

1 **Subtitle D—Physician Payments**
2 **Sunshine Provisions**

3 **SEC. 1451. REPORTS ON FINANCIAL RELATIONSHIPS BE-**
4 **TWEEN MANUFACTURERS AND DISTRIBUTU-**
5 **TORS OF COVERED DRUGS, DEVICES,**
6 **BIOLOGICALS, OR MEDICAL SUPPLIES**
7 **UNDER MEDICARE, MEDICAID, OR CHIP AND**
8 **PHYSICIANS AND OTHER HEALTH CARE ENTI-**
9 **TIES AND BETWEEN PHYSICIANS AND OTHER**
10 **HEALTH CARE ENTITIES.**

11 (a) IN GENERAL.—Part A of title XI of the Social
12 Security Act (42 U.S.C. 1301 et seq.), as amended by sec-
13 tion 1631(a), is further amended by inserting after section
14 1128G the following new section:

15 **“SEC. 1128H. FINANCIAL REPORTS ON PHYSICIANS’ FINAN-**
16 **CIAL RELATIONSHIPS WITH MANUFACTUR-**
17 **ERS AND DISTRIBUTORS OF COVERED**
18 **DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL**
19 **SUPPLIES UNDER MEDICARE, MEDICAID, OR**
20 **CHIP AND WITH ENTITIES THAT BILL FOR**
21 **SERVICES UNDER MEDICARE.**

22 “(a) REPORTING OF PAYMENTS OR OTHER TRANS-
23 FERS OF VALUE.—

24 “(1) IN GENERAL.—Except as provided in this
25 subsection, not later than March 31 of each year

1 (beginning with 2011), each applicable manufacturer
2 or distributor that provides a payment or other
3 transfer of value, directly, indirectly, or through an
4 agent, subsidiary, or other third party, to a covered
5 recipient (or to an entity or individual at the request
6 of or designated on behalf of a covered recipient)
7 shall submit to the Secretary, acting through the Of-
8 fice of the Inspector General of the Department of
9 Health and Human Services, in such electronic form
10 as the Secretary shall require, the following informa-
11 tion with respect to the preceding calendar year:

12 “(A) With respect to the covered recipient,
13 the recipient’s name, business address, physi-
14 cian specialty, and national provider identifier.

15 “(B) With respect to the payment or other
16 transfer of value, other than a drug sample—

17 “(I) its value and date;

18 “(ii) the name of the related drug, de-
19 vice, or supply, if available;

20 “(iii) a description of its form, indi-
21 cated (as appropriate for all that apply)

22 as—

23 “(I) cash or a cash equivalent;

24 “(II) in-kind items or services;

1 “(III) stock, a stock option, or
2 any other ownership interest, divi-
3 dend, profit, or other return on invest-
4 ment; or

5 “(IV) any other form (as defined
6 by the Secretary); and

7 “(iv) a description of its nature, indi-
8 cated (as appropriate for all that apply) by
9 the category described in a clause of sub-
10 section (g)(10)(A).

11 “(C) With respect to a drug sample, the
12 name, number, date, and dosage units of the
13 sample.

14 “(2) AGGREGATE REPORTING.—Information
15 submitted by an applicable manufacturer or dis-
16 tributor under paragraph (1) shall include the ag-
17 gregate amount of all payments or other transfers of
18 value provided by the manufacturer or distributor to
19 covered recipients (and to entities or individuals at
20 the request of or designated on behalf of a covered
21 recipient) during the year involved, including all pay-
22 ments and transfers of value regardless of whether
23 such payments or transfer of value were individually
24 disclosed.

1 “(3) SPECIAL RULE FOR CERTAIN PAYMENTS
2 OR OTHER TRANSFERS OF VALUE.—In the case
3 where an applicable manufacturer or distributor pro-
4 vides a payment or other transfer of value to an en-
5 tity or individual at the request of or designated on
6 behalf of a covered recipient, the manufacturer or
7 distributor shall disclose that payment or other
8 transfer of value under the name of the covered re-
9 cipient.

