fer of value was provided to the covered re-
7 cipient, the form of the payment or other
8 transfer of value, indicated (as appro-
9 priate) under subsection (a)(1)(A)(v), the
10 nature of the payment or other transfer of
11 value, indicated (as appropriate) under
12 subsection (a)(1)(A)(vi), and the name of
13 the covered drug, device, biological, or
14 medical supply, as applicable;

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

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

22 “(v) contains background information
23 on industry-physician relationships;

24 “(vi) in the case of information sub-
25 mitted with respect to a payment or other

1 transfer of value described in subsection
2 (e), lists such information separately from
3 the other information submitted under
4 subsection (a) and designates such sepa-
5 rately listed information as funding for
6 clinical research;

7 “(vii) contains any other information
8 the Secretary determines would be helpful
9 to the average consumer; and

10 “(viii) provides the covered recipient
11 an opportunity to submit corrections to the
12 information made available to the public
13 with respect to the covered recipient.

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

22 “(d) ANNUAL REPORTS AND RELATION TO STATE
23 LAWS.—

24 “(1) ANNUAL REPORT TO CONGRESS.—Not
25 later than April 1 of each year beginning with 2012,

1 the Secretary shall submit to Congress a report that
2 includes the following:

3 “(A) The information submitted under
4 subsection (a) during the preceding year, aggre-
5 gated for each applicable manufacturer and ap-
6 plicable group purchasing organization that
7 submitted such information during such year.

8 “(B) A description of any enforcement ac-
9 tions taken to carry out this section, including
10 any penalties imposed under subsection (b),
11 during the preceding year.

12 “(2) ANNUAL REPORTS TO STATES.—Not later
13 than April 1 of each year beginning with 2012, the
14 Secretary shall submit to States a report that in-
15 cludes a summary of the information submitted
16 under subsection (a) during the preceding year with
17 respect to covered recipients in the State.

18 “(3) RELATION TO STATE LAWS.—

19 “(A) IN GENERAL.—Effective on January
20 1, 2010, subject to subparagraph (B), the pro-
21 visions of this section shall preempt any law or
22 regulation of a State or of a political subdivi-
23 sion of a State that requires an applicable man-
24 ufacturer (as defined in subsection (g)) to dis-
25 close or report information in the categories (as

1 described in subsection (a)) and the exclusions
2 in (g)(11)(B) regarding a payment or other
3 transfer of value provided by the applicable
4 manufacturer to a covered recipient (as so de-
5 scribed), including such laws or regulations that
6 impose different schedules or frequency of re-
7 porting (including the timing of reporting of
8 payments made pursuant to product develop-
9 ment agreements and clinical investigations as
10 provided under subsection (e)), threshold
11 amounts for reporting of such payments or
12 transfers of value, reporting formats, or defini-
13 tions of covered recipients.

14 “(B) NO PREEMPTION OF ADDITIONAL RE-
15 QUIREMENTS.—Subparagraph (A) shall not
16 preempt any law or regulation of a State or of
17 a political subdivision of a State that requires
18 the disclosure or reporting of information not
19 required to be disclosed or reported under this
20 section to the extent such information is not
21 specifically excluded from the reporting require-
22 ments under subsection (g)(11)(B).

23 “(e) DELAYED REPORTING FOR PAYMENTS MADE
24 PURSUANT TO PRODUCT RESEARCH AND DEVELOPMENT
25 AGREEMENTS, CLINICAL INVESTIGATIONS, AND PRE-DE-

1 VELOPMENT RESEARCH.—In the case of a payment or
2 other transfer of value made to a covered recipient by an
3 applicable manufacturer pursuant to a product research
4 and development agreement for services furnished in con-
5 nection with research of a potential new medical tech-
6 nology or application, the development of a new drug, de-
7 vice, biological, or medical supply, or by an applicable
8 manufacturer in connection with a clinical investigation,
9 the applicable manufacturer may report the value of such
10 payment or other transfer of value in the first reporting
11 period under subsection (a) after the earlier of the fol-
12 lowing:

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

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

18 “(f) IMPLEMENTATION.—The Secretary shall consult
19 with the Inspector General of the Department of Health
20 and Human Services on the implementation of this sec-
21 tion.

22 “(g) DEFINITIONS.—In this section:

23 “(1) APPLICABLE DISTRIBUTOR.—The term
24 ‘applicable distributor’ means an entity, other than
25 an applicable group purchasing organization, that

1 buys and resells, or receives a commission or other
2 similar form of payment, from another seller, for
3 selling or arranging for the sale of a covered drug,
4 device, biological, 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 (as defined by the Secretary) that purchases, ar-
9 ranges for, or negotiates the purchase of a covered
10 drug, device, biological, or medical supply.

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

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

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

23 “(6) COVERED DRUG, DEVICE, BIOLOGICAL, OR
24 MEDICAL SUPPLY.—The term ‘covered drug, device,
25 biological, or medical supply’ means any drug, bio-

1 logical product, device, or medical supply for which
2 payment is available under title XVIII or a State
3 plan under title XIX or XXI (or a waiver of such
4 a plan).

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

7 “(A) A physician.

8 “(B) A physician medical practice.

9 “(C) A physician group practice.

10 “(8) EMPLOYEE.—The term ‘employee’ has the
11 meaning given such term in section 1877(h)(2).

12 “(9) KNOWINGLY.—The term ‘knowingly’ has
13 the meaning given such term in section 3729(b) of
14 title 31, United States Code.

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

24 “(11) PAYMENT OR OTHER TRANSFER OF
25 VALUE.—

1 “(A) IN GENERAL.—The term ‘payment or
2 other transfer of value’ means a transfer of
3 anything of value that exceeds \$25 and in-
4 cludes, subject to subparagraph (B), without
5 limitation, any compensation, gift, honorarium,
6 speaking fee, consulting fee, travel, services,
7 dividend, profit distribution, stock or stock op-
8 tion grant, or ownership or investment interest.

9 “(B) EXCLUSIONS.—An applicable manu-
10 facturer shall not be required to submit infor-
11 mation under subsection (a) with respect to the
12 following:

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

16 “(ii) Educational materials that di-
17 rectly benefit patients or are intended for
18 patient use.

19 “(iii) The loan of a covered device for
20 a short-term trial period, not to exceed 90
21 days, to permit evaluation of the covered
22 device by the covered recipient.

23 “(iv) Items or services provided under
24 a contractual warranty, including the re-
25 placement of a covered device, where the

1 terms of the warranty are set forth in the
2 purchase or lease agreement for the cov-
3 ered device.

4 “(v) A transfer of anything of value to
5 a covered recipient when the covered re-
6 cipient is a patient and not acting in the
7 professional capacity of a covered recipient.

8 “(vi) Discounts (including rebates).

9 “(vii) In-kind items used for the pro-
10 vision of charity care.

11 “(viii) A dividend or other profit dis-
12 tribution from, or ownership or investment
13 interest in, a publicly traded security and
14 mutual fund (as described in section
15 1877(e)).

16 “(ix) Payments made to a covered re-
17 cipient by an applicable manufacturer or
18 by a health plan affiliated with an applica-
19 ble manufacturer for medical care provided
20 to employees of such manufacturer and
21 their dependents.

22 “(12) PHYSICIAN.—The term ‘physician’ has
23 the meaning given that term in section 1861(r). For
24 purposes of this section, such term does not include
25 a physician who is an employee of the applicable

- 1 manufacturer that is required to submit information
- 2 under subsection (a).”.

○