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New Federal Payment Sunshine Rule: Implications for Manufacturers and Providers

Navigating Regulations for Collecting Data and Reporting Payments and Transfers of Value

TUESDAY, APRIL 2, 2013

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Eve M. Brunts, Partner, **Ropes & Gray**, Boston

Seth H. Lundy, Partner, **King & Spalding**, Washington, D.C.

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New Federal Payment Sunshine Rule: Implications for Manufacturers and Providers

Strafford Publications

April 2, 2013

Eve Brunts
Ropes & Gray LLP
eve.brunts@ropesgray.com
617-951-7911

Agenda

- Introduction (Brunts)
- Applicable Manufacturers (Lundy)
- Covered Recipients (Lundy)
- Transfers of Value (Brunts)
- Reporting Transfers of Value (Brunts)
- Special Reporting Requirements (Lundy)
- Reporting and Disclosure Process (Lundy)
- *Focus on reporting transfers of value (not physician ownership)*

Introduction

- Purpose
  - Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Basic Mandate
  - Manufacturers of a drug, device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient (*i.e.*, physicians and teaching hospitals)

Introduction

- Tracking
  - Manufacturers must begin tracking transfers of value August 1, 2013
- Reporting
  - Manufacturers must submit reports annually to the Centers for Medicare & Medicaid Services (CMS)
  - Report for August 1 to December 31, 2013 due March 31, 2014
  - Subsequent reports cover full calendar year
- Disclosure
  - Information reported will be posted on public website
    - Easily searchable and understandable format
    - Information on enforcement actions
    - Background on industry-physician relationships
  - Information from 2013 reported September 30, 2014

Introduction

- Penalties for Non-Compliance
  - Failure to Report: Civil money penalty from $1,000 to $10,000 for each unreported transfer of value up to $150,000
  - Knowing Failure to Report: Civil money penalty from $10,000 to $100,000 for each unreported transfer of value up to $1,000,000

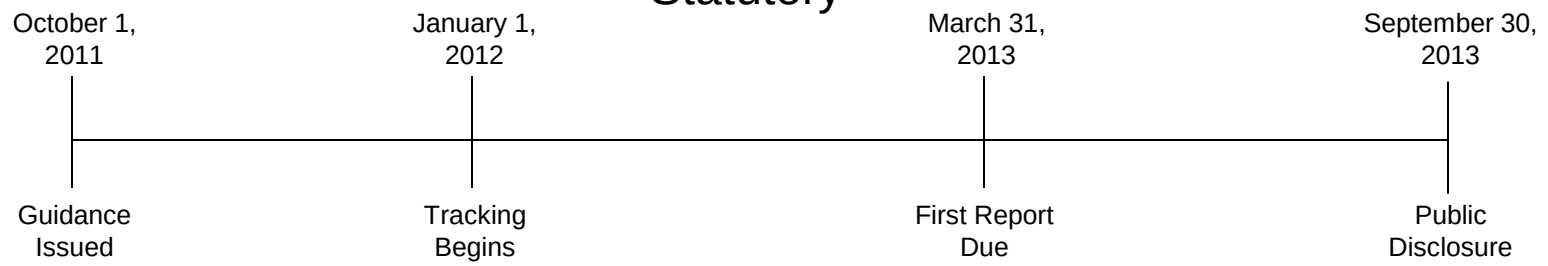
Introduction

- Final Rule
  - Revises statutory timeline for implementation
  - Regulations and commentary provide extensive guidance
    - Commentary responds to 373 comments
    - Numerous changes from CMS proposed position in proposed rule issued in 2011
- Impact
  - Manufacturers previously “in limbo” attempting to prepare for compliance without final guidance and uncertain implementation dates
  - Manufacturers now need to re-evaluate policies, processes and systems

