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Overview of the Physician Payment Transparency Provisions of the Affordable Care Act

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NAVIGANT

Affordable Care Act Provisions

- Section 6002
  - Requires reporting of certain payments or other transfers of value to covered recipients (e.g., physicians) and teaching hospitals
  - Requires reporting of physician ownership and investment interests in an applicable manufacturer or applicable group purchasing organization (GPO)
  - To be reported separately
  - Both will be subject to public posting on the CMS website by June 30th of the year subsequent to the reporting period -- will be downloadable, searchable and easily aggregated
- Section 6004
  - Requires reporting of drug sample information

Status and Implementation

- Regulations proposed by the Centers for Medicare & Medicaid Services (CMS) on December 19, 2011
  - 76 Fed. Reg. 78,742
  - Comment period closed on February 17, 2012
  - Proposed new 42 CFR Subpart I (Transparency Reports and Reporting of Physician Ownership or Investment Interests)
  - *References in this presentation are to language in the proposed regulation, unless otherwise noted.*
  - ***Some of the proposed interpretations described in this presentation will change -- possibly in significant ways -- in the final rule***

Status and Implementation (cont'd.)

- Section 6002 statutory timing of implementation
  - First report on payments and ownership interests due March 31, 2013, based on transactions that occurred in 2012
- Actual implementation
  - Depends on timing of finalization of rule and feasibility
    - "We hope to finalize this rule as soon as possible during calendar year…2012 and, depending upon the publication date of the final rule, we are considering requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013." (76 Fed. Reg. at 78743)

Status and Implementation (cont'd.)

- Section 6004 statutory timing of implementation
  - First report on drug sample information due not later than April 1, 2012
- Actual implementation
  - "The Electronic Submissions Gateway will be available to facilitate submissions under Affordable Care Act section 6004 shortly, as will further information concerning compliance with ACA section 6004."
    - http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm

Transparency Reporting Requirements

- ACA requires annual reporting of:
  - Certain "**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 third party on behalf of an applicable manufacturer)

Definitions

- “Applicable Manufacturer “is 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*

Definitions (cont'd.)

- "Applicable Manufacturer" (cont'd.)
  - (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.
    - "Common ownership" 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
      - CMS also considering an interpretation that would use the above definition, but limit it to circumstances where the same individual, individuals, entity or entities own 5 percent or more of total ownership in two or more entities

Definitions (cont'd.)

- "Applicable Manufacturer" (cont'd.)
  - Only one covered product is required – triggers reporting of all payments or transfers of value made by the applicable manufacturer to a covered recipient, regardless of whether they are associated with a covered drug, device, biological or medical supply
  - If entities are under common ownership with one another, and both individually meet the applicable manufacturer definition, then they report separately
    - Conversely, if only one company under common ownership meets the first prong of the definition of applicable manufacturer, and the other company meets the second, then they can choose whether to report together

Definitions (cont'd.)

- "Covered Drug, Device, Biological, or Medical Supply"
  - Any drug, biological product, device, or medical supply for which payment is available under title XVIII of the Social Security Act (SSA) [Medicare] or under a State plan under title XIX [Medicaid] or XXI [the Children's Health Insurance Program] of the SSA (or a waiver of such plan), either separately, as part of a fee schedule payment, or as part of a composite payment rate.
  - Limited to prescription drugs
  - Limited to devices or medical supplies that by law require premarket approval by or premarket notification to the Food and Drug Administration
    - Excludes exempt Class I and II devices

Definitions (cont'd.)

- "Covered Recipient"
  - Any **physician**, except for a physician who is an employee of an applicable manufacturer (as defined in section 1877(h)(2) of the SSA)
    - "Physician" = definition in SSA section 1861(r)
      - Includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.
    - "Employee" means an individual who is considered to be "employed by" or an "employee" of an entity of 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)
  - A **teaching hospital**, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the SSA during the last calendar year for which such information is available (i.e., hospitals that receive IME or GME payments for support of training of residents)

Definitions (cont'd.)

