

**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 (1) *ENSURING COMPLIANCE.*—*The Secretary of*
2 *Health and Human Services shall establish policies*
3 *and procedures to ensure compliance with the require-*
4 *ments described in subsection (i)(1) of section 1877 of*
5 *the Social Security Act, as added by subsection*
6 *(a)(3), beginning on the date such requirements first*
7 *apply. Such policies and procedures may include un-*
8 *announced site reviews of hospitals.*

9 (2) *AUDITS.*—*Beginning not later than Novem-*
10 *ber 1, 2011, the Secretary of Health and Human*
11 *Services shall conduct audits to determine if hospitals*
12 *violate the requirements referred to in paragraph (1).*

13 **SEC. 6002. TRANSPARENCY REPORTS AND REPORTING OF**
14 **PHYSICIAN OWNERSHIP OR INVESTMENT IN-**
15 **TERESTS.**

16 *Part A of title XI of the Social Security Act (42 U.S.C.*
17 *1301 et seq.) is amended by inserting after section 1128F*
18 *the following new section:*

19 **“SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING OF**
20 **PHYSICIAN OWNERSHIP OR INVESTMENT IN-**
21 **TERESTS.**

22 **“(a) TRANSPARENCY REPORTS.**—

23 **“(1) PAYMENTS OR OTHER TRANSFERS OF**
24 **VALUE.**—

1 “(A) *IN GENERAL.*—On March 31, 2013,
2 and on the 90th day of each calendar year begin-
3 ning thereafter, any applicable manufacturer
4 that provides a payment or other transfer of
5 value to a covered recipient (or to an entity or
6 individual at the request of or designated on be-
7 half of a covered recipient), shall submit to the
8 Secretary, in such electronic form as the Sec-
9 retary shall require, the following information
10 with respect to the preceding calendar year:

11 “(i) *The name of the covered recipient.*

12 “(ii) *The business address of the cov-*
13 *ered recipient and, in the case of a covered*
14 *recipient who is a physician, the specialty*
15 *and National Provider Identifier of the cov-*
16 *ered recipient.*

17 “(iii) *The amount of the payment or*
18 *other transfer of value.*

19 “(iv) *The dates on which the payment*
20 *or other transfer of value was provided to*
21 *the covered recipient.*

22 “(v) *A description of the form of the*
23 *payment or other transfer of value, indi-*
24 *cated (as appropriate for all that apply)*
25 *as—*

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- “(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;*

1 “(XI) *royalty or license;*

2 “(XII) *current or prospective*
3 *ownership or investment interest;*

4 “(XIII) *direct compensation for*
5 *-serving as faculty or as a speaker for*
6 *a medical education program;*

7 “(XIV) *grant; or*

8 “(XV) *any other nature of the*
9 *payment or other transfer of value (as*
10 *defined by the Secretary).*

11 “(vii) *If the payment or other transfer*
12 *of value is related to marketing, education,*
13 *or research specific to a covered drug, de-*
14 *vice, biological, or medical supply, the name*
15 *of that covered drug, device, biological, or*
16 *medical supply.*

17 “(viii) *Any other categories of informa-*
18 *tion regarding the payment or other trans-*
19 *fer of value the Secretary determines appro-*
20 *priate.*

21 “(B) *SPECIAL RULE FOR CERTAIN PAY-*
22 *MENTS OR OTHER TRANSFERS OF VALUE.—In*
23 *the case where an applicable manufacturer pro-*
24 *vides a payment or other transfer of value to an*
25 *entity or individual at the request of or des-*

1 *ignated on behalf of a covered recipient, the ap-*
2 *plicable manufacturer shall disclose that pay-*
3 *ment or other transfer of value under the name*
4 *of the covered recipient.*