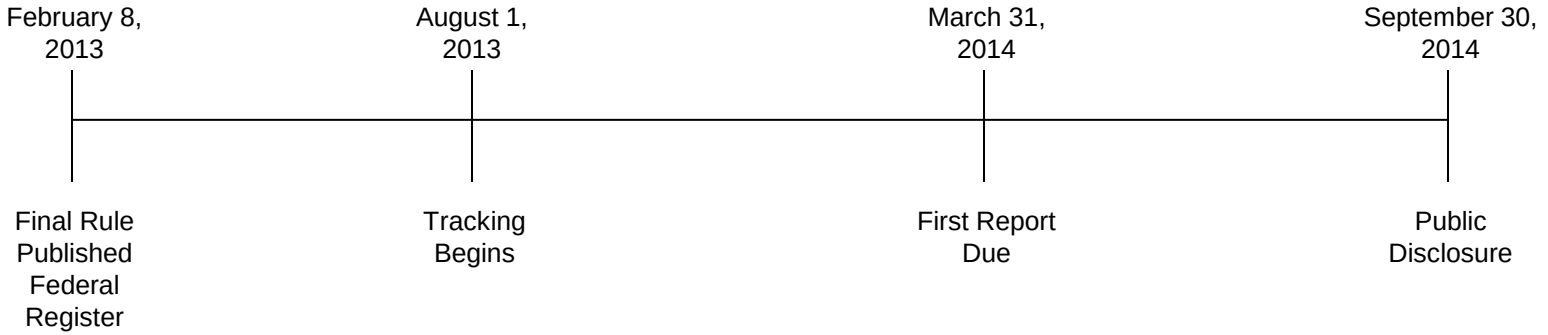
Introduction

Timelines for Implementation

Statutory



Final Rule



Understanding the Physician Payments Sunshine Act Requirements

April 2, 2013

Seth H. Lundy
Partner
King & Spalding LLP
(202) 626-2924
slundy@kslaw.com

Implementation Timeline

- **August 1, 2013 -** Applicable manufacturers must begin tracking payments or other transfers of value they provide to covered recipients

- **March 31, 2014 -** First disclosure reports due to CMS, covering the period August 1 to December 31, 2013

- **September 30, 2014**
  - CMS will publicly post data from 2013 reporting period
  - CMS will report to the states regarding data from 2013 reporting period

- **April 1, 2015 -** CMS will report to Congress regarding data from **2013** reporting period

"Applicable Manufacturers"

"Applicable Manufacturer"

42 C.F.R. § 403.902

– Applicable manufacturer means an entity that is **"that is operating in the United States"** and that falls within one of the following categories:

1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a **"covered drug, device, biological, or medical supply"** ("covered product"), but not if such covered product is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers that do not hold title to any covered product; or

2) An entity 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 product.

"Applicable Manufacturer"

42 C.F.R. § 403.902

- **"Operating in the United States"** means "having a physical location within the United States or in a territory, possession, or commonwealth of the United States, or otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent."

- **"Common ownership"** refers to "circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations."

- **"Assistance or support"** means "providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a [covered product]."

"Applicable Manufacturer"

Notable Issues - Foreign Entities

- Foreign Entities - CMS states that it did not intend to capture foreign entities that may contribute to the manufacturing process of a covered product, but have no "business presence" in the U.S.
  - "Business presence" may mean minimum contacts in U.S., including agency
- Wholesalers and Distributors - Are considered applicable manufacturers if they take title to covered products
- Contract Manufacturers - Entities that *either* manufacture or hold an FDA approval, licensure, or clearance for a covered product are applicable manufacturers
- New Applicable Manufacturers - Have 180 days from the introduction of a covered product to come into compliance

"Applicable Manufacturer"

Key Takeaways

- Foreign affiliates involved in the manufacturing of covered products that are sold or distributed in the U.S. may not be applicable manufacturers
- Affiliates that produce active ingredients used to manufacture covered products are considered assisting or supporting with the manufacturing of covered products
- Affiliates that only provide corporate shared services (*e.g.*, Human Resources, Legal, Compliance) may reasonably not be considered assisting or supporting with the manufacturing, selling, marketing, or distributing of covered products
- As a general matter, manufacturers who sell their products through independent distributors that take title to the products do not need to report payments or other transfers of value that those independent distributors provide to covered recipients

"Covered Drug, Device, Biological, Medical Supply"

42 C.F.R. § 403.902

– Any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Plan (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a:

- Drug or biological, by law, requires a prescription to be dispensed; or
- Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA

"Covered Drug, Device, Biological, Medical Supply"

