

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

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, 2011 and an-

1 nually thereafter, each applicable manufacturer or  
2 distributor that provides a payment or other transfer  
3 of value to a covered recipient, or to an entity or in-  
4 dividual at the request of or designated on behalf of  
5 a covered recipient, shall submit to the Secretary, in  
6 such electronic form as the Secretary shall require,  
7 the following information with respect to the pre-  
8 ceding calendar year:

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

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

14 “(i) its value and date;

15 “(ii) the name of the related drug, de-  
16 vice, or supply, if available; and

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

19 as—

20 “(I) cash or a cash equivalent;

21 “(II) in-kind items or services;

22 “(III) stock, a stock option, or  
23 any other ownership interest, divi-  
24 dend, profit, or other return on invest-  
25 ment; or

1                                   “(IV) any other form (as defined  
2                                   by the Secretary).

3                                   “(C) With respect to a drug sample, the  
4                                   name, number, date, and dosage units of the  
5                                   sample.

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

17                                  “(3) SPECIAL RULE FOR CERTAIN PAYMENTS  
18                                  OR OTHER TRANSFERS OF VALUE.—In the case  
19                                  where an applicable manufacturer or distributor pro-  
20                                  vides a payment or other transfer of value to an en-  
21                                  tity or individual at the request of or designated on  
22                                  behalf of a covered recipient, the manufacturer or  
23                                  distributor shall disclose that payment or other  
24                                  transfer of value under the name of the covered re-  
25                                  cipient.

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

14                 “(A) The date of the approval or clearance  
15                 of the covered drug, device, biological, or med-  
16                 ical supply by the Food and Drug Administra-  
17                 tion.

18                 “(B) Two calendar years after the date  
19                 such payment or other transfer of value was  
20                 made.

21           “(5) DELAYED REPORTING FOR PAYMENTS  
22           MADE PURSUANT TO CLINICAL INVESTIGATIONS.—In  
23           the case of a payment or other transfer of value  
24           made to a covered recipient by an applicable manu-  
25           facturer or distributor in connection with a clinical

1 investigation regarding a new drug, device, biologi-  
2 cal, or medical supply, the applicable manufacturer  
3 or distributor may report as required under this sec-  
4 tion in the next reporting period under this sub-  
5 section after the earlier of the following:

6 “(A) The date that the clinical investiga-  
7 tion is registered on the website maintained by  
8 the National Institutes of Health pursuant to  
9 section 671 of the Food and Drug Administra-  
10 tion Amendments Act of 2007.

11 “(B) Two calendar years after the date  
12 such payment or other transfer of value was  
13 made.

14 “(6) CONFIDENTIALITY.—Information de-  
15 scribed in paragraph (4) or (5) shall be considered  
16 confidential and shall not be subject to disclosure  
17 under section 552 of title 5, United States Code, or  
18 any other similar Federal, State, or local law, until  
19 or after the date on which the information is made  
20 available to the public under such paragraph.

21 “(b) REPORTING OF OWNERSHIP INTEREST BY PHY-  
22 SICIANS IN HOSPITALS AND OTHER ENTITIES THAT BILL  
23 MEDICARE.—Not later than March 31 of each year (be-  
24 ginning with 2011), each hospital or other health care en-  
25 tity (not including a Medicare Advantage organization)

1 that bills the Secretary under part A or part B of title  
2 XVIII for services shall report on the ownership shares  
3 (other than ownership shares described in section 1877(c))  
4 of each physician who, directly or indirectly, owns an in-  
5 terest in the entity. In this subsection, the term ‘physician’  
6 includes a physician’s immediate family members (as de-  
7 fined for purposes of section 1877(a)).

8 “(c) PUBLIC AVAILABILITY.—

9 “(1) IN GENERAL.—The Secretary shall estab-  
10 lish procedures to ensure that, not later than Sep-  
11 tember 30, 2011, and on June 30 of each year be-  
12 ginning thereafter, the information submitted under  
13 subsections (a) and (b), other than information re-  
14 gard drug samples, with respect to the preceding  
15 calendar year is made available through an Internet  
16 website that—

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

19 “(B) contains information that is pre-  
20 sented by the name of the applicable manufac-  
21 turer or distributor, the name of the covered re-  
22 cipient, the business address of the covered re-  
23 cipient, the specialty (if applicable) of the cov-  
24 ered recipient, the value of the payment or  
25 other transfer of value, the date on which the