10 “(4) DELAYED REPORTING FOR PAYMENTS
11 MADE PURSUANT TO PRODUCT DEVELOPMENT
12 AGREEMENTS.—In the case of a payment or other
13 transfer of value made to a covered recipient by an
14 applicable manufacturer or distributor pursuant to a
15 product development agreement for services fur-
16 nished in connection with the development of a new
17 drug, device, biological, or medical supply, the appli-
18 cable manufacturer or distributor may report the
19 value and recipient of such payment or other trans-
20 fer of value in the first reporting period under this
21 subsection in the next reporting deadline after the
22 earlier of the following:

23 “(A) The date of the approval or clearance
24 of the covered drug, device, biological, or med-

1 ical supply by the Food and Drug Administra-
2 tion.

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

6 “(b) REPORTING OF OWNERSHIP INTEREST BY PHY-
7 SICIANS IN HOSPITALS AND OTHER ENTITIES THAT BILL
8 MEDICARE.—Not later than March 31 of each year (be-
9 ginning with 2011), each hospital or other health care en-
10 tity (not including a Medicare Advantage organization)
11 that bills the Secretary under part A or part B of title
12 XVIII for services shall report on the ownership shares
13 (other than ownership shares described in section 1877(e))
14 of each physician who, directly or indirectly, owns an in-
15 terest in the entity. In this subsection, the term ‘physician’
16 includes a physician’s immediate family members (as de-
17 fined for purposes of section 1877(a)).

18 “(c) PUBLIC AVAILABILITY.—The Secretary shall es-
19 tablish procedures to ensure that, not later than Sep-
20 tember 30, 2011, and on June 30 of each year beginning
21 thereafter, the information submitted under subsections
22 (a) and (b), other than information regard drug samples,
23 with respect to the preceding calendar year is made avail-
24 able through an Internet website that—

1 “(1) is searchable and is in a format that is
2 clear and understandable;

3 “(2) contains information that is presented by
4 the name of the applicable manufacturer or dis-
5 tributor, the name of the covered recipient, the busi-
6 ness address of the covered recipient, the specialty
7 (if applicable) of the covered recipient, the value of
8 the payment or other transfer of value, the date on
9 which the payment or other transfer of value was
10 provided to the covered recipient, the form of the
11 payment or other transfer of value, indicated (as ap-
12 propriate) under subsection (a)(1)(B)(ii), the nature
13 of the payment or other transfer of value, indicated
14 (as appropriate) under subsection (a)(1)(B)(iii), and
15 the name of the covered drug, device, biological, or
16 medical supply, as applicable;

17 “(3) contains information that is able to be eas-
18 ily aggregated and downloaded;

19 “(4) contains a description of any enforcement
20 actions taken to carry out this section, including any
21 penalties imposed under subsection (b), during the
22 preceding year;

23 “(5) contains background information on indus-
24 try-physician relationships;

1 “(6) in the case of information submitted with
2 respect to a payment or other transfer of value de-
3 scribed in subsection (e), lists such information sep-
4 arately from the other information submitted under
5 subsection (a) and designates such separately listed
6 information as funding for clinical research;

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

10 “(8) provides the covered recipient an oppor-
11 tunity to submit corrections to the information made
12 available to the public with respect to the covered re-
13 cipient.

14 Information relating to drug samples provided under sub-
15 section (a) shall not be made available to the public but
16 may be made available outside the Department of Health
17 and Human Services by the Secretary for research or le-
18 gitimate business purposes pursuant to data use agree-
19 ments.

20 “(d) 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 or distributor that
25 fails to submit information required under sub-

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

16 “(B) LIMITATION.—The total amount of
17 civil money penalties imposed under subpara-
18 graph (A) with respect to each annual submis-
19 sion of information under subsection (a) by an
20 applicable manufacturer or distributor or other
21 entity shall not exceed \$150,000.

