Subpart I – Transparency Reports and Reporting of Physician Ownership or Investment Interests Sec.

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### Subpart I – Transparency Reports and Reporting of Physician Ownership or Investment Interests

### § 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value to physicians and teaching hospitals, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians.

### § 403.902 Definitions.

Applicable group purchasing organization means an entity that—

(1) Operates in the United States, or in a territory, possession or commonwealth of the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

Applicable manufacturer means an entity that is—

- (1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or
- (2) Under common ownership with an entity in paragraph (1) of this definition, 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 for sale and distribution in the United States, or in a territory, possession, or commonwealth of the United States.

<u>Charity care</u> means services provided by a covered recipient specifically for a patient who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

<u>Charitable contribution</u> includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986.

<u>Clinical investigation</u> means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

<u>Common ownership</u> means entities that are owned, in whole or in part, by the same individual, individuals, entity, or entities, directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered device means any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). This definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

#### Covered recipient means—

(1) Any physician, except for a physician who is an employee (as defined in section 1877(h)(2) of the Act) of an applicable manufacturer; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be "employed by" or an "employee" of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

<u>Immediate family member</u> means any of the following:

- (1) Spouse.
- (2) Natural or adoptive parent, child, or sibling.
- (3) Stepparent, stepchild, stepbrother, or stepsister.
- (4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.
- (5) Grandparent or grandchild.
- (6) Spouse of a grandparent or grandchild.

Know, knowing, or knowingly. (1) Means that a person, with respect to information-

- (i) Has actual knowledge of the information;
- (ii) Acts in deliberate ignorance of the truth or falsity of the information; or
- (iii) Acts in reckless disregard of the truth or falsity of the information; and
- (2) Requires no proof of a specific intent to defraud.

Ownership or investment interest. (1) Includes, but is not limited to—

- (i) Stock, stock option(s) (other than those received as compensation, until they are exercised);
  - (ii) Partnership share(s);

- (iii) Limited liability company membership(s);
- (iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.
  - (2) May be direct or indirect and through debt, equity or other means; and
- (3) Must not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act, nor any of the following:
- (i) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.
- (ii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.
  - (iii) An unsecured loan subordinated to a credit facility.

<u>Physician</u> has the same meaning given that term in section 1861(r) of the Act.

### § 403.904 Reports of payments or other transfers of value.

- (a) <u>General rule</u>. Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer) must be reported to CMS by the applicable manufacturer on an annual basis.
- (b) <u>Required information to report</u>. A report must contain all of the following of information for each payment or other transfer of value:

(1) Name of the covered recipient. If the payment or other transfer of value was provided to another individual or entity at the request of (or designated on behalf of) any covered recipient, the payment or transfer of value must be disclosed in the name of that covered recipient.

- (2) Business address of the covered recipient, including street address, suite or office number (if applicable), city, state, and ZIP code.
- (3) In the case of a covered recipient who is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient.
  - (4) Amount of each payment or other transfer of value to the covered recipient.
  - (5) Date of each payment or transfer of value to the covered recipient.
- (6) Form of each payment or other transfer of value, as described in paragraph (c) of this section.
- (7) Nature of each payment or other transfer of value, as described in paragraph (d) of this section.
- (8) If a 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 under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value.
- (9) The applicable manufacturer must indicate that a payment or other transfer of value is subject to delayed publication, if the payment or other transfer of value is made under any of the following arrangements:

(i) In accordance with a product research or development agreement for services furnished in connection with research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological or medical supply.

- (ii) In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.
- (10) If the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other individual or entity that receives the payment or other transfer of value.
- (11) Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined §403.902) in the applicable manufacturer.
- (c) Reporting the form of payment or other transfer of value. An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms, using the designation that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value. Each of the following terms has its dictionary definition:
  - (1) Cash or cash equivalent.
  - (2) In-kind items or services.
- (3) Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.
- (d) Reporting the nature of the payment or other transfer of value. (1) General rule. The categories describing the nature of a payment or other transfer of value are mutually exclusive.

(2) Rules for categorizing natures of payment. An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, in one of the categories listed in this paragraph (d)(2), using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value. Each of the following terms has its dictionary definition:

- (i) Consulting fee.
- (ii) Compensation for services other than consulting.
- (iii) Honoraria.
- (iv) Gift.
- (v) Entertainment.
- (vi) Food and beverage.
- (vii) Travel and lodging.
- (viii) Education.
- (ix) Research.
- (x) Charitable contribution.
- (xii) Royalty or license.
- (xiii) Current or prospective ownership or investment interests.
- (xiv) Direct compensation for serving as a faculty or as a speaker for a medical education program.
  - (xv) Grant.

(xvi) Other.

(e) <u>Special rules for research payments</u>. (1) Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research.