- Payment or Other Transfer of Value
  - A transfer of anything of value provided to any covered recipient, unless otherwise excluded
    - 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)
    - Whether or not requested
    - Includes payments/transfer of value through a physician group or practice (will be reported individually)
    - Transfers of value do *not* include a transfer that is made indirectly to a covered recipient through a third party where the manufacturer is *unaware of the identity* of the covered recipient

Content of Transparency Reports

- Name of covered recipient (first name, last name, middle initial)
  - If 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 the covered recipient
  - CMS will publish a list of teaching hospital covered recipients once per year, including name and address

Content of Transparency Reports (cont'd.)

- Business address of covered recipient (street, address, suite or office number, city, state and zip code)
  - Primary practice location address (listed in National Plan and Provider and Enumeration System (NPPES) as the "provider business practice location")
  - If a physician, the specialty and individual National Provider Identifier (NPI) number (if applicable) of the covered recipient
  - Use NPPES "provider taxonomy" field when reporting specialty
  - CMS considering also requiring another identifier, such as state license number, for physicians without an NPI

Content of Transparency Reports (cont'd.)

- The amount of each payment or other transfer of value
- The date of each payment or other transfer of value
  - For consulting agreement with multiple dates of payment, use discretion in whether to report total payment on the date of the first payment as a single line item, or to report each individual payment under a separate line item
- Associated covered drug, device, biological or medical supply
  - Use "scientific name"
  - Where "reasonably associated"
  - Only one for each payment/transfer of value

Content of Transparency Reports (cont'd.)

- The form of the payment/transfer of value (or separable part of that payment/transfer of value), using the designation that best describes the form:
  - Cash or cash equivalent
  - In-kind items or services
  - Stock, a stock option, or any other ownership interest, dividend profit, or other return on investment

  These terms have their "dictionary definition"

Content of Transparency Reports (cont'd.)

- The "nature" of each payment/transfer of value
- Categorize each payment/transfer of value, or separable part of that payment/transfer of value, in *one* of the following categories (next slide), using the designation that best describes the payment/transfer of value (or separable part)
  - Note: If the payment/transfer of value could reasonably be considered as falling within more than one category, select one category that the manufacturer deems to most accurately describe the nature of the payment/transfer of value
  - Break out each segregable payment
  - For lump sums break out the disparate aspects of the payment for both form and nature of payment
  - Manufacturers may submit a reasonable assumptions document explaining the reasoning behind choice of categorization of natures of payments
    - Not posted on the public website

Categories for Nature of Payments/Transfers of Value

- Consulting fee
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and lodging
- Education
- Research
- Royalty or license
- Current or prospective ownership or investment interests
- Charitable contribution
  - Any payment or transfer of value, made to an organization with tax-exempt status under the Internal Revenue Code of 1986, that is not more specifically described in another category
- Direct compensation for serving as a faculty or as a speaker for a medical education program
  - CMS interpreting as including *all* speaker programs, but may consider adding another category
- Grant
- Other

Meals

- In group meal settings (e.g., buffet-style food in a physician's office), report the cost per covered recipient receiving the meal (even if the covered recipient does not eat).
- No need to report any buffet meals, snacks or coffee at booths at conferences or similar events where you cannot definitively establish identities

Special Rules for Research Payments

- All payments/transfers of value for research must be the subject of a written agreement and research protocol
- Research payments/transfers of value must be designated as:
  - **Direct:** provided to a covered entity directly by an applicable manufacturer or through a contract research organization (CRO) or similar entity
  - **Indirect:** provided by an applicable manufacturer (including through a CRO 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)

Special Rules for Research Payments (cont'd.)

- Research payments/transfers of value must be reported as follows:
  - 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 clinical, hospital, or other institution conducting the research must be reported for each principal investigator.
  - For **direct research**, individually under the name(s and NPI(s) (if applicable) of the covered recipient. The total must indicate the mount the covered recipient received.
    - For **direct or indirect** payments to physician covered recipients, CMS will report the total payment amount separately from other payments or transfers of value.
  - For research payments/transfers of value to **teaching hospitals**:
    - Direct research under the name of the teaching hospital
    - Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s)

Exclusions From Reporting

- Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of (i.e., does not know) the identity of the covered recipient
  - "Know" means that a person, with respect to information:
    - Has actual knowledge of the information
    - Acts in deliberate ignorance of the truth or falsity of the information, or
    - Acts in reckless disregard of the truth or falsity of the information, and
    - Requires no proof of specific intent to defraud

Exclusions From Reporting (cont'd.)