22 “(2) KNOWING FAILURE TO REPORT.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graph (B), any applicable manufacturer or dis-
25 tributor that knowingly fails to submit informa-

1 tion required under subsection (a) in a timely
2 manner in accordance with regulations promul-
3 gated to carry out such subsection and any hos-
4 pital or other entity that fails to submit infor-
5 mation required under subsection (b) in a time-
6 ly manner in accordance with regulations pro-
7 mulgated to carry out such subsection, shall be
8 subject to a civil money penalty of not less than
9 \$10,000, but not more than \$100,000, for each
10 payment or other transfer of value or ownership
11 or investment interest not reported as required
12 under such subsection. Such penalty shall be
13 imposed and collected in the same manner as
14 civil money penalties under subsection (a) of
15 section 1128A are imposed and collected under
16 that section.

17 “(B) LIMITATION.—The total amount of
18 civil money penalties imposed under subpara-
19 graph (A) with respect to each annual submis-
20 sion of information under subsection (a) by an
21 applicable manufacturer, distributor, or entity
22 described in subsection (c) shall not exceed
23 \$1,000,000, or, if greater, 0.1 percentage of the
24 total annual revenues of the manufacturer, dis-
25 tributor, or entity.

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

5 “(4) ENFORCEMENT THROUGH STATE ATTOR-
6 NEYS GENERAL.—The attorney general of a State,
7 after providing notice to the Secretary of an intent
8 to proceed under this paragraph in a specific case
9 and providing the Secretary with an opportunity to
10 bring an action under this subsection and the Sec-
11 retary declining such opportunity, may proceed
12 under this subsection against a manufacturer or dis-
13 tributor in the State.

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

18 “(1) The information submitted under this sec-
19 tion during the preceding year, aggregated for each
20 applicable manufacturer or distributor of a covered
21 drug, device, biological, or medical supply that sub-
22 mitted such information during such year.

23 “(2) A description of any enforcement actions
24 taken to carry out this section, including any pen-

1 alties imposed under subsection (d), during the pre-
2 ceding year.

3 “(3) A description, based on the disclosure of
4 financial relationships report provided under section
5 1877(f), of the types and prevalence of financial ar-
6 rangements between hospitals and physicians.

7 “(f) DEFINITIONS.—In this section:

8 “(1) APPLICABLE MANUFACTURER; APPLICA-
9 BLE DISTRIBUTOR.—The term ‘applicable manufac-
10 turer’ means a manufacturer of a covered drug, de-
11 vice, biological, or medical supply, and the term ‘ap-
12 plicable distributor’ means a distributor of a covered
13 drug, device, or medical supply.

14 “(2) COVERED DRUG, DEVICE, BIOLOGICAL, OR
15 MEDICAL SUPPLY.—The term ‘covered’ means, with
16 respect to a drug, device, biological, or medical sup-
17 ply, such a drug, device, biological, or medical supply
18 for which payment is available under title XVIII or
19 a State plan under title XIX or XXI (or a waiver
20 of such a plan).

21 “(3) COVERED RECIPIENT.—The term ‘covered
22 recipient’ means the following:

23 “(A) A physician.

24 “(B) A physician group practice.

1 “(C) An other prescriber of a covered
2 drug, device, biological, or medical supply.

3 “(D) A pharmacy or pharmacist.

4 “(E) A health insurance issuer, group
5 health plan, or other entity offering a health
6 benefits plan, including any employee of such
7 an issuer, plan, or entity.

8 “(F) A pharmacy benefit manager, includ-
9 ing any employee of such a manager.

10 “(G) A hospital.

11 “(H) A medical school.

12 “(I) A sponsor of a continuing medical
13 education program.

14 “(J) A patient advocacy or disease specific
15 group.

16 “(K) A organization of health care profes-
17 sionals.

18 “(L) A biomedical researcher

19 “(4) DISTRIBUTOR OF A COVERED DRUG, DE-
20 VICE, OR MEDICAL SUPPLY.—The term ‘distributor
21 of a covered drug, device, or medical supply’ means
22 any entity which is engaged in the marketing or dis-
23 tribution of a covered drug, device, or medical sup-
24 ply (or any subsidiary of or entity affiliated with
25 such entity).

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

3 “(6) KNOWINGLY.—The term ‘knowingly’ has
4 the meaning given such term in section 3729(b) of
5 title 31, United States Code.

