Legislative text of Physician Payment and other transparency provisions included in H.R. 3590: Patient Protection and Affordable Care Act of 2009
Passed by the Senate (12/24/09) and the House (3/21/10)

Section 6002: Transparency Reports and Reporting of Physician Ownership or Investment Interests
[commonly known as the Physician Payment Sunshine Provision]

Section 6003: Disclosure Requirements for In-Office Ancillary Services Exception to the Prohibition on Physician Self-Referral for Certain Imaging Services

Section 6004: Prescription Drug Sample Transparency

Section 6005: Pharmacy Benefit Managers Transparency Requirements

(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act, as added by subsection (a)(3), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

(2) AUDITS.—Beginning not later than November 1, 2011, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1).

SEC. 6002. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

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

"SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

"(a) TRANSPARENCY REPORTS.—

"(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

"(A) IN GENERAL.—On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual 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 preceding calendar year:

"(i) The name of the covered recipient.

"(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

"(iii) The amount of the payment or other transfer of value.

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

"(v) A description of the form of the payment or other transfer of value, indicated (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, dividend, profit, or other return on investment; or

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

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

"(I) consulting fees;

"(II) compensation for services other than consulting;

"(III) honoraria;

"(IV) gift;

"(V) entertainment;

"(VI) food;

"(VII) travel (including the specified destinations);

"(VIII) education;

"(IX) research;

"(X) charitable contribution;

"(XI) royalty or license;

"(XII) current or prospective ownership or investment interest;

"(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

"(XIV) grant; or

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

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

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

"(B) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or des-

ignated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

"(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

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

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

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

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

"(b) PENALTIES FOR NONCOMPLIANCE.—

"(1) FAILURE TO REPORT.—

"(A) IN GENERAL.—Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or 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 own-

ership 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 applicable group purchasing organization shall not exceed $150,000.

"(2) KNOWING FAILURE TO REPORT.—

"(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated 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) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

"(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.

"(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

"(1) IN GENERAL.—

"(A) ESTABLISHMENT.—Not later than October 1, 2011, the Secretary shall establish procedures—

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

"(ii) for the Secretary to make such information submitted available to the public.

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

"(C) PUBLIC AVAILABILITY.—Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

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

"(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other trans-

fer 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)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

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

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

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

"(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such sepa-

rately listed information as funding for clinical research;

"(vii) contains any other information the Secretary determines would be helpful to the average consumer;

"(viii) does not contain the National Provider Identifier of the covered recipient, and

"(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

"(D) CLARIFICATION OF TIME PERIOD FOR REVIEW AND CORRECTIONS.—In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with

the dates described in the matter preceding clause (i) in subparagraph (C).

"(E) DELAYED PUBLICATION FOR PAYMENTS MADE PURSUANT TO PRODUCT RESEARCH OR DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—

"(i) IN GENERAL.—In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the

matter preceding clause (i) in subparagraph (C) after the earlier of the following:

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

"(II) Four calendar years after the date such payment or other transfer of value was made.

"(ii) CONFIDENTIALITY OF INFORMATION PRIOR TO PUBLICATION.—Information described in clause (i) 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 on or after the date on which the information is made available to the public under such clause.

"(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made

available to the public under such paragraph is presented in the appropriate overall context.

"(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

"(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

"(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

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

"(2) ANNUAL REPORTS TO STATES.—Not later than September 30, 2013 and on June 30 of each cal-

endar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

"(3) RELATION TO STATE LAWS.—

"(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

"(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not pre-

empt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

"(i) not of the type required to be disclosed or reported under this section;

"(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

"(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

"(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

"(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

"(4) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

"(e) DEFINITIONS.—In this section:

"(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

"(2) APPLICABLE MANUFACTURER.—The term 'applicable manufacturer' means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

"(3) CLINICAL INVESTIGATION.—The term 'clinical investigation' means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

"(4) COVERED DEVICE.—The term 'covered device' means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

"(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term 'covered drug, device, biological, or medical supply' means any drug, biological product, device, 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).

"(6) COVERED RECIPIENT.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered recipient' means the following:

"(i) A physician.

"(ii) A teaching hospital.

"(B) EXCLUSION.—Such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

"(7) EMPLOYEE.—The term 'employee' has the meaning given such term in section 1877(h)(2).

"(8) KNOWINGLY.—The term 'knowingly' has the meaning given such term in section 3729(b) of title 31, United States Code.

"(9) 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, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

"(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

"(A) IN GENERAL.—The term 'payment or other transfer of value' means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

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

"(i) A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

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

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

"(iv) 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.

"(v) Items or services provided under a contractual warranty, including the re-

placement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

"(vi) 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.

"(vii) Discounts (including rebates).

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

"(ix) 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)).

"(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

"(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional serv-

ices of such licensed non-medical professional.

"(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

"(11) PHYSICIAN.—The term 'physician' has the meaning given that term in section 1861(r).".

SEC. 6003. DISCLOSURE REQUIREMENTS FOR IN-OFFICE ANCILLARY SERVICES EXCEPTION TO THE PROHIBITION ON PHYSICIAN SELF-REFERRAL FOR CERTAIN IMAGING SERVICES.

(a) IN GENERAL.—Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)) is amended by adding at the end the following new sentence: "Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual

is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to services furnished on or after January 1, 2010.

SEC. 6004. PRESCRIPTION DRUG SAMPLE TRANSPARENCY.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 6002, is amended by inserting after section 1128G the following new section:

"SEC. 1128H. REPORTING OF INFORMATION RELATING TO DRUG SAMPLES.

"(a) IN GENERAL.—Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized distributor of record of an applicable drug shall submit to the Secretary (in a form and manner specified by the Secretary) the following information with respect to the preceding year:

"(1) In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier under subsection (d)(2) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353), the identity and quantity of

drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

"(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

"(B) any other category of information determined appropriate by the Secretary.

"(2) In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier under subsection (d)(3) of such section 503, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

"(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

"(B) any other category of information determined appropriate by the Secretary.

"(b) DEFINITIONS.—In this section:

"(1) APPLICABLE DRUG.—The term 'applicable drug' means a drug—

"(A) which is subject to subsection (b) of such section 503; and

"(B) for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

"(2) AUTHORIZED DISTRIBUTOR OF RECORD.—The term 'authorized distributor of record' has the meaning given that term in subsection (e)(3)(A) of such section.

"(3) MANUFACTURER.—The term 'manufacturer' has the meaning given that term for purposes of subsection (d) of such section.".

SEC. 6005. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1150 the following new section:

"SEC. 1150A. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

"(a) PROVISION OF INFORMATION.—A health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as a 'PBM') that manages prescription drug coverage under a contract with—

"(1) a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or

"(2) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act,

shall provide the information described in subsection (b) to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify.

"(b) INFORMATION DESCRIBED.—The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:

"(1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed

(generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.

"(2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

"(3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

"(c) CONFIDENTIALITY.—Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

"(1) As the Secretary determines to be necessary to carry out this section or part D of title XVIII.

"(2) To permit the Comptroller General to review the information provided.

"(3) To permit the Director of the Congressional Budget Office to review the information provided.

"(4) To States to carry out section 1311 of the Patient Protection and Affordable Care Act.

"(d) PENALTIES.—The provisions of subsection (b)(3)(C) of section 1927 shall apply to a health benefits plan or PBM that fails to provide information required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.".