- For CY 2012, payments/transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of a covered recipient exceeds $100 in a calendar year
  - For CY 2012 and subsequent years, this amount will be increased by the same percentage increase as 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

Exclusions From Reporting (cont'd.)

- Product samples that are not intended to be sold and are intended for patient use
- Educational materials (e.g., pamphlets, not services) that directly benefit patients or are intended for patient use
- 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
- 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

Exclusions From Reporting (cont'd.)

- A transfer of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts (including rebates)
- In-kind items used for the provision of charity care
  - 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
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund

Exclusions From Reporting (cont'd.)

- If the applicable manufacturer offers a self-insured plan, payments for the provision of healthcare to employees under the plan
- In the case of a covered recipient who is a licensed non-medical professional, payments/transfers of value solely for non-medical professional services of that licensed non-medical professional
- Payments solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding

Physician Ownership Reporting

- Any applicable manufacturer or GPO must report on annual basis information regarding any ownership or investment interest held by a physician (or an immediate family member) in the applicable manufacturer or GPO during the preceding year
  - **Applicable GPO** is a GPO that
    - Operates in the United States, or in a territory, commonwealth or possession of the United States
    - Purchases, arranges for or negotiates the purchase of a covered drug, device, biological or medical supply for distribution to a group of individuals or entities, but not solely for its own use (broader than normal GPO definition)
    - Note differences with definition of GPO in the GPO safe harbor to Anti-Kickback Act
  - **Immediate family member** means a spouse, natural or adoptive parent, child or sibling, stepparent, stepchild, stepbrother or stepsister, father-, mother-, daughter-, son-, brother-, or sister-in-law, grandparent or grandchild, or spouse of a grandparent or grandchild.

Ownership or Investment Interests

- Defined consistent with Stark Law, and thus broadly includes, but is not limited to:
  - Stock, stock option(s) (other than those received as compensation, until they are exercised
  - Partnership share(s)
  - Limited liability company membership(s)
  - Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue
- May be direct or indirect and through debt, equity or other means, and
- Not an ownership or investment interest in a publicly traded security or mutual fund as described in section 1877(c) of the SSA, nor any of the following:
  - An interest arising from a retirement plan through employment with the applicable manufacturer or GPO
  - Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity
  - An unsecured loan subordinated to a credit facility

Physician Ownership Reporting

- Reports for physicians must include:
  - Name of the physician, and whether the ownership is held by an immediate family member of the physician.
  - Business address of the physician, including street address, suite or office number (if applicable), city, State, and ZIP code.
  - The physician owner's specialty and NPI (if applicable)
  - The dollar amount invested by each physician or immediate family member of the physician
  - The value and terms of each ownership or investment interest.
- Reports for immediate family must include:
  - all above required information for physicians plus identify that interest is held by immediate family member
  - CMS requests comments on whether to require identification of the immediate family member – concerns about privacy

Physician Ownership Reporting (cont'd.)

- Any payments to such physician from applicable manufacturers and GPOs must be reported
  - Same exceptions apply
- CMS requests one consolidated report if information is duplicative of covered recipient reporting, but directs manufacturers to note that report is for an investment or ownership interest

Mechanics of Reporting Payments and Ownership Interests

- Registration process
- CMS asked for comments on “pre-submission review” process
- Electronic format in comma separated value (CSV) format
- Submission on March 13, 2013 (unless delayed), and the 90th-day of each calendar year thereafter
- Annual attestation by an authorized representative (CEO, CFO or CCO) of the applicable manufacturer/GPO, certifying to the truth, correctness and completeness of the data submitted to the best of the signer’s knowledge and belief

Mechanics of Reporting (cont'd.)