5 “(2) *PHYSICIAN OWNERSHIP.*—*In addition to the*
6 *requirement under paragraph (1)(A), on March 31,*
7 *2013, and on the 90th day of each calendar year be-*
8 *ginning thereafter, any applicable manufacturer or*
9 *applicable group purchasing organization shall sub-*
10 *mit to the Secretary, in such electronic form as the*
11 *Secretary shall require, the following information re-*
12 *garding any ownership or investment interest (other*
13 *than an ownership or investment interest in a pub-*
14 *licly traded security and mutual fund, as described in*
15 *section 1877(c)) held by a physician (or an imme-*
16 *diate family member of such physician (as defined for*
17 *purposes of section 1877(a))) in the applicable manu-*
18 *facturer or applicable group purchasing organization*
19 *during the preceding year:*

20 “(A) *The dollar amount invested by each*
21 *physician holding such an ownership or invest-*
22 *ment interest.*

23 “(B) *The value and terms of each such own-*
24 *ership or investment interest.*

1 “(C) *Any payment or other transfer of*
2 *value provided to a physician holding such an*
3 *ownership or investment interest (or to an entity*
4 *or individual at the request of or designated on*
5 *behalf of a physician holding such an ownership*
6 *or investment interest), including the informa-*
7 *tion described in clauses (i) through (viii) of*
8 *paragraph (1)(A), except that in applying such*
9 *clauses, ‘physician’ shall be substituted for ‘cov-*
10 *ered recipient’ each place it appears.*

11 “(D) *Any other information regarding the*
12 *ownership or investment interest the Secretary*
13 *determines appropriate.*

14 “(b) *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 applicable group*
19 *purchasing organization that fails to submit in-*
20 *formation required under subsection (a) in a*
21 *timely manner in accordance with rules or regu-*
22 *lations promulgated to carry out such subsection,*
23 *shall be subject to a civil money penalty of not*
24 *less than \$1,000, but not more than \$10,000, for*
25 *each payment or other transfer of value or own-*

1 *ership or investment interest not reported as re-*
2 *quired under such subsection. Such penalty shall*
3 *be imposed and collected in the same manner as*
4 *civil money penalties under subsection (a) of sec-*
5 *tion 1128A are imposed and collected under that*
6 *section.*

7 “(B) *LIMITATION.—The total amount of*
8 *civil money penalties imposed under subpara-*
9 *graph (A) with respect to each annual submis-*
10 *sion of information under subsection (a) by an*
11 *applicable manufacturer or applicable group*
12 *purchasing organization shall not exceed*
13 *\$150,000.*

14 “(2) *KNOWING FAILURE TO REPORT.—*

15 “(A) *IN GENERAL.—Subject to subpara-*
16 *graph (B), any applicable manufacturer or ap-*
17 *plicable group purchasing organization that*
18 *knowingly fails to submit information required*
19 *under subsection (a) in a timely manner in ac-*
20 *cordance with rules or regulations promulgated*
21 *to carry out such subsection, shall be subject to*
22 *a civil money penalty of not less than \$10,000,*
23 *but not more than \$100,000, for each payment or*
24 *other transfer of value or ownership or invest-*
25 *ment interest not reported as required under*

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

5 *“(B) LIMITATION.—The total amount of*
6 *civil money penalties imposed under subpara-*
7 *graph (A) with respect to each annual submis-*
8 *sion of information under subsection (a) by an*
9 *applicable manufacturer or applicable group*
10 *purchasing organization shall not exceed*
11 *\$1,000,000.*

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

16 *“(c) PROCEDURES FOR SUBMISSION OF INFORMATION*
17 *AND PUBLIC AVAILABILITY.—*

18 *“(1) IN GENERAL.—*

19 *“(A) ESTABLISHMENT.—Not later than Oc-*
20 *tober 1, 2011, the Secretary shall establish proce-*
21 *dures—*

22 *“(i) for applicable manufacturers and*
23 *applicable group purchasing organizations*
24 *to submit information to the Secretary*
25 *under subsection (a); and*

1 “(ii) for the Secretary to make such in-
2 formation submitted available to the public.

3 “(B) *DEFINITION OF TERMS.*—The proce-
4 dures established under subparagraph (A) shall
5 provide for the definition of terms (other than
6 those terms defined in subsection (e)), as appro-
7 priate, for purposes of this section.