Key Takeaways

- To be a covered product, payment must only be *available* for the product under Medicare, Medicaid, CHIP; generally, it makes no difference whether any individual or entity has actually sought reimbursement for the product
- Regarding drugs and biologics, to be a covered product, the product must *require* a prescription to be dispensed; the focus is not on whether a product may be dispensed by prescription

Certain Limited Reporting Obligations

- Applicable manufacturers with gross revenues from covered products of less than 10 percent of gross revenue during the fiscal year preceding the reporting year need only report payments or other transfers of value that are related to one or more covered products
- Paragraph (2) applicable manufacturers need only report payments or other transfers of value that are related to a covered product for which they provided assistance or support to a paragraph (1) applicable manufacturer
- Applicable manufacturers with separate operating divisions that do not manufacture any covered products need only report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered product
- Contract manufacturers that do not hold the FDA approval, licensure, or clearance for the covered product, and are not involved in the sale, marketing, or distribution of the product, need only report payments or other transfers of value that are related to one or more covered products

Limited Reporting Obligations for Certain Applicable Manufacturers

Key Takeaways

– If an entity is deemed to be an applicable manufacturer, then all of its interactions with covered recipients potentially implicate the Sunshine provisions (the "all in" rule), unless it reasonably satisfies one of the four limited reporting situations, in which case it must only report payments or other transfers of value that relate to covered products.

"Covered Recipients"

"Covered Recipients"

42 C.F.R. § 403.902

1) Any **physician**, except for a physician who is an employee (as defined in section 1861(r) of the Act) of the applicable manufacturer that is reporting the payment; or
   - Section 1861(r) defines physician to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.
2) A **teaching hospital**, which is any institution that received direct or indirect graduate medical education ("GME" or "IME") payments from CMS during the last calendar year for which such information is available.

"Covered Recipients"

Notable Issues

- Physicians - Must be "legally authorized" to practice, i.e., have a current license
- Residents - Are not subject to reporting (interns and fellows are)
- Physicians who are employees of other applicable manufacturers - Are subject to reporting and not exempted
- Teaching Hospitals - CMS will annually publish a list and make it available for download at least 90 days before the beginning of the reporting year
  - Payments to non-healthcare departments of universities affiliated with teaching hospitals are not subject to the reporting requirements, unless indirect payments
  - Payments to physician employees of a teaching hospital are reportable only as payments to the physician
  - Treatment of payments to other employees of the teaching hospital are unclear

"Covered Recipients"

Key Takeaways

- Generally, any physician who has a current license is a covered recipient, unless he/she is a resident
- Transfers of value (*e.g.*, meals) that one applicable manufacturer provides to another applicable manufacturer's physician employees are not excluded from disclosure
- Manufacturers will need to undertake a case by case analysis to determine whether board members, retirees, and other physicians with similar relationship to the manufacturer are appropriately considered "employees"
- Universities affiliated with teaching hospitals are not covered recipients
- Remember that research related payments furnished to teaching hospitals must be reported in accordance with the special rules for research payments (discussed in more detail below)

Transfers of Value

Transfers of Value: General Rule

- Manufacturers must report *direct* and *indirect* payments and other transfers of value to covered recipients *or* third parties at the request of or designated on behalf of a covered recipient *other than* transfers of value expressly exempt from reporting
  - Direct and indirect transfers of value
  - Transfers of value to third parties
  - Exclusions
    - Certain transfers of value
    - Certain manufacturers (limited transfers of value)
- Voluntary (non-public) assumptions document

Transfers of Value: Types

- Types
  - *Direct* transfer of value to covered recipient
  - *Indirect* transfer of value to covered recipient *through* a third party
  - Transfer of value to a third party at *the request of* covered recipient
    - Covered recipient directs transfer to third party
    - Example: Physician directs payment to physician group or practice
  - Transfer of value to a third party *designated on behalf of* covered recipient
    - Manufacturer makes transfer to third party in name of covered recipient
    - Example: Manufacturer makes charitable contribution to charity in the name of physician
  - No transfer of value if covered recipient waives transfer (*i.e.*, neither accepts transfer nor directs transfer to third party)

Transfers of Value: Indirect Transfers of Value

- Indirect transfers of value include transfers *through* a third party if the manufacturer "requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part" to a covered recipient
  - Sufficient that manufacturer *cause* transfer to go to a covered recipient
  - Not required that manufacturer *control* selection of covered recipient
  - *No* indirect transfer of value if a covered recipient is *not an intended recipient*