1 payment or other transfer of value was provided  
2 to the covered recipient, the form of the pay-  
3 ment or other transfer of value, indicated (as  
4 appropriate) under subsection (a)(1)(B)(ii), the  
5 nature of the payment or other transfer of  
6 value, indicated (as appropriate) under sub-  
7 section (a)(1)(B)(iii), and the name of the cov-  
8 ered drug, device, biological, or medical supply,  
9 as applicable;

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

12 “(D) contains a description of any enforce-  
13 ment actions taken to carry out this section, in-  
14 cluding any penalties imposed under subsection  
15 (d), during the preceding year;

16 “(E) contains background information on  
17 industry-physician relationships;

18 “(F) in the case of information submitted  
19 with respect to a payment or other transfer of  
20 value described in subsection (a)(5), lists such  
21 information separately from the other informa-  
22 tion submitted under subsection (a) and des-  
23 ignates such separately listed information as  
24 funding for clinical research;

1           “(G) contains any other information the  
2           Secretary determines would be helpful to the  
3           average consumer; and

4           “(H) provides the covered recipient an op-  
5           portunity to submit corrections to the informa-  
6           tion made available to the public with respect to  
7           the covered recipient.

8           “(2) ACCURACY OF REPORTING.—The accuracy  
9           of the information that is submitted under sub-  
10          sections (a) and (b) and made available under para-  
11          graph (1) shall be the responsibility of the applicable  
12          manufacturer or distributor of a covered drug, de-  
13          vice, biological, or medical supply reporting under  
14          subsection (a) or hospital or other health care entity  
15          reporting physician ownership under subsection (b).  
16          The Secretary shall establish procedures to ensure  
17          that the covered recipient is provided with an oppor-  
18          tunity to submit corrections to the manufacturer,  
19          distributor, hospital, or other entity reporting under  
20          subsection (a) or (b) with regard to information  
21          made public with respect to the covered recipient  
22          and, under such procedures, the corrections shall be  
23          transmitted to the Secretary.

24          “(3) SPECIAL RULE FOR DRUG SAMPLES.—In-  
25          formation relating to drug samples provided under

1 subsection (a) shall not be made available to the  
2 public by the Secretary but may be made available  
3 outside the Department of Health and Human Serv-  
4 ices by the Secretary for research or legitimate busi-  
5 ness purposes pursuant to data use agreements.

6 “(4) SPECIAL RULE FOR NATIONAL PROVIDER  
7 IDENTIFIERS.—Information relating to national pro-  
8 vider identifiers provided under subsection (a) shall  
9 not be made available to the public by the Secretary  
10 but may be made available outside the Department  
11 of Health and Human Services by the Secretary for  
12 research or legitimate business purposes pursuant to  
13 data use agreements.

14 “(d) 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 or distributor that  
19 fails to submit information required under sub-  
20 section (a) in a timely manner in accordance  
21 with regulations promulgated to carry out such  
22 subsection, and any hospital or other entity that  
23 fails to submit information required under sub-  
24 section (b) in a timely manner in accordance  
25 with regulations promulgated to carry out such

1 subsection shall be subject to a civil money pen-  
2 alty of not less than \$1,000, but not more than  
3 \$10,000, for each payment or other transfer of  
4 value or ownership or investment interest not  
5 reported as required under such subsection.  
6 Such penalty shall be imposed and collected in  
7 the same manner as civil money penalties under  
8 subsection (a) of section 1128A are imposed  
9 and collected under that section.

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

16 “(2) KNOWING FAILURE TO REPORT.—

17 “(A) IN GENERAL.—Subject to subpara-  
18 graph (B), any applicable manufacturer or dis-  
19 tributor that knowingly fails to submit informa-  
20 tion required under subsection (a) in a timely  
21 manner in accordance with regulations promul-  
22 gated to carry out such subsection and any hos-  
23 pital or other entity that fails to submit infor-  
24 mation required under subsection (b) in a time-  
25 ly manner in accordance with regulations pro-

1           mulgated to carry out such subsection, shall be  
2           subject to a civil money penalty of not less than  
3           \$10,000, but not more than \$100,000, for each  
4           payment or other transfer of value or ownership  
5           or investment interest not reported as required  
6           under such subsection. Such penalty shall be  
7           imposed and collected in the same manner as  
8           civil money penalties under subsection (a) of  
9           section 1128A are imposed and collected under  
10          that section.

