

**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, indi-
cated (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 speci-
fied 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 *diante 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.”.*