Transfers of Value: Indirect Transfers of Value

- Examples
  - *No* Indirect Transfer
    - Consultant firm engaged to undertake project that does not require the services of a physician and firm happens to staff with physician
  - Indirect Transfer
    - Clinic engaged to provide physician to undertake work even if particular physician unspecified

Transfers of Value: Indirect Transfers of Value

- Indirect transfers of value are exempt from reporting if the manufacturer is unaware of the identity of the covered recipient
  - Manufacturer "aware" of identity if actual knowledge of identity or deliberate ignorance or reckless disregard of the identity
  - Manufacturer may become "aware" at any point during the calendar year in which the transfer was made through the second quarter of the following year
  - Transfers of value excluded if manufacturer deliberately seeks to remain unaware for anonymity reasons (*e.g.*, payment to physicians through a research firm for double-blinded market research)

Transfers of Value: Indirect Transfers of Value

- Indirect transfer of value to covered recipient *through* third party
  - Treatment
    - Third party "pass-through" individual/entity not identified
  - General Allocation
    - Value generally allocated to covered recipient
    - Payment to covered recipient through covered recipient (*e.g.*, to physician through teaching hospital)
      - Apportion payment between direct and indirect recipients if direct recipient retains some portion

Transfers of Value:
Other Transfers of Value to Third Parties

- Transfer of value to a third party *at the request of or designated on behalf* of covered recipient
  - Treatment
    - Third party recipient identified (*but* third party has no opportunity to review/dispute information)
      - Entity ⟶ Name
      - Individual ⟶ Individual
  - General Allocation
    - Allocate transfers of value in manner that most fairly represents the situation
    - Example: Allocate evenly, based on who requested transfer, or based on who intended to benefit from transfer

Transfers of Value: Exclusions

- Scope of reportable transfers of value limited for certain manufacturers with limited manufacturing functions
  - Manufacturer's gross revenue from the covered product is less than 10%
  - Manufacturer is manufacturer only because provides support or assistance to another manufacturer engaged in core manufacturing activities
  - Manufacturer has separate operating divisions that do not manufacture any covered products
  - Manufacturer is only third party contract manufacturer
- Manufacturers report only transfers related to covered products or made by manufacturing functions
  - Manufacturers must be able to identify and segregate transfers of value "related to" covered product

Transfers of Value: Exclusions

- Generally
  - Certain transfers of value excluded from reporting
  - Absent guidance, scope to be defined by dictionary definitions
- Minimal Value
  - Transfers of less than $10 unless annual aggregate exceeds $100
    - If aggregate threshold reached, report separately or bundle with other small payments in same nature of payment category
  - Transfers of less than $10 provided at large-scale conferences and similar events or public events are excluded from reporting *even if* annual aggregate exceeds $100
  - Thresholds updated for inflation in calendar years after 2013
    - Urban consumer price index (all items and U.S. city average)

Transfers of Value: Exclusions

- Common Business Transactions
  - Discounts (including rebates)
  - Items/services provided under warranty set forth in purchase/lease agreement for device (even if warranty period has expired)
    - Warranty, service, maintenance agreement and replacement product for product recall
  - Loan of device for 90 days or less per calendar year to permit evaluation *plus* appropriate amount of disposable supplies for use in connection with the device
    - Covered devices or products in development

Transfers of Value: Exclusions

- Patient Focused Activities
  - Educational materials (and services) that directly benefit patients or are intended for patient use
    - Must be for patient education and not physician/practitioner education
    - Example: Anatomical models/wall charts for patient education excluded but not textbooks or article reprints for physician education
  - Product samples not intended to be sold and intended for patient use
    - Product provided for patient use and coupons/vouchers to obtain samples
    - Manufacturer need not track actual use if written agreement concerning use
    - Does not apply to product provided for research purposes (reported instead as part of research payment)

Transfers of Value: Exclusions

- Patient Focused Activities
  - In-kind items used for the provision of charity care
    - Patients unable to pay or for which payment would be significant hardship
    - Written agreement regarding use recommended
    - Does not include financial support

