Subtitle D—Physician Payments

Sunshine Provision

SEC. 1451. REPORTS ON FINANCIAL RELATIONSHIPS BETWEEN MANUFACTURERS AND DISTRIBUTORS OF COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR CHIP AND PHYSICIANS AND OTHER HEALTH CARE ENTITIES AND BETWEEN PHYSICIANS AND OTHER HEALTH CARE ENTITIES.

(a) In General.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 1631(a), is further amended by inserting after section 1128G the following new section:

"SEC. 1128H. FINANCIAL REPORTS ON PHYSICIANS' FINANCIAL RELATIONSHIPS WITH MANUFACTURERS AND DISTRIBUTORS OF COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR CHIP AND WITH ENTITIES THAT BILL FOR SERVICES UNDER MEDICARE.

"(a) Reporting of Payments or Other Transfers of Value.—

"(1) In General.—Except as provided in this subsection, not later than March 31, 2011 and an-
ually thereafter, each applicable manufacturer or
distributor that provides a payment or other transfer
of value to a covered recipient, or to an entity or in-
dividual at the request of or designated on behalf of
a covered recipient, shall submit to the Secretary, in
such electronic form as the Secretary shall require,
the following information with respect to the pre-
ceding calendar year:

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

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

“(i) its value and date;

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

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

as—

“(I) cash or a cash equivalent;

“(II) in-kind items or services;

“(III) stock, a stock option, or
any other ownership interest, divi-
dend, profit, or other return on invest-
ment; or
“(IV) any other form (as defined by the Secretary).

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

“(2) AGGREGATE REPORTING.—Information submitted by an applicable manufacturer or distributor under paragraph (1) shall include the aggregate amount of all payments or other transfers of value provided by the manufacturer or distributor to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the year involved, including all payments and transfers of value regardless of whether such payments or transfer of value were individually disclosed.

“(3) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer or distributor provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the manufacturer or distributor shall disclose that payment or other transfer of value under the name of the covered recipient.
“(4) Delayed Reporting for Payments Made Pursuant to Product Development Agreements.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report the value and recipient of such payment or other transfer of value in the first reporting period under this subsection in the next reporting deadline after the earlier of the following:

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

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

“(5) Delayed Reporting for Payments Made Pursuant to Clinical Investigations.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor in connection with a clinical
investigation regarding a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report as required under this section in the next reporting period under this subsection after the earlier of the following:

“(A) The date that the clinical investigation is registered on the website maintained by the National Institutes of Health pursuant to section 671 of the Food and Drug Administration Amendments Act of 2007.

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

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

“(b) REPORTING OF OWNERSHIP INTEREST BY PHYSICIANS IN HOSPITALS AND OTHER ENTITIES THAT BILL MEDICARE.—Not later than March 31 of each year (beginning with 2011), each hospital or other health care entity (not including a Medicare Advantage organization)
that bills the Secretary under part A or part B of title XVIII for services shall report on the ownership shares (other than ownership shares described in section 1877(c)) of each physician who, directly or indirectly, owns an interest in the entity. In this subsection, the term ‘physician’ includes a physician’s immediate family members (as defined for purposes of section 1877(a)).

“(c) Public Availability.—

“(1) In general.—The Secretary shall establish procedures to ensure that, not later than September 30, 2011, and on June 30 of each year beginning thereafter, the information submitted under subsections (a) and (b), other than information regarding drug samples, with respect to the preceding calendar year is made available through an Internet website that—

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

“(B) contains information that is presented by the name of the applicable manufacturer or distributor, the name of the covered recipient, the business address of the covered recipient, the specialty (if applicable) of the covered recipient, the value of the payment or other transfer of value, the date on which the
payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(ii), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(iii), and the name of the covered drug, device, biological, or medical supply, as applicable;

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

“(D) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (d), during the preceding year;

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

“(F) in the case of information submitted with respect to a payment or other transfer of value described in subsection (a)(5), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;
(G) contains any other information the Secretary determines would be helpful to the average consumer; and

(H) provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.

(2) Accuracy of Reporting.—The accuracy of the information that is submitted under subsections (a) and (b) and made available under paragraph (1) shall be the responsibility of the applicable manufacturer or distributor of a covered drug, device, biological, or medical supply reporting under subsection (a) or hospital or other health care entity reporting physician ownership under subsection (b). The Secretary shall establish procedures to ensure that the covered recipient is provided with an opportunity to submit corrections to the manufacturer, distributor, hospital, or other entity reporting under subsection (a) or (b) with regard to information made public with respect to the covered recipient and, under such procedures, the corrections shall be transmitted to the Secretary.

(3) Special Rule for Drug Samples.—Information relating to drug samples provided under
subsection (a) shall not be made available to the public by the Secretary but may be made available outside the Department of Health and Human Services by the Secretary for research or legitimate business purposes pursuant to data use agreements.

