

1 Title: To amend title XI of the Social Security Act to provide for transparency in the relationship  
2 between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for  
3 which payment is made under Medicare, Medicaid, or SCHIP.  
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6 Be it enacted by the Senate and House of Representatives of the United States of America in  
7 Congress assembled,

## 8 SECTION 1. SHORT TITLE.

9 This Act may be cited as the “Physician Payments Sunshine Act of 2009”.

## 10 SEC. 2. TRANSPARENCY REPORTS AND REPORTING OF 11 PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

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

### 14 “SEC. 1128G. TRANSPARENCY REPORTS AND 15 REPORTING OF PHYSICIAN OWNERSHIP OR 16 INVESTMENT INTERESTS.

17 “(a) Transparency Reports.—

18 “(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

19 “(A) IN GENERAL.—Except as provided in subsection (e), on March 31, 2011, and on  
20 the 90th day of each calendar year beginning thereafter, any applicable manufacturer  
21 that provides a payment or other transfer of value to a covered recipient (or to an entity  
22 or individual at the request of or designated on behalf of a covered recipient), shall  
23 submit to the Secretary, in such electronic form as the Secretary shall require, the  
24 following information with respect to the preceding calendar year:

25 “(i) The name of the covered recipient.

26 “(ii) The business address of the covered recipient and, in the case of a covered  
27 recipient who is a physician, the specialty and Medicare billing number of the  
28 covered recipient.

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

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

32 “(v) A description of the form of the payment or other transfer of value,  
33 indicated (as appropriate for all that apply) as—

34 “(I) cash or a cash equivalent;

35 “(II) in-kind items or services;

36 “(III) stock, a stock option, or any other ownership interest, dividend,

1 profit, or other return on investment; or

2 “(IV) any other form of payment or other transfer of value (as defined by  
3 the Secretary).

4 “(vi) A description of the nature of the payment or other transfer of value,  
5 indicated (as appropriate for all that apply) as—

6 “(I) consulting fees;

7 “(II) compensation for services other than consulting;

8 “(III) honoraria;

9 “(IV) gift;

10 “(V) entertainment;

11 “(VI) food;

12 “(VII) travel;

13 “(VIII) education;

14 “(IX) research;

15 “(X) charitable contribution;

16 “(XI) royalty or license;

17 “(XII) current or prospective ownership or investment interest;

18 “(XIII) compensation for serving as faculty or as a speaker for a  
19 continuing medical education program;

20 “(XIV) grant; or

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

23 “(vii) If the payment or other transfer of value is related to marketing,  
24 education, or research specific to a covered drug, device, biological, or medical  
25 supply, the name of that covered drug, device, biological, or medical supply.

26 “(viii) Any other categories of information regarding the payment or other  
27 transfer of value the Secretary determines appropriate.

28 “(B) AGGREGATE REPORTING.—Information submitted by an applicable  
29 manufacturer under subparagraph (A) shall include the aggregate amount of all  
30 payments or other transfers of value provided by the applicable manufacturer to  
31 covered recipients (and to entities or individuals at the request of or designated on  
32 behalf of a covered recipient) during the preceding year.

33 “(C) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the  
34 case where an applicable manufacturer provides a payment or other transfer of value to  
35 an entity or individual at the request of or designated on behalf of a covered recipient,  
36 the applicable manufacturer shall disclose that payment or other transfer of value under  
37 the name of the covered recipient.

1           “(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on  
2 March 31, 2011, and on the 90th day of each calendar year beginning thereafter, any  
3 applicable manufacturer or applicable group purchasing organization shall submit to the  
4 Secretary, in such electronic form as the Secretary shall require, the following information  
5 regarding any ownership or investment interest (other than an ownership or investment  
6 interest in a publicly traded security and mutual fund, as described in section 1877(c)) held  
7 by a physician (or an immediate family member of such physician (as defined for purposes  
8 of section 1877(a))) in the applicable manufacturer or applicable group purchasing  
9 organization during the preceding year:

10           “(A) The dollar amount invested by each physician holding such an ownership or  
11 investment interest.

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

13           “(C) Any payment or other transfer of value provided to a physician holding such an  
14 ownership or investment interest (or to an entity or individual at the request of or  
15 designated on behalf of a physician holding such an ownership or investment interest),  
16 including the information described in clauses (i) through (viii) of paragraph (1)(A),  
17 except that in applying such clauses, ‘physician’ shall be substituted for ‘covered  
18 recipient’ each place it appears.