Transfers of Value: Exclusions

- Unrelated Activities
  - Transfer to physician when not acting in professional capacity (as patient, research subject, or participant in data collection research)
  - Dividend or ownership/investment interest in publicly traded security or mutual fund
  - Payment by self-insured employer for healthcare to employees and families (includes employer health clinic)
  - Payment for non-medical professional services of licensed non-medical professional
  - Payment for services of physician related to legal proceeding (*e.g.*, civil or criminal action)
  - Transfer made solely in context of personal (non-business) relationship

Reporting Transfers of Value

Reporting Transfers of Value: General

- Manufacturers must report specific data elements for each transfer of value
  - Special reporting requirements apply to research and continuing education programs
- Manufacturers may include voluntary (non-public) assumptions document
- Transfers of value covering multiple payment categories must be reported separately
  - Example: Consultant compensation and expenses related to consultant meeting
    - Consultant fee (Cash)
    - Meal (at meeting) (In-kind)
    - Travel (reimbursed) (Cash)
    - Travel (arranged) (In-kind)

Reporting Transfers of Value: General

- Data Elements
  - Name (first, middle initial, last)
  - Business address (physician primary practice location, teaching hospital list)
  - Physician: Specialty, national provider number, and state professional license number
  - Amount
  - Date(s) of transfer (some flexibility for multiple payments within single reporting year)
  - Form
  - Nature
  - Name of related covered product (if any)
  - Eligibility for delayed publication
  - If transfer made to a physician owner/investor
  - Contextual information (voluntary)

Reporting Transfers of Value: Form of Payment

- Form
  - Cash or cash equivalent
  - In-kind items or services
  - Stock, stock option, or any other ownership interest
  - Dividend, profit or other return on investment

Reporting Transfers of Value: Nature of Payment

- Nature
  - Category must be identified for each transfer or portion of transfer
  - If transfer could fall within more than one category, most accurate category should be selected
  - No “other” category
    - Gift category serves as “catch-all” category

Reporting Transfers of Value: Nature of Payment

- Nature
  - Consulting fee
  - Compensation for services other than consulting (includes faculty/speaker at event other than continuing education program)
  - Compensation (direct/indirect) for faculty/speaker for unaccredited continuing education program
  - Compensation (direct/indirect) for faculty/speaker for accredited continuing education program
  - Honoraria
    - Similar to category for compensation for services other than consulting but payment provided for services for which custom prohibits a price from being set

Reporting Transfers of Value: Nature of Payment

- Nature
  - Entertainment
    - Includes attendance at recreational, cultural, sporting or other events that would generally have a cost
  - Food and beverage
  - Travel and lodging (including the specified destinations)
    - Includes any means of transportation
  - Education
    - Includes transfers for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills (e.g., those used for a profession)
  - Space rental or facility fees (teaching hospital only)

Reporting Transfers of Value: Nature of Payment

- Nature
  - Research
    - Common Rule definition of research (broader than research subject to delayed publication)
    - Written agreement or protocol
  - Charitable contribution
    - Transfers made to an organization with an IRS tax-exempt status
    - Does not include transfers made in exchange for any service or benefit
  - Grant
    - Transfers in support of a specific cause or activity
  - Royalty or license
  - Current or prospective ownership or investment interest
    - Includes ownership that a covered recipient currently has and ownership and investment interests yet to be exercise

Reporting Transfers of Value: Related Covered Product

- Related Covered Product
  - Up to five related products (identify most closely related if more than five)
  - Drugs and biologicals
    - Name and NDC number (if available)
    - If unapproved product, then name on clinicaltrials.gov
  - Medical devices
    - Name or therapeutic area or product category

Reporting Transfers of Value: Determining Value

- Guidance on valuing certain transfers of value
  - Value would generally be interpreted as “discernible economic value on the open market in the United States” but acknowledgement of some flexibility in interpretation
  - Transfers of value must be reported if the transfer has discernible economic value generally (even if not to the covered recipient)
  - Transfers of value must be reported even if the covered recipient does not request the transfer
  - All value (tax or shipping) must be included when calculating value
  - Manufacturers must make a good faith effort to determine value
  - Manufacturers may include methodology/assumptions for value in the voluntary assumptions document that manufacturers may submit with their reports

