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.
2122	TERESTS. "(a) Transparency Reports.—

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—

1	"(I) cash or a cash equivalent;
2	"(II) in-kind items or services;
3	"(III) stock, a stock option, or
4	any other ownership interest, dividend,
5	profit, or other return on investment;
6	or
7	"(IV) any other form of payment
8	or other transfer of value (as defined
9	by the Secretary).
10	"(vi) A description of the nature of the
11	payment or other transfer of value, indi-
12	cated (as appropriate for all that apply)
13	as—
14	$``(I)\ consulting\ fees;$
15	"(II) compensation for services
16	other than consulting;
17	"(III) honoraria;
18	"(IV) $gift$;
19	$"(V)\ entertainment;$
20	"(VI) food;
21	"(VII) travel (including the speci-
22	$fied\ destinations);$
23	$"(VIII)\ education;$
24	"(IX) research;
25	"(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

"(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

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
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"(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

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-

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 RE-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	Ι "
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- "(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).

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	plicable 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 drua, device, biological, or

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medical supply' means any entity which is engaged intheproduction, 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 theproduction, 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:

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-
1314	CILLARY SERVICES EXCEPTION TO THE PRO- HIBITION ON PHYSICIAN SELF-REFERRAL
14	HIBITION ON PHYSICIAN SELF-REFERRAL
14 15	HIBITION ON PHYSICIAN SELF-REFERRAL FOR CERTAIN IMAGING SERVICES.
14 15 16 17	HIBITION ON PHYSICIAN SELF-REFERRAL FOR CERTAIN IMAGING SERVICES. (a) IN GENERAL.—Section 1877(b)(2) of the Social Se-
14 15 16 17	HIBITION 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
14 15 16 17 18	HIBITION 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"
14 15 16 17 18	HIBITION 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, com-
14 15 16 17 18 19 20 21	HIBITION 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
14 15 16 17 18 19 20 21	HIBITION 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
14 15 16 17 18 19 20 21 22	HIBITION 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, in-