11           “(B) LIMITATION.—The total amount of  
12          civil money penalties imposed under subpara-  
13          graph (A) with respect to each annual submis-  
14          sion of information under subsection (a) or (b)  
15          by an applicable manufacturer, distributor, or  
16          entity shall not exceed \$1,000,000, or, if great-  
17          er, 0.1 percentage of the total annual revenues  
18          of the manufacturer, distributor, or entity.

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

23           “(4) ENFORCEMENT THROUGH STATE ATTOR-  
24          NEYS GENERAL.—The attorney general of a State,  
25          after providing notice to the Secretary of an intent

1 to proceed under this paragraph in a specific case  
2 and providing the Secretary with an opportunity to  
3 bring an action under this subsection and the Sec-  
4 retary declining such opportunity, may proceed  
5 under this subsection against a manufacturer or dis-  
6 tributor in the State.

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

11 “(1) The information submitted under this sec-  
12 tion during the preceding year, aggregated for each  
13 applicable manufacturer or distributor of a covered  
14 drug, device, biological, or medical supply that sub-  
15 mitted such information during such year.

16 “(2) A description of any enforcement actions  
17 taken to carry out this section, including any pen-  
18 alties imposed under subsection (d), during the pre-  
19 ceding year.

20 “(f) DEFINITIONS.—In this section:

21 “(1) APPLICABLE MANUFACTURER; APPLICA-  
22 BLE DISTRIBUTOR.—The term ‘applicable manufac-  
23 turer’ means a manufacturer of a covered drug, de-  
24 vice, biological, or medical supply, and the term ‘ap-

1       plicable distributor’ means a distributor of a covered  
2       drug, device, or medical supply.

3           “(2) CLINICAL INVESTIGATION.—The term  
4       ‘clinical investigation’ means any experiment involv-  
5       ing one or more human subjects, or materials de-  
6       rived from human subjects, in which a drug or de-  
7       vice is administered, dispensed, or used.

8           “(3) COVERED DRUG, DEVICE, BIOLOGICAL, OR  
9       MEDICAL SUPPLY.—The term ‘covered’ means, with  
10      respect to a drug, device, biological, or medical sup-  
11      ply, such a drug, device, biological, or medical supply  
12      for which payment is available under title XVIII or  
13      a State plan under title XIX or XXI (or a waiver  
14      of such a plan).

15          “(4) COVERED RECIPIENT.—The term ‘covered  
16      recipient’ means the following:

17           “(A) A physician.

18           “(B) A physician group practice.

19           “(C) Any other prescriber of a covered  
20      drug, device, biological, or medical supply.

21           “(D) A pharmacy or pharmacist.

22           “(E) A health insurance issuer, group  
23      health plan, or other entity offering a health  
24      benefits plan, including any employee of such  
25      an issuer, plan, or entity.

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

3           “(G) A hospital.

4           “(H) A medical school.

5           “(I) A sponsor of a continuing medical  
6           education program.

7           “(J) A patient advocacy or disease specific  
8           group.

9           “(K) A organization of health care profes-  
10          sionals.

11          “(L) A biomedical researcher.

12          “(M) A group purchasing organization.

13          “(5) DISTRIBUTOR OF A COVERED DRUG, DE-  
14          VICE, OR MEDICAL SUPPLY.—The term ‘distributor  
15          of a covered drug, device, or medical supply’ means  
16          any entity which is engaged in the marketing or dis-  
17          tribution of a covered drug, device, or medical sup-  
18          ply (or any subsidiary of or entity affiliated with  
19          such entity), but does not include a wholesale phar-  
20          maceutical distributor.

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

23          “(7) KNOWINGLY.—The term ‘knowingly’ has  
24          the meaning given such term in section 3729(b) of  
25          title 31, United States Code.

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

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

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

15                   “(i) Gift, food, or entertainment.

16                   “(ii) Travel or trip.

17                   “(iii) Honoraria.

18                   “(iv) Research funding or grant.

19                   “(v) Education or conference funding.

20                   “(vi) Consulting fees.

21                   “(vii) Ownership or investment inter-  
22                   est and royalties or license fee.