8 “(C) *PUBLIC AVAILABILITY.*—Except as
9 provided in subparagraph (E), the procedures es-
10 tablished under subparagraph (A)(ii) shall en-
11 sure that, not later than September 30, 2013,
12 and on June 30 of each calendar year beginning
13 thereafter, the information submitted under sub-
14 section (a) with respect to the preceding calendar
15 year is made available through an Internet
16 website that—

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

19 “(ii) contains information that is pre-
20 sented by the name of the applicable manu-
21 facturer or applicable group purchasing or-
22 ganization, the name of the covered recipi-
23 ent, the business address of the covered re-
24 cipient, the specialty of the covered recipi-
25 ent, the value of the payment or other trans-

1 *fer of value, the date on which the payment*
2 *or other transfer of value was provided to*
3 *the covered recipient, the form of the pay-*
4 *ment or other transfer of value, indicated*
5 *(as appropriate) under subsection*
6 *(a)(1)(A)(v), the nature of the payment or*
7 *other transfer of value, indicated (as appro-*
8 *priate) under subsection (a)(1)(A)(vi), and*
9 *the name of the covered drug, device, bio-*
10 *logical, or medical supply, as applicable;*

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

13 *“(iv) contains a description of any en-*
14 *forcement actions taken to carry out this*
15 *section, including any penalties imposed*
16 *under subsection (b), during the preceding*
17 *year;*

18 *“(v) contains background information*
19 *on industry-physician relationships;*

20 *“(vi) in the case of information sub-*
21 *mitted with respect to a payment or other*
22 *transfer of value described in subparagraph*
23 *(E)(i), lists such information separately*
24 *from the other information submitted under*
25 *subsection (a) and designates such sepa-*

1 *rately listed information as funding for*
2 *clinical research;*

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

6 *“(viii) does not contain the National*
7 *Provider Identifier of the covered recipient,*
8 *and*

9 *“(ix) subject to subparagraph (D), pro-*
10 *vides the applicable manufacturer, applica-*
11 *ble group purchasing organization, or cov-*
12 *ered recipient an opportunity to review and*
13 *submit corrections to the information sub-*
14 *mitted with respect to the applicable manu-*
15 *facturer, applicable group purchasing orga-*
16 *nization, or covered recipient, respectively,*
17 *for a period of not less than 45 days prior*
18 *to such information being made available to*
19 *the public.*

20 *“(D) CLARIFICATION OF TIME PERIOD FOR*
21 *REVIEW AND CORRECTIONS.—In no case may the*
22 *45-day period for review and submission of cor-*
23 *rections to information under subparagraph*
24 *(C)(ix) prevent such information from being*
25 *made available to the public in accordance with*

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

3 “(E) *DELAYED PUBLICATION FOR PAY-*
4 *MENTS MADE PURSUANT TO PRODUCT RESEARCH*
5 *OR DEVELOPMENT AGREEMENTS AND CLINICAL*
6 *INVESTIGATIONS.—*

7 “(i) *IN GENERAL.—In the case of in-*
8 *formation submitted under subsection (a)*
9 *with respect to a payment or other transfer*
10 *of value made to a covered recipient by an*
11 *applicable manufacturer pursuant to a*
12 *product research or development agreement*
13 *for services furnished in connection with re-*
14 *search on a potential new medical tech-*
15 *nology or a new application of an existing*
16 *medical technology or the development of a*
17 *new drug, device, biological, or medical sup-*
18 *ply, or by an applicable manufacturer in*
19 *connection with a clinical investigation re-*
20 *garding a new drug, device, biological, or*
21 *medical supply, the procedures established*
22 *under subparagraph (A)(ii) shall provide*
23 *that such information is made available to*
24 *the public on the first date described in the*

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

3 *“(I) The date of the approval or*
4 *clearance of the covered drug, device,*
5 *biological, or medical supply by the*
6 *Food and Drug Administration.*

7 *“(II) Four calendar years after*
8 *the date such payment or other trans-*
9 *fer of value was made.*