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

21           “(b) Penalties for Noncompliance.—

22           “(1) FAILURE TO REPORT.—

23           “(A) IN GENERAL.—Subject to subparagraph (B), except as provided in paragraph  
24 (2), any applicable manufacturer or applicable group purchasing organization that fails  
25 to submit information required under subsection (a) in a timely manner in accordance  
26 with rules or regulations promulgated to carry out such subsection, shall be subject to a  
27 civil money penalty of not less than \$1,000, but not more than \$10,000, for each  
28 payment or other transfer of value or ownership or investment interest not reported as  
29 required under such subsection. Such penalty shall be imposed and collected in the  
30 same manner as civil money penalties under subsection (a) of section 1128A are  
31 imposed and collected under that section.

32           “(B) LIMITATION.—The total amount of civil money penalties imposed under  
33 subparagraph (A) with respect to each annual submission of information under  
34 subsection (a) by an applicable manufacturer or applicable group purchasing  
35 organization shall not exceed \$150,000.

36           “(2) KNOWING FAILURE TO REPORT.—

37           “(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or  
38 applicable group purchasing organization that knowingly fails to submit information  
39 required under subsection (a) in a timely manner in accordance with rules or  
40 regulations promulgated to carry out such subsection, shall be subject to a civil money  
41 penalty of not less than \$10,000, but not more than \$100,000, for each payment or  
42 other transfer of value or ownership or investment interest not reported as required

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

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

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

10 “(c) Procedures for Submission of Information and Public Availability.—

11 “(1) IN GENERAL.—

12 “(A) ESTABLISHMENT.—Not later than November 1, 2009, the Secretary shall  
13 establish procedures—

14 “(i) for applicable manufacturers and applicable group purchasing  
15 organizations to submit information to the Secretary under subsection (a); and

16 “(ii) for the Secretary to make such information submitted available to the  
17 public.

18 “(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A)  
19 shall provide for the definition of terms (other than those terms defined in subsection  
20 (g)), as appropriate, for purposes of this section.

21 “(C) PUBLIC AVAILABILITY.—The procedures established under subparagraph (A)(ii)  
22 shall ensure that, not later than September 30, 2011, and on June 30 of each calendar  
23 year beginning thereafter, the information submitted under subsection (a) with respect  
24 to the preceding calendar year is made available through an Internet website that—

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

26 “(ii) contains information that is presented by the name of the applicable  
27 manufacturer or applicable group purchasing organization, the name of the  
28 covered recipient, the business address of the covered recipient, the specialty of  
29 the covered recipient, the value of the payment or other transfer of value, the date  
30 on which the payment or other transfer of value was provided to the covered  
31 recipient, the form of the payment or other transfer of value, indicated (as  
32 appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other  
33 transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and  
34 the name of the covered drug, device, biological, or medical supply, as applicable;

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

36 “(iv) contains a description of any enforcement actions taken to carry out this  
37 section, including any penalties imposed under subsection (b), during the  
38 preceding year;

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

40 “(vi) in the case of information submitted with respect to a payment or other

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

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

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

8 “(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary  
9 shall consult with the Inspector General of the Department of Health and Human Services,  
10 affected industry, consumers, consumer advocates, and other interested parties in order to  
11 ensure that the information made available to the public under such paragraph is presented  
12 in the appropriate overall context.

13 “(d) Annual Reports and Relation to State Laws.—

14 “(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with  
15 2011, the Secretary shall submit to Congress a report that includes the following:

16 “(A) The information submitted under subsection (a) during the preceding year,  
17 aggregated for each applicable manufacturer and applicable group purchasing  
18 organization that submitted such information during such year.

19 “(B) A description of any enforcement actions taken to carry out this section,  
20 including any penalties imposed under subsection (b), during the preceding year.

21 “(2) ANNUAL REPORTS TO STATES.—Not later than April 1 of each year beginning with  
22 2011, the Secretary shall submit to States a report that includes a summary of the  
23 information submitted under subsection (a) during the preceding year with respect to  
24 covered recipients in the State.