- 45-day review period prior to data being made available to the public, in order to correct errors
  - CMS may allow covered recipients and physician owners/investors to register to receive reports
  - No subsequent amendments to data due to changes or disputes for that calendar year
  - True errors may be corrected for only the current and previous year
- CMS will not arbitrate disputes, but it may create a process for reporting disputes
  - If cannot be resolved, contradictory data may be posted

Delayed Publication of R&D/Clinical Investigation Agreements

- Delayed website publication for payments/transfers of value made to covered recipients under a *bona fide* product research or development agreement, or in connection with a clinical investigation
  - "Bona fide" means that, if made public, disclosure would damage manufacturer's competitive or proprietary interests
    - Question whether to define broadly to include all medical supplies or more narrowly to include just a subset?
  - "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 is eligible for delay

Delayed Publication of R&D/Clinical Investigation Agreements (cont'd)

- Clinical investigations regarding a *new* drug, device, biological or medical supply also eligible for delay
  - Means an experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed or used (different from FDA definition)
  - Note: no delay for **clinical** investigations for new applications of existing products
- For R&D, must have written agreement and protocol between manufacturer and covered recipient
- For clinical investigations, must have written protocol.
- Where a CRO performs the research, a written agreement between manufacturer and CRO satisfies requirement

Delayed Publication of R&D/Clinical Investigation Agreements (cont'd.)

- Payments must be reported to CMS like other payments, but CMS will not publicly post the payment until the first annual publication date after the *earlier* of the following:
  - The date of the approval, licensure or clearance of the covered drug, device, biological or medical supply by FDA
  - Four calendar years after the date the payment or other transfer of value was made
    - E.g., payments made in 2014 will not be published until 2019, unless FDA approval is earlier

Delayed Publication of R&D/Clinical Investigation Agreements (cont'd.)

- Manufacturer must indicate in both the initial year's report as well as any subsequent reports that the payment/transfer of value is eligible for delay
  - Failure to indicate eligibility for delay will result in publication of the payment
- Manufacturer bears responsibility for notifying CMS when FDA approval occurs
  - Failure to do so is considered a failure to report, subject to civil penalties.

Drug Sample Reporting (Section 6004 reports)

- PPACA also requires each manufacturer and authorized distributor of record to report, starting April 2012:
  - The identity and quantity of drug samples requested and distributed in a year, aggregated by name, address, professional designation and signature of practitioner and any other category of information determined appropriate by the Secretary
  - Reporting will be required for samples distributed by mail or common carrier, or otherwise
- Drug = prescription drug for which payment is made under Medicare, Medicaid, or CHIP.
- FDA will administer, but rules or guidance not yet issued
- Manufacturers should already have access to this information by virtue of PDMA compliance (if HHS or FDA does not add non-PDMA required information to the Section 6004 reports)

Penalties

- Failure to accurately, completely, and timely report in accordance with requirements
  - Civil penalty of not less than $1,000, but not more than $10,000, for each payment/transfer of value not reported as required
  - Total penalty imposed on an applicable manufacturer or GPO shall not exceed $150,000 for each annual submission
- Knowing failure to accurately and completely report in accordance with requirements
  - Not less than $10,000, but not more than $100,000 for each payment/transfer of value not reported as required
  - Total shall not exceed $1,000,000 for each annual submission
  - “Knowingly” defined as under 31 USC §3729(b) (False Claims Act)
    - Means that a person, with respect to information-- (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information
      - no proof of specific intent to defraud is required.

Penalties (cont'd.)

- In determining civil penalties, factors to be considered will include, but will not be limited to:
  - The length of time of the failure to report, including the length of time the applicable manufacturer and applicable GPO know of the payment or other transfer of value, or ownership or investment interest
  - Amount of the payment that was not reported
  - Level of culpability
  - Nature and amount of information reported in error
  - Degree of diligence exercised in correcting information reported in error
- Enforcement actions will be posted on the web site

Records Retention/Auditing

- Records retention
  - Must maintain – for *5 years* from the date the payment or other transfer of value or ownership or investment interest is published on the website -- all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of compliance with the requirement to accurately and completely submit information in a timely manner
  - HHS, CMS, OIG or designees may audit

Government Reporting

- Annual reports by HHS to Congress, aggregated by manufacturer, including description of enforcement actions taken to implement transparency requirements
- Annual reports to States summarizing information submitted during the preceding year with respect to covered recipients in that State

Questions?

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