- (i) Direct research, is a payment or other transfer of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity).
- (ii) Indirect research, is a payment or other transfer of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).
- (2) All payments or other transfers of value designated as research (direct or indirect) must be subject to a written agreement and research protocol. Direct or indirect research payments (whether made directly by an applicable manufacturer or through a clinical research organization or similar entity) must be reported as follows:
- (i) For indirect research, individually under the name(s) and NPI(s) (if applicable) of the physician covered recipient principal investigator(s). The total amount paid to the clinic, hospital or other institution conducting the research, must be reported for each principal investigator.
- (ii) For direct research, individually under the name(s) and NPI(s) (if applicable) of the covered recipient. The total must indicate the amount the covered recipient received.
- (3) If payment is made to a teaching hospital, the payment to the teaching hospital must be reported as follows:

- (i) Direct research under the name of the teaching hospital.
- (ii) Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s).
- (4) For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.
- (f) <u>Exclusions from reporting</u>. The following types of payments or other transfers of value are excluded from the reporting requirements specified in this section:
- (1) Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in §403.902) the identity of the covered recipient.
- (2)(i) For CY 2012, transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in a calendar year.
- (ii) For CY 2013 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (f)(2)(i) of this paragraph must 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.
  - (3) Product samples that are not intended to be sold and are intended for patient use.
  - (4) Educational materials that directly benefit patients or are intended for patient use.
- (5) 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.

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

- (7) 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.
  - (8) Discounts, including rebates.
  - (9) In-kind items used for the provision of charity care.
- (10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.
- (11) 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.
- (12) 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 services of the licensed non-medical professional.
- (13) 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.

### §403.906 Reports of physician ownership and investment interests.

(a) <u>General rule</u>. Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership or investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding year.

(b) <u>Identifying information</u>. Reports on physician ownership or investment interests must include the following identifying information:

- (1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician.
- (2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code.
- (3) The physician owner's specialty and NPI (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician's specialty and National Provider Identifier must be reported.
- (4) Dollar amount invested by each physician or immediate family member of the physician.
  - (5) Value and terms of each ownership or investment interest.
- (6) For any payment or other transfer of value provided to a physician holding 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), an applicable manufacturer or applicable group purchasing organization must report the information requested in § 403.904(b). The same exclusions from reporting in § 403.904(f) apply to payments or other transfers of value made by applicable manufacturers and applicable group purchasing organizations to physician owners or investors under this section.

### § 403.908 Procedures for electronic submission of reports.

(a) <u>File format</u>. Reports required under this subpart must be electronically submitted as comma separated value (CSV) files to CMS by March 31, 2013, and by the 90<sup>th</sup> day of each subsequent calendar year.

- (b) <u>General rules</u>. (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician's immediate family member (as defined in §403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.
- (2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.
- (c) <u>Registration</u>. Any applicable manufacturer or applicable group purchasing organization that is required to report under this subpart must register with CMS before March 31, 2013. During registration, applicable manufacturers and applicable group purchasing organizations must name a point of contact with appropriate contact information.
- (d) Other rules. (1) An applicable manufacturer under paragraph (1) of the definition of "applicable manufacturer" in § 403.902 and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of "applicable manufacturer" may, but are not required to, file a consolidated report of payments or other transfers of value to covered recipients, and physician ownership or investment interests.
- (2) If an applicable manufacturer and an entity (or entities) under common ownership choose to file a consolidated report, the report must provide the names of each applicable

manufacturer and entity (or entities) under common ownership that the report covers. It is up to the discretion of the applicable manufacturer and entity (or entities) under common ownership whether or not specific payments need to be identified to the entity that provided the payment.

- (3) If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported--
- (i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and
  - (ii) Only once by one applicable manufacturer.
- (e) <u>Errors or omissions</u>. If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon discovery of the error or omission.
- (f) Attestation. Each report, including any subsequent corrections to a filed report, must include a certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.
- (g) <u>45-day review period for review and error correction.</u> (1) <u>General rule</u>. Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the

information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

- (2) <u>Notification</u>. CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.
- (i) Applicable manufacturers and applicable group purchasing organizations are notified through the point of contact the applicable manufacturer or applicable group purchasing organization identified during registration.
  - (ii) Physicians and teaching hospitals--
  - (A) Are notified using a CMS' list serve and through a posting.
  - (B) May also register with CMS to receive notification about the review processes.
- (iii) The 45-day review period begins on the date of this notification, but in no case may the 45-day review period begin later than August 16, 2013, or May 16 of any subsequent year.
- (3) <u>Process</u>. (i) An applicable manufacturer, applicable group purchasing organization, covered recipient, and a physician owner or investor may log into a secure website where each applicable manufacturer, applicable group purchasing organization, covered recipient, and physician owner is able to view the information reported specific to it.
- (ii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(4) <u>Data disputes</u>. (i) Upon request by a covered recipient, physician owner or investor, CMS provides the point of contact information for the applicable manufacturer or applicable group purchasing organization in the event that the covered recipient or physician owner disputes the reported data.