25 “(3) RELATION TO STATE LAWS.—

26 “(A) IN GENERAL.—Effective on January 1, 2010, subject to subparagraph (B), the  
27 provisions of this section shall preempt any law or regulation of a State or of a political  
28 subdivision of a State that requires an applicable manufacturer (as defined in  
29 subsection (g)) to disclose or report information (as described in subsection (a))  
30 regarding a payment or other transfer of value provided by the applicable manufacturer  
31 to a covered recipient (as so described).

32 “(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not  
33 preempt any law or regulation of a State or of a political subdivision of a State that  
34 requires the disclosure or reporting of information not required to be disclosed or  
35 reported under this section.

36 “(e) Delayed Reporting for Payments Made Pursuant to Product Development Agreements  
37 and Clinical Investigations.—In the case of a payment or other transfer of value made to a  
38 covered recipient by an applicable manufacturer pursuant to a product development agreement  
39 for services furnished in connection with the development of a new drug, device, biological, or  
40 medical supply, or by an applicable manufacturer in connection with a clinical investigation, the  
41 applicable manufacturer may report the value of such payment or other transfer of value in the

1 first reporting period under subsection (a) after the earlier of the following:

2 “(1) The date of the approval or clearance of the covered drug, device, biological, or  
3 medical supply by the Food and Drug Administration.

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

5 “(f) Implementation.—

6 “(1) CONSULTATION.—The Secretary shall consult with the Inspector General of the  
7 Department of Health and Human Services on the implementation of this section.

8 “(2) LIMITATION ON REVIEW.—There shall be no judicial review of the implementation of  
9 this section.

10 “(g) Definitions.—In this section:

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

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

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

20 “(4) COVERED DEVICE.—The term ‘covered device’ means any device for which payment  
21 is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a  
22 plan).

23 “(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term ‘covered  
24 drug, device, biological, or medical supply’ means any drug, biological product, device, or  
25 medical supply for which payment is available under title XVIII or a State plan under title  
26 XIX or XXI (or a waiver of such a plan).

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

28 “(A) A physician.

29 “(B) A physician medical practice.

30 “(C) A physician group practice.

31 “(7) EMPLOYEE.—The term ‘employee’ has the meaning given such term in section  
32 1877(h)(2).

33 “(8) KNOWINGLY.—The term ‘knowingly’ has the meaning given such term in section  
34 3729(b) of title 31, United States Code.

35 “(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—  
36 The term ‘manufacturer of a covered drug, device, biological, or medical supply’ means any  
37 entity which is engaged in the production, preparation, propagation, compounding,  
38 conversion, processing, marketing, or distribution of a covered drug, device, biological, or  
39 medical supply (or any subsidiary of or entity affiliated with such entity).

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

2 “(A) IN GENERAL.—The term ‘payment or other transfer of value’ means a transfer  
3 of anything of value and includes, subject to subparagraph (B), without limitation, any  
4 compensation, gift, honorarium, speaking fee, consulting fee, travel, services,  
5 dividend, profit distribution, stock or stock option grant, or ownership or investment  
6 interest.

7 “(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit  
8 information under subsection (a) with respect to the following:

9 “(i) Any payment or other transfer of value provided by an applicable  
10 manufacturer to a covered recipient where the aggregate amount transferred to,  
11 requested by, or designated on behalf of the covered recipient does not exceed  
12 \$100 during the calendar year. Such aggregate amount shall be determined  
13 without taking into account any payment or other transfer of value described in  
14 clauses (ii) through (ix).

15 “(ii) Product samples that are not intended to be sold and are intended for  
16 patient use.

17 “(iii) Educational materials that directly benefit patients or are intended for  
18 patient use.

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

21 “(v) Items or services provided under a contractual warranty, including the  
22 replacement of a covered device, where the terms of the warranty are set forth in  
23 the purchase or lease agreement for the covered device.

24 “(vi) A transfer of anything of value to a covered recipient when the covered  
25 recipient is a patient and not acting in the professional capacity of a covered  
26 recipient.

27 “(vii) Discounts (including rebates).

28 “(viii) In-kind items used for the provision of charity care.

29 “(ix) A dividend or other profit distribution from, or ownership or investment  
30 interest in, a publicly traded security and mutual fund (as described in section  
31 1877(c)).

32 “(11) PHYSICIAN.—The term ‘physician’ has the meaning given that term in section  
33 1861(r). For purposes of this section, such term does not include a physician who is an  
34 employee of the applicable manufacturer that is required to submit information under  
35 subsection (a).”.