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

“(d) PENALTIES FOR NONCOMPLIANCE.—

“(1) FAILURE TO REPORT.—

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

“(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or distributor or other entity shall not exceed $150,000.

“(2) KNOWING FAILURE TO REPORT.—

“(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or distributor that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with regulations promulgated to carry out such subsection and any hospital or other entity that fails to submit information required under subsection (b) in a timely manner in accordance with regulations pro-
mulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

“(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) or (b) by an applicable manufacturer, distributor, or entity shall not exceed $1,000,000, or, if greater, 0.1 percentage of the total annual revenues of the manufacturer, distributor, or entity.

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

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

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

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

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

“(f) DEFINITIONS.—In this section:

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

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

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

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

“(A) A physician.

“(B) A physician group practice.

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

“(D) A pharmacy or pharmacist.

“(E) A health insurance issuer, group
health plan, or other entity offering a health
benefits plan, including any employee of such
an issuer, plan, or entity.
“(F) A pharmacy benefit manager, including any employee of such a manager.

“(G) A hospital.

“(H) A medical school.

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

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

“(K) A organization of health care professionals.

“(L) A biomedical researcher.

“(M) A group purchasing organization.

“(5) DISTRIBUTOR OF A COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term ‘distributor of a covered drug, device, or medical supply’ means any entity which is engaged in the marketing or distribution of a covered drug, device, or medical supply (or any subsidiary of or entity affiliated with such entity), but does not include a wholesale pharmaceutical distributor.

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

“(7) KNOWINGLY.—The term ‘knowingly’ has the meaning given such term in section 3729(b) of title 31, United States Code.
“(8) Manufacturer of a covered drug, device, biological, or medical supply.—The term ‘manufacturer of a covered drug, device, biological, or medical supply’ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply (or any subsidiary of or entity affiliated with such entity).

“(9) Payment or other transfer of value.—

“(A) In general.—The term ‘payment or other transfer of value’ means a transfer of anything of value for or of any of the following:

“(i) Gift, food, or entertainment.

“(ii) Travel or trip.

“(iii) Honoraria.

“(iv) Research funding or grant.

“(v) Education or conference funding.

“(vi) Consulting fees.

“(vii) Ownership or investment interest and royalties or license fee.

“(B) Inclusions.—Subject to subparagraph (C), the term ‘payment or other transfer of value’ includes any compensation, gift, hono-
rarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund (as described in section 1877(c))).

“(C) EXCLUSIONS.—The term ‘payment or other transfer of value’ does not include the following:

“(i) Any payment or other transfer of value provided by an applicable manufacturer or distributor to a covered recipient where the amount transferred to, requested by, or designated on behalf of the covered recipient does not exceed $5.

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

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

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

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

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

“(vii) Compensation paid by a manufacturer or distributor of a covered drug, device, biological, or medical supply to a covered recipient who is directly employed by and works solely for such manufacturer or distributor.

“(viii) Any discount or cash rebate.

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

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

“(h) RELATION TO STATE LAWS.—

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

“(2) NO PREEMPTION OF ADDITIONAL RE-
QUIREMENTS.—Paragraph (1) shall not preempt any
law or regulation of a State or of a political subdivi-
sion of a State that requires any of the following:
“(A) The disclosure or reporting of information not of the type required to be disclosed or reported under this section.

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

“(C) The discovery or admissibility of information described in this section in a criminal, civil, or administrative proceeding.”.

(b) AVAILABILITY OF INFORMATION FROM THE DISCLOSURE OF FINANCIAL RELATIONSHIP REPORT (DFRR).—The Secretary of Health and Human Services shall submit to Congress a report on the full results of the Disclosure of Physician Financial Relationships surveys required pursuant to section 5006 of the Deficit Reduction Act of 2005. Such report shall be submitted to Congress not later than the date that is 6 months after the date such surveys are collected and shall be made publicly available on an Internet website of the Department of Health and Human Services.
Subtitle E—Public Reporting on Health Care-Associated Infections

SEC. 1461. REQUIREMENT FOR PUBLIC REPORTING BY HOSPITALS AND AMBULATORY SURGICAL CENTERS ON HEALTH CARE-ASSOCIATED INFECTIONS.

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

“SEC. 1138A. REQUIREMENT FOR PUBLIC REPORTING BY HOSPITALS AND AMBULATORY SURGICAL CENTERS ON HEALTH CARE-ASSOCIATED INFECTIONS.

“(a) REPORTING REQUIREMENT.—

“(1) IN GENERAL.—The Secretary shall provide that a hospital (as defined in subsection (g)) or ambulatory surgical center meeting the requirements of titles XVIII or XIX may participate in the programs established under such titles (pursuant to the applicable provisions of law, including sections 1866(a)(1) and 1832(a)(1)(F)(i)) only if, in accordance with this section, the hospital or center reports such information on health care-associated infections that develop in the hospital or center (and such de-