23           “(B) INCLUSIONS.—Subject to subpara-  
24           graph (C), the term ‘payment or other transfer  
25           of value’ includes any compensation, gift, hono-

1 rarium, speaking fee, consulting fee, travel,  
2 services, dividend, profit distribution, stock or  
3 stock option grant, or any ownership or invest-  
4 ment interest held by a physician in a manufac-  
5 turer (excluding a dividend or other profit dis-  
6 tribution from, or ownership or investment in-  
7 terest in, a publicly traded security or mutual  
8 fund (as described in section 1877(e))).

9 “(C) EXCLUSIONS.—The term ‘payment or  
10 other transfer of value’ does not include the fol-  
11 lowing:

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

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

22 “(iii) Items or services provided under  
23 a contractual warranty, including the re-  
24 placement of a covered device, where the  
25 terms of the warranty are set forth in the

1 purchase or lease agreement for the cov-  
2 ered device.

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

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

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

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

20 “(viii) Any discount or cash rebate.

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

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

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

9 “(h) RELATION TO STATE LAWS.—

10 “(1) IN GENERAL.—Effective on January 1,  
11 2011, subject to paragraph (2), the provisions of  
12 this section shall preempt any law or regulation of  
13 a State or of a political subdivision of a State that  
14 requires an applicable manufacturer and applicable  
15 distributor (as such terms are defined in subsection  
16 (f)) to disclose or report, in any format, the type of  
17 information (described in subsection (a)) regarding a  
18 payment or other transfer of value provided by the  
19 manufacturer to a covered recipient (as so defined).

20 “(2) NO PREEMPTION OF ADDITIONAL RE-  
21 QUIREMENTS.—Paragraph (1) shall not preempt any  
22 law or regulation of a State or of a political subdivi-  
23 sion of a State that requires any of the following:

1           “(A) The disclosure or reporting of infor-  
2           mation not of the type required to be disclosed  
3           or reported under this section.

4           “(B) The disclosure or reporting, in any  
5           format, of the type of information required to  
6           be disclosed or reported under this section to a  
7           Federal, State, or local governmental agency for  
8           public health surveillance, investigation, or  
9           other public health purposes or health oversight  
10          purposes.

11          “(C) The discovery or admissibility of in-  
12          formation described in this section in a crimi-  
13          nal, civil, or administrative proceeding.”.

14          (b) AVAILABILITY OF INFORMATION FROM THE DIS-  
15          CLOSURE OF FINANCIAL RELATIONSHIP REPORT  
16          (DFRR).—The Secretary of Health and Human Services  
17          shall submit to Congress a report on the full results of  
18          the Disclosure of Physician Financial Relationships sur-  
19          veys required pursuant to section 5006 of the Deficit Re-  
20          duction Act of 2005. Such report shall be submitted to  
21          Congress not later than the date that is 6 months after  
22          the date such surveys are collected and shall be made pub-  
23          licly available on an Internet website of the Department  
24          of Health and Human Services.

1     **Subtitle E—Public Reporting on**  
2     **Health Care-Associated Infections**

3     **SEC. 1461. REQUIREMENT FOR PUBLIC REPORTING BY**  
4                   **HOSPITALS AND AMBULATORY SURGICAL**  
5                   **CENTERS ON HEALTH CARE-ASSOCIATED IN-**  
6                   **FECTIONS.**

7           (a) IN GENERAL.—Title XI of the Social Security Act  
8 is amended by inserting after section 1138 the following  
9 section:

10    **“SEC. 1138A. REQUIREMENT FOR PUBLIC REPORTING BY**  
11                   **HOSPITALS AND AMBULATORY SURGICAL**  
12                   **CENTERS ON HEALTH CARE-ASSOCIATED IN-**  
13                   **FECTIONS.**

14           “(a) REPORTING REQUIREMENT.—

15                   “(1) IN GENERAL.—The Secretary shall provide  
16           that a hospital (as defined in subsection (g)) or am-  
17           bulatory surgical center meeting the requirements of  
18           titles XVIII or XIX may participate in the programs  
19           established under such titles (pursuant to the appli-  
20           cable provisions of law, including sections  
21           1866(a)(1) and 1832(a)(1)(F)(i)) only if, in accord-  
22           ance with this section, the hospital or center reports  
23           such information on health care-associated infections  
24           that develop in the hospital or center (and such de-