10 *“(ii) CONFIDENTIALITY OF INFORMA-*
11 *TION PRIOR TO PUBLICATION.—Information*
12 *described in clause (i) shall be considered*
13 *confidential and shall not be subject to dis-*
14 *closure under section 552 of title 5, United*
15 *States Code, or any other similar Federal,*
16 *State, or local law, until on or after the*
17 *date on which the information is made*
18 *available to the public under such clause.*

19 *“(2) CONSULTATION.—In establishing the proce-*
20 *dures under paragraph (1), the Secretary shall con-*
21 *sult with the Inspector General of the Department of*
22 *Health and Human Services, affected industry, con-*
23 *sumers, consumer advocates, and other interested par-*
24 *ties in order to ensure that the information made*

1 *available to the public under such paragraph is pre-*
2 *sented in the appropriate overall context.*

3 “(d) *ANNUAL REPORTS AND RELATION TO STATE*
4 *LAWS.—*

5 “(1) *ANNUAL REPORT TO CONGRESS.—Not later*
6 *than April 1 of each year beginning with 2013, the*
7 *Secretary shall submit to Congress a report that in-*
8 *cludes the following:*

9 “(A) *The information submitted under sub-*
10 *section (a) during the preceding year, aggregated*
11 *for each applicable manufacturer and applicable*
12 *group purchasing organization that submitted*
13 *such information during such year (except, in*
14 *the case of information submitted with respect to*
15 *a payment or other transfer of value described in*
16 *subsection (c)(1)(E)(i), such information shall be*
17 *included in the first report submitted to Congress*
18 *after the date on which such information is made*
19 *available to the public under such subsection).*

20 “(B) *A description of any enforcement ac-*
21 *tions taken to carry out this section, including*
22 *any penalties imposed under subsection (b), dur-*
23 *ing the preceding year.*

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

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

11 *“(3) RELATION TO STATE LAWS.—*

12 *“(A) IN GENERAL.—In the case of a pay-*
13 *ment or other transfer of value provided by an*
14 *applicable manufacturer that is received by a*
15 *covered recipient (as defined in subsection (e))*
16 *on or after January 1, 2012, subject to subpara-*
17 *graph (B), the provisions of this section shall*
18 *preempt any statute or regulation of a State or*
19 *of a political subdivision of a State that requires*
20 *an applicable manufacturer (as so defined) to*
21 *disclose or report, in any format, the type of in-*
22 *formation (as described in subsection (a)) re-*
23 *garding such payment or other transfer of value.*

24 *“(B) NO PREEMPTION OF ADDITIONAL RE-*
25 *QUIREMENTS.—Subparagraph (A) shall not pre-*

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

4 *“(i) not of the type required to be dis-*
5 *closed or reported under this section;*

6 *“(ii) described in subsection (e)(10)(B),*
7 *except in the case of information described*
8 *in clause (i) of such subsection;*

9 *“(iii) by any person or entity other*
10 *than an applicable manufacturer (as so de-*
11 *fined) or a covered recipient (as defined in*
12 *subsection (e)); or*

13 *“(iv) to a Federal, State, or local gov-*
14 *ernmental agency for public health surveil-*
15 *lance, investigation, or other public health*
16 *purposes or health oversight purposes.*

17 *“(C) Nothing in subparagraph (A) shall be*
18 *construed to limit the discovery or admissibility*
19 *of information described in such subparagraph*
20 *in a criminal, civil, or administrative pro-*
21 *ceeding.*

22 *“(4) CONSULTATION.—The Secretary shall con-*
23 *sult with the Inspector General of the Department of*
24 *Health and Human Services on the implementation*
25 *of this section.*

1 “(e) *DEFINITIONS.*—*In this section:*

2 “(1) *APPLICABLE GROUP PURCHASING ORGANI-*
3 *ZATION.*—*The term ‘applicable group purchasing or-*
4 *ganization’ means a group purchasing organization*
5 *(as defined by the Secretary) that purchases, arranges*
6 *for, or negotiates the purchase of a covered drug, de-*
7 *vice, biological, or medical supply which is operating*
8 *in the United States, or in a territory, possession, or*
9 *commonwealth of the United States.*