6 “(7) MANUFACTURER OF A COVERED DRUG,
7 DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The
8 term ‘manufacturer of a covered drug, device, bio-
9 logical, or medical supply’ means any entity which is
10 engaged in the production, preparation, propagation,
11 compounding, conversion, processing, marketing, or
12 distribution of a covered drug, device, biological, or
13 medical supply (or any subsidiary of or entity affili-
14 ated with such entity).

15 “(8) PAYMENT OR OTHER TRANSFER OF
16 VALUE.—

17 “(A) IN GENERAL.—The term ‘payment or
18 other transfer of value’ means a transfer of
19 anything of value for or of any of the following:

20 “(i) Gift, food, or entertainment.

21 “(ii) Travel or trip.

22 “(iii) Honoraria.

23 “(iv) Research funding or grant.

24 “(v) Education or conference funding.

25 “(vi) Consulting fees.

1 “(vii) Ownership or Investment inter-
2 est and royalties or license fee.

3 “(viii) any includes any compensation,
4 gift, honorarium, speaking fee, consulting
5 fee, travel, discount, cash rebate, services,
6 or dividend, profit distribution, stock or
7 stock option grant, or any ownership or in-
8 vestment interest held by a physician in a
9 manufacturer (excluding a dividend or
10 other profit distribution from, or ownership
11 or investment interest in, a publicly traded
12 security or mutual fund (as described in
13 section 1877(c)).

14 “(B) EXCLUSIONS.—Such term does not
15 include the following:

16 “(i) Any payment or other transfer of
17 value provided by an applicable manufac-
18 turer or distributor to a covered recipient
19 where the amount transferred to, requested
20 by, or designated on behalf of the covered
21 recipient does not exceed \$5.

22 “(ii) The loan of a covered device for
23 a short-term trial period, not to exceed 90
24 days, to permit evaluation of the covered
25 device by the covered recipient.

1 “(iii) Items or services provided under
2 a contractual warranty, including the re-
3 placement of a covered device, where the
4 terms of the warranty are set forth in the
5 purchase or lease agreement for the cov-
6 ered device.

7 “(iv) A transfer of anything of value
8 to a covered recipient when the covered re-
9 cipient is a patient and not acting in the
10 professional capacity of a covered recipient.

11 “(v) In-kind items used for the provi-
12 sion of charity care.

13 “(vi) A dividend or other profit dis-
14 tribution from, or ownership or investment
15 interest in, a publicly traded security and
16 mutual fund (as described in section
17 1877(c)).

18 “(vii) Compensation paid by a manu-
19 facturer or distributor of a covered drug,
20 device, biological, or medical supply to a
21 covered recipient who is directly employed
22 by and works solely for such manufacturer
23 or distributor.

24 “(9) PHYSICIAN.—The term ‘physician’ has the
25 meaning given that term in section 1861(r). For

1 purposes of this section, such term does not include
2 a physician who is an employee of the applicable
3 manufacturer that is required to submit information
4 under subsection (a).

5 “(g) ANNUAL REPORTS TO STATES.—Not later than
6 April 1 of each year beginning with 2011, the Secretary
7 shall submit to States a report that includes a summary
8 of the information submitted under subsections (a) and
9 (d) during the preceding year with respect to covered re-
10 cipients or other hospitals and entities in the State.”.

11 (b) AVAILABILITY OF INFORMATION FROM THE DIS-
12 CLOSURE OF FINANCIAL RELATIONSHIP REPORT
13 (DFRR).—Pursuant to section 5006 of the Deficit Reduc-
14 tion Act of 2005 (Public Law 109–171), the Secretary of
15 Health and Human Services—

16 (1) may conduct surveys of hospitals with re-
17 spect to the financial relationship (through owner-
18 ship, investment, or otherwise) physicians in such
19 hospitals; and

20 (2) shall make the full results of such surveys
21 available to the Congress and shall make a sum-
22 mary, and such details as the Secretary may specify,
23 of such surveys available to public through an Inter-
24 net website of the Department of Health and
25 Human Services.