- (ii) The covered recipient or physician owner or investor must directly contact the applicable manufacturer or applicable group purchasing organization to attempt to resolve any dispute regarding a reported payment or other transfer of value or an ownership or investment interest.
- (iii) At the discretion of the parties involved, one entity must notify CMS that a specific payment or other transfer of value, or ownership or investment interest is disputed and the outcome of the dispute at the end of the 45-day review period.
- (iv) If the dispute is not resolved by the end of the 45-day review period, CMS publicly reports both the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, as well as the covered recipient's or physician owner's version of the payment or other transfer of value, or ownership or investment interest data.

# § 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) General rule. In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, payments may be delayed from publication on the website. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply.

- (2) Clinical investigations regarding a new drug, device, biological, or medical supply.
- (b) Research or development agreement. The research or development agreement must include a written agreement and research protocol between the applicable manufacturer and covered recipient.
- (c) <u>Date of publication</u>. Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:
- (1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.
  - (2) Four calendar years after the date the payment or other transfer of value was made.
- (d) <u>Notification of delayed publication</u>. It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.
- (1) An applicable manufacturer must indicate on its report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report results in CMS posting all payments publicly in the first year of public reporting.
- (2) An applicable manufacturer must continue to indicate annually in its report that FDA approval of the new drug, device, biological or medical supply, with which the payment is associated, is pending.
- (3) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(4) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

### § 403.912 Penalties for failure to report.

- (a) <u>Failure to report</u>. (1) Any applicable manufacturer or applicable group purchasing organization that fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported.
- (2) The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization under this subpart with respect to each annual submission of information will not exceed \$150,000.
- (b) Knowing failure to report. (1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary 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.
- (2) The total amount of civil monetary penalties imposed on an applicable manufacturer or group purchasing organization for knowing failure to report under this subpart with respect to each annual submission of information will not exceed \$1,000,000.
- (c) <u>Determinations regarding the amount of civil monetary penalties</u>. In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the

following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.

- (2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.
  - (3) Level of culpability.
  - (4) Nature and amount of information reported in error.
  - (5) Degree of diligence exercised in correcting information reported in error.
- (d) Record retention and audits. (1) Maintenance of records. (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules established under this subpart.
- (ii) The items described in paragraph (d)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website.
- (2) <u>Audit</u>. HHS, CMS, OIG or their designees may audit, inspect, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules

established under this subpart.

(3) The record retention and audit requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

### § 403.914 Preemption of State laws.

- (a) <u>General rule</u>. In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.
- (b) <u>Information collected for public health purposes</u>. (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.
  - (2) Governmental agencies include, but are not limited to, the following:
  - (i) Agencies that are charged with preventing or controlling disease, injury, disability.
- (ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

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(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: November 9, 2011

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 13, 2011

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

[GPO: PHOTO]

This Addendum will not appear in the Code of Federal Regulations.

## ADDENDUM: SAMPLE REPORTING TEMPLATE TABLE A: PAYMENT OR OTHER TRANSFER OF VALUE TEMPLATE

### Notes:

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file

Recipient = Covered Recipient or Physician Owner or Investor

Form of payment must be 1) cash or cash equivalent, 2) in-kind items or services, 3) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Nature of payment must be 1) Consulting fee, 2) Compensation for services other than consulting, 3) Honoraria, 4) Gift, 5) Entertainment, 6) Food and beverage, 7) Travel and lodging, 8) Education, 9) Direct Research, 10) Indirect Research, 11) Charitable contribution, 12)Royalty or license, 13) Current or prospective ownership of investment interests, 14) Direct compensation for serving as a faculty or as a speaker for a medical education program, 15) Grant, or 16) Other.

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Amount of Payment (US dollars)	Date of Payment	Form of Payment	Nature of Payment	Name of Associated Drug, Device, Biological, or Medical Supply *if necessary	Entity Paid Name	Physician Owner or Investor (y/n)	Delayed Publication (y/n)

### TABLE B: SAMPLE PHYSICIAN OWNERSHIP OR INVESTMENT INTEREST TEMPLATE

### Notes:

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file.

Owner = Physician Owner or Investor.

All payments or other transfers of value provided to physician owners or investors must be reported on the Payment & Transfer of Value tab and designated as that to a physician owner or investor.

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Interest Held by Immediate Family Member (y/n)	Dollar Amount Invested	Value of Interest	Terms of Interest
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