10 “(2) *APPLICABLE MANUFACTURER.*—*The term*
11 *‘applicable manufacturer’ means a manufacturer of a*
12 *covered drug, device, biological, or medical supply*
13 *which is operating in the United States, or in a terri-*
14 *tory, possession, or commonwealth of the United*
15 *States.*

16 “(3) *CLINICAL INVESTIGATION.*—*The term ‘clin-*
17 *ical investigation’ means any experiment involving 1*
18 *or more human subjects, or materials derived from*
19 *human subjects, in which a drug or device is admin-*
20 *istered, dispensed, or used.*

21 “(4) *COVERED DEVICE.*—*The term ‘covered de-*
22 *vice’ means any device for which payment is avail-*
23 *able under title XVIII or a State plan under title*
24 *XIX or XXI (or a waiver of such a plan).*

1 “(5) *COVERED DRUG, DEVICE, BIOLOGICAL, OR*
2 *MEDICAL SUPPLY.*—*The term ‘covered drug, device,*
3 *biological, or medical supply’ means any drug, bio-*
4 *logical product, device, or medical supply for which*
5 *payment is available under title XVIII or a State*
6 *plan under title XIX or XXI (or a waiver of such a*
7 *plan).*

8 “(6) *COVERED RECIPIENT.*—

9 “(A) *IN GENERAL.*—*Except as provided in*
10 *subparagraph (B), the term ‘covered recipient’*
11 *means the following:*

12 “(i) *A physician.*

13 “(ii) *A teaching hospital.*

14 “(B) *EXCLUSION.*—*Such term does not in-*
15 *clude a physician who is an employee of the ap-*
16 *licable manufacturer that is required to submit*
17 *information under subsection (a).*

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

20 “(8) *KNOWINGLY.*—*The term ‘knowingly’ has the*
21 *meaning given such term in section 3729(b) of title*
22 *31, United States Code.*

23 “(9) *MANUFACTURER OF A COVERED DRUG, DE-*
24 *VICE, BIOLOGICAL, OR MEDICAL SUPPLY.*—*The term*
25 *‘manufacturer of a covered drug, device, biological, or*

1 *medical supply’ means any entity which is engaged*
2 *in the production, preparation, propagation,*
3 *compounding, or conversion of a covered drug, device,*
4 *biological, or medical supply (or any entity under*
5 *common ownership with such entity which provides*
6 *assistance or support to such entity with respect to*
7 *the production, preparation, propagation,*
8 *compounding, conversion, marketing, promotion, sale,*
9 *or distribution of a covered drug, device, biological, or*
10 *medical supply).*

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

13 “(A) *IN GENERAL.—The term ‘payment or*
14 *other transfer of value’ means a transfer of any-*
15 *thing of value. Such term does not include a*
16 *transfer of anything of value that is made indi-*
17 *rectly to a covered recipient through a third*
18 *party in connection with an activity or service*
19 *in the case where the applicable manufacturer is*
20 *unaware of the identity of the covered recipient.*

21 “(B) *EXCLUSIONS.—An applicable manu-*
22 *facturer shall not be required to submit informa-*
23 *tion under subsection (a) with respect to the fol-*
24 *lowing:*

1 “(i) A transfer of anything the value of
2 which is less than \$10, unless the aggregate
3 amount transferred to, requested by, or des-
4 ignated on behalf of the covered recipient by
5 the applicable manufacturer during the cal-
6 endar year exceeds \$100. For calendar years
7 after 2012, the dollar amounts specified in
8 the preceding sentence shall be increased by
9 the same percentage as the percentage in-
10 crease in the consumer price index for all
11 urban consumers (all items; U.S. city aver-
12 age) for the 12-month period ending with
13 June of the previous year.

14 “(ii) Product samples that are not in-
15 tended to be sold and are intended for pa-
16 tient use.

17 “(iii) Educational materials that di-
18 rectly benefit patients or are intended for
19 patient use.