Transfers of Value: Implications for Manufacturers

- Manufacturers need to re-assess current policies, processes and systems in light of revised interpretations
- Clear and consistent assumptions are critical (whether or not submitted in voluntary assumptions document)
- Third party relationships may be affected
  - Manufacturers seek to ensure access to needed information
    - Potential resistance from covered recipients or third parties receiving payments
    - Covered recipient education on reporting and disclosure
  - Need for additional documentation to support treatment of transfers of value (*e.g.*, written agreements for samples or product provided for charity care)

Transfers of Value: Implications for Providers

- Payments to covered recipients will be reported as payments *even if* made to third party
  - Example: Charitable donation in lieu of payment does not avoid report
- Third parties (*e.g.,* physician employers) receiving payments will be reported but not have advance notice/opportunity to dispute
  - Right to review reports of physicians
- Separation of payments (*e.g*., meals from consultant compensation)/use of "gift" as catch-all category may result in reports of payments apparently inconsistent with many provider policies on interactions with industry
- Teaching hospitals/physician employers consider internal education
- Information must be reconciled with other disclosures known to providers
  - Public Health Service financial conflicts of interest
  - Food and Drug Administration financial disclosure
  - Other internal requirements (*e.g*., disclosure of outside commitments)

Transfers of Value: Implications for Providers

- Contractual obligations for covered recipients or employers/contractors of covered recipients will increase
  - Provision of information about covered recipients
    - Information about specific amount "passed through" may be requested
    - Provision of information may be condition of payment
  - Representation/warranty about accuracy of information
  - Indemnification for inaccuracies
- Contractual obligations may require new internal systems for tracking

Transfers of Value: Scenario

- Manufacturer buys table at charity benefit for teaching hospital that is tax-exempt
- Manufacturer invites local physicians to join manufacturer representatives at table
  - What transfer(s) of value?
  - How categorized?
  - How allocated?
  - How valued?

Transfers of Value: Scenario

- Manufacturer engages select hospitals nationwide (including teaching hospitals) to serve as “show site” for new equipment
- Equipment provided at no cost/significantly reduced price
- Prominent physicians associated with hospitals made available to demonstrate/discuss equipment for potential customers
  - What transfer(s) of value?
  - How categorized?
  - How allocated?
  - How valued?

Special Payment Rules

Special Rules for Reporting Food and Beverage

42 C.F.R. § 403.904(h)

- When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff).
- The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

Special Rules for Reporting Food and Beverage

Key Takeaways

- CMS is focused on equitable and accurate reporting of meals
- Generally, meals provided to office staff are not reportable
- Dropping food off at a physician's office does not avoid the reporting requirements

Special Rules for Research Payments

42 C.F.R. § 403.904(f)

- "All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported [in accordance with special rules for such payments]." (emphasis added)
- **"Research"** includes "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development." (42 C.F.R. § 403.902)

Special Rules for Research Payments

42 C.F.R. § 403.904(f)

– Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported separately from other payments or transfers of value, and must include the following information:

1. Name of the research institution, individual or entity receiving the payment or other transfer of value
   - If paid to a physician, list the physician's name, NPI, a state license number, specialty, and primary business address
   - If paid to a teaching hospital, list the name and primary business address
   - If paid to a non-covered recipient (e.g., non-teaching hospital or clinic), list the primary business address

Special Rules for Research Payments

42 C.F.R. § 403.904(f)

– Research-related payments or other transfers of value must be reported separately from other payments or transfers of value, and must include the following information (cont'd):

2. Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both
3. Name of the research study
4. Name(s) of any related covered products, and for drugs and biologicals, the relevant NDC(s), if any
5. For each covered recipient physician principal investigator, the physician's name, NPI, a state license number, specialty, and primary business address
6. If desired, contextual information for research
7. If desired, the ClinicalTrials.gov identifier

Special Rules for Research Payments

42 C.F.R. § 403.904(f)

– For **pre-clinical studies** (before human studies have begun), only report the following:

1. Name of the research institution, individual or entity receiving the payment or other transfer of value
   - If paid to a physician, list the physician's name, NPI, a state license number, specialty, and primary business address
   - If paid to a teaching hospital, list the name and primary business address
   - If paid to a non-covered recipient (e.g., non-teaching hospital or clinic), list the primary business address
2. Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both
3. For each covered recipient physician principal investigator, the physician's name, NPI, a state license number, specialty, and primary business address

Special Rules for Research Payments

Key Takeaways

- Research payments need only be reported once, even if both a teaching hospital and physician are associated with the payment
- Research payments do not need to be itemized (this in an exception to the general rule that each separable part of a payment or other transfer of value be separately reported)
- There are abbreviated reporting requirements for payments associated with pre-clinical research
- If a payment or other transfer of value is not provided in connection with an activity that reasonably satisfies the definition of "research", it may not be described as "research" and must be reported in accordance with the general rules
- Only payments or other transfers of value that are included in the written research agreement or research protocol may be reported as "research"

Delayed Publication of Certain Research Payments

42 C.F.R. § 403.910

– Payments or transfers of value may be delayed from publication if they are furnished pursuant to a product research or development agreement:

1. For research on or development of a new product, or a new application of an existing product; or
2. In connection with a "clinical investigation" regarding a new product
    - Clinical investigation is defined as "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." (42 C.F.R. § 403.902)

Delayed Publication of Certain Research Payments

42 C.F.R. § 403.910

– Payments eligible for delayed publication 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:

- The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration
- Four calendar years after the date the payment or other transfer of value was made

Delayed Publication of Certain Research Payments

42 C.F.R. § 403.910

– Notification of delayed publication:

- 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
- 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
- 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

Other Key Considerations

Reports of Physician Ownership and Investment Interests

42 C.F.R. §403.906(a)

- Each applicable manufacturer and applicable group purchasing organization ("GPO") must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable GPO that were held by a physician or an immediate family member of a physician during the preceding calendar year.
- For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

45-day Review Period and Error Correction

42 C.F.R. § 403.908(g)

- Applicable manufacturers, applicable GPOs, covered recipients, and physician owners will have a period of 45-days to review reported information before CMS makes the information available to the public.
- CMS will notify the applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors when the reported information is ready for review.
  - If the party agrees with the information reported, he or she may electronically certify that the information reported is accurate.
  - CMS will not arbitrate disputes between parties.
  - If the dispute is not resolved by the end of the 45-day review period, CMS will make the applicable manufacturer's version of the data public, but mark the payment as disputed.

Errors, Omissions, and Attestation

42 C.F.R. § 403.908(e) - Errors or omissions

- If an applicable manufacturer discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

42 C.F.R. § 403.908(h) - Attestation

- Each report, including any subsequent corrections to a filed report, must include a certification by the CEO, CFO, Chief Compliance Officer, or other Officer of the applicable manufacturer that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.
- If filing a consolidated report, the attestation applies to all applicable manufacturers covered by the consolidate report.

Record Retention and Audits

42 C.F.R. § 403.912(e)

Maintenance of records

- Applicable manufacturers and GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the entity's compliance with the reporting requirements.
- The materials listed above must be maintained for a period of at least 5 years from the date the information is published publicly on the website.

Audits

- HHS, CMS, OIG or their designees may audit, inspect, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and GPOs that pertain to their compliance with the reporting requirements.

Penalties for Failure to Report

42 C.F.R. § 403.912

Failure to report

– Any applicable manufacturer or GPO that fails to timely, accurately, or completely submit the information required in a timely manner is subject to a civil monetary penalty between $1,000 and $10,000 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely (the total amount shall not exceed $150,000).

Knowing failure to report

– A knowing failure to timely, accurately, or completely submit the required information is subject to a civil monetary penalty between $10,000 and $100,000 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely (the total amount shall not to exceed $1,000,000).

Penalties for Failure to Report

42 C.F.R. § 403.912

Determinations regarding the amount of civil monetary penalties

– In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

- The length of time the applicable manufacturer or GPO failed to report, including the length of time the applicable manufacturer and GPO knew of the payment or other transfer of value, or ownership or investment interest
- Amount of the payment the applicable manufacturer or applicable GPO failed to report
- Level of culpability
- Nature and amount of information reported in error
- Degree of diligence exercised in correcting information reported in error

Assumptions Documents

42 C.F.R. § 403.908(f)

- Applicable manufacturers and applicable GPOs may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests.
- The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.