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

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

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

5 “(vi) *A transfer of anything of value to*
6 *a covered recipient when the covered recipi-*
7 *ent is a patient and not acting in the pro-*
8 *fessional capacity of a covered recipient.*

9 “(vii) *Discounts (including rebates).*

10 “(viii) *In-kind items used for the pro-*
11 *vision of charity care.*

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

17 “(x) *In the case of an applicable man-*
18 *ufacturer who offers a self-insured plan,*
19 *payments for the provision of health care to*
20 *employees under the plan.*

21 “(xi) *In the case of a covered recipient*
22 *who is a licensed non-medical professional,*
23 *a transfer of anything of value to the cov-*
24 *ered recipient if the transfer is payment*
25 *solely for the non-medical professional serv-*

1 ices of such licensed non-medical profes-
2 sional.

3 “(xii) In the case of a covered recipient
4 who is a physician, a transfer of anything
5 of value to the covered recipient if the trans-
6 fer is payment solely for the services of the
7 covered recipient with respect to a civil or
8 criminal action or an administrative pro-
9 ceeding.

10 “(11) PHYSICIAN.—The term ‘physician’ has the
11 meaning given that term in section 1861(r).”.

12 **SEC. 6003. DISCLOSURE REQUIREMENTS FOR IN-OFFICE AN-**
13 **CILLARY SERVICES EXCEPTION TO THE PRO-**
14 **HIBITION ON PHYSICIAN SELF-REFERRAL**
15 **FOR CERTAIN IMAGING SERVICES.**

16 (a) *IN GENERAL.*—Section 1877(b)(2) of the Social Se-
17 curity Act (42 U.S.C. 1395nn(b)(2)) is amended by adding
18 at the end the following new sentence: “Such requirements
19 shall, with respect to magnetic resonance imaging, com-
20 puted tomography, positron emission tomography, and any
21 other designated health services specified under subsection
22 (h)(6)(D) that the Secretary determines appropriate, in-
23 clude a requirement that the referring physician inform the
24 individual in writing at the time of the referral that the
25 individual may obtain the services for which the individual

1 *is being referred from a person other than a person de-*
2 *scribed in subparagraph (A)(i) and provide such individual*
3 *with a written list of suppliers (as defined in section*
4 *1861(d)) who furnish such services in the area in which*
5 *such individual resides.”.*

6 (b) *EFFECTIVE DATE.*—*The amendment made by this*
7 *section shall apply to services furnished on or after January*
8 *1, 2010.*

9 **SEC. 6004. PRESCRIPTION DRUG SAMPLE TRANSPARENCY.**

10 *Part A of title XI of the Social Security Act (42 U.S.C.*
11 *1301 et seq.), as amended by section 6002, is amended by*
12 *inserting after section 1128G the following new section:*

13 **“SEC. 1128H. REPORTING OF INFORMATION RELATING TO**
14 **DRUG SAMPLES.**

15 *“(a) IN GENERAL.—Not later than April 1 of each*
16 *year (beginning with 2012), each manufacturer and author-*
17 *ized distributor of record of an applicable drug shall submit*
18 *to the Secretary (in a form and manner specified by the*
19 *Secretary) the following information with respect to the pre-*
20 *ceding year:*

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

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

4 “(A) *the name, address, professional des-*
5 *ignation, and signature of the practitioner mak-*
6 *ing the request under subparagraph (A)(i) of*
7 *such subsection, or of any individual who makes*
8 *or signs for the request on behalf of the practi-*
9 *tioner; and*

10 “(B) *any other category of information de-*
11 *termined appropriate by the Secretary.*

12 “(2) *In the case of a manufacturer or authorized*
13 *distributor of record which makes distributions by*
14 *means other than mail or common carrier under sub-*
15 *section (d)(3) of such section 503, the identity and*
16 *quantity of drug samples requested and the identity*
17 *and quantity of drug samples distributed under such*
18 *subsection during that year, aggregated by—*

19 “(A) *the name, address, professional des-*
20 *ignation, and signature of the practitioner mak-*
21 *ing the request under subparagraph (A)(i) of*
22 *such subsection, or of any individual who makes*
23 *or signs for the request on behalf of the practi-*
24 *tioner; and*

1 “(B) any other category of information de-
2 termined appropriate by the Secretary.

3 “(b) DEFINITIONS.—In this section:

4 “(1) APPLICABLE DRUG.—The term ‘applicable
5 drug’ means a drug—

6 “(A) which is subject to subsection (b) of
7 such section 503; and

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

11 “(2) AUTHORIZED DISTRIBUTOR OF RECORD.—
12 The term ‘authorized distributor of record’ has the
13 meaning given that term in subsection (e)(3)(A) of
14 such section.

15 “(3) MANUFACTURER.—The term ‘manufacturer’
16 has the meaning given that term for purposes of sub-
17 section (d) of such section.”.

18 **SEC. 6005. PHARMACY BENEFIT MANAGERS TRANSPARENCY**
19 **REQUIREMENTS.**

20 Part A of title XI of the Social Security Act (42 U.S.C.
21 1301 et seq.) is amended by inserting after section 1150
22 the following new section:

1 **“SEC. 1150A. PHARMACY BENEFIT MANAGERS TRANS-**
2 **PARENCY REQUIREMENTS.**

3 “(a) *PROVISION OF INFORMATION.*—A health benefits
4 plan or any entity that provides pharmacy benefits man-
5 agement services on behalf of a health benefits plan (in this
6 section referred to as a ‘PBM’) that manages prescription
7 drug coverage under a contract with—

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

11 “(2) a qualified health benefits plan offered
12 through an exchange established by a State under sec-
13 tion 1311 of the Patient Protection and Affordable
14 Care Act,

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

19 “(b) *INFORMATION DESCRIBED.*—The information de-
20 scribed in this subsection is the following with respect to
21 services provided by a health benefits plan or PBM for a
22 contract year:

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

1 *(generic dispensing rate), by pharmacy type (which*
2 *includes an independent pharmacy, chain pharmacy,*
3 *supermarket pharmacy, or mass merchandiser phar-*
4 *macy that is licensed as a pharmacy by the State and*
5 *that dispenses medication to the general public), that*
6 *is paid by the health benefits plan or PBM under the*
7 *contract.*

8 *“(2) The aggregate amount, and the type of re-*
9 *bates, discounts, or price concessions (excluding bona*
10 *fide service fees, which include but are not limited to*
11 *distribution service fees, inventory management fees,*
12 *product stocking allowances, and fees associated with*
13 *administrative services agreements and patient care*
14 *programs (such as medication compliance programs*
15 *and patient education programs)) that the PBM ne-*
16 *gotiates that are attributable to patient utilization*
17 *under the plan, and the aggregate amount of the re-*
18 *bates, discounts, or price concessions that are passed*
19 *through to the plan sponsor, and the total number of*
20 *prescriptions that were dispensed.*

21 *“(3) The aggregate amount of the difference be-*
22 *tween the amount the health benefits plan pays the*
23 *PBM and the amount that the PBM pays retail phar-*
24 *macies, and mail order pharmacies, and the total*
25 *number of prescriptions that were dispensed.*

1 “(c) *CONFIDENTIALITY.*—*Information disclosed by a*
2 *health benefits plan or PBM under this section is confiden-*
3 *tial and shall not be disclosed by the Secretary or by a plan*
4 *receiving the information, except that the Secretary may*
5 *disclose the information in a form which does not disclose*
6 *the identity of a specific PBM, plan, or prices charged for*
7 *drugs, for the following purposes:*

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

10 “(2) *To permit the Comptroller General to re-*
11 *view the information provided.*

12 “(3) *To permit the Director of the Congressional*
13 *Budget Office to review the information provided.*

14 “(4) *To States to carry out section 1311 of the*
15 *Patient Protection and Affordable Care Act.*

16 “(d) *PENALTIES.*—*The provisions of subsection*
17 *(b)(3)(C) of section 1927 shall apply to a health benefits*
18 *plan or PBM that fails to provide information required*
19 *under subsection (a) on a timely basis or that knowingly*
20 *provides false information in the same manner as such pro-*
21 *visions apply to a manufacturer with an agreement under*
22 *that section.”.*