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Overview of CMS Final Rule for U.S. Sunshine

March 26, 2013

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Discussion Topics

- CMS Final Rule
  - Applicable Manufacturer
  - Applicable Definitions
  - Reportable Information
  - Research-Related Payments
  - Delayed Publication
  - Continuing Education Payments
  - Reporting Exclusions
  - Physician Ownership or Investment Interest
- Implementation, Tracking & Reporting
- Questions
- Additional Resources

CMS Final Rule – Significant Changes

- Most notable changes that will be discussed today:
  - **Applicable Manufacturer**
  - **Research-Related Payments**
  - **Delayed Publication**
  - **Continuing Education Payments**
  - **Reporting Templates**

CMS Final Rule – Applicable Manufacturer

42 C.F.R. § 403.902

- **"Applicable Manufacturer"**
  - An entity operating in the United States that:
    - *Manufactures a covered drug, device, biological, or medical supply*
      - Does not include distributors or wholesalers that do not hold title to any covered drugs, devices, biologicals, or medical supplies
      - Does not include an entity that manufactures or distributes covered products that are used solely by or within the entity or by the entity's own patients
    - *Is under common ownership with a manufacturer of a covered product and provides assistance or support with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product*

CMS Final Rule – Applicable Manufacturer

42 C.F.R. § 403.902

- "**Operating in the United States**" (new definition)
  - Means that an entity:
    - *has 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 (e.g., by selling a product in the United States) or in a territory, possession, or commonwealth of the United States, either directly or through a legally authorized agent.*
  - Does not include foreign entities that may contribute to the manufacturing process of a covered product but have no business presence or activities in the United States.

CMS Final Rule – Applicable Manufacturer

42 C.F.R. § 403.902

- "**Applicable Manufacturer**" may include:
  - Any entity outside of the United States that sells or distributes products within the United States
  - An entity that manufactures various products–**one** of which meets the definition of a covered drug, biological, device, or medical supply
  - An entity that holds the FDA approval, licensure, or clearance for a covered drug, device, biological, or medical supply – even if the entity contracts out the physical manufacturing process
  - Contract manufacturer of covered drugs, biologicals, devices, or medical supplies
  - Distributor and wholesaler of covered products that hold title to the covered products

CMS Final Rule – Other Applicable Definitions

42 C.F.R. § 403.902

- **"Applicable GPO" is defined as:**
  - An entity that:
    - *Operates in the United States, and*
    - *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.*
  - Physician-owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies would fall under this definition.

CMS Final Rule – Applicable Definitions

42 C.F.R. § 403.902

- **"Covered Recipient" is defined as:**
  - A physician, other than a physician who is a bona fide employee of the applicable manufacturer reporting the payment
    - *Includes doctors of medicine or osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.*
  - A teaching hospital
    - *Any institution that received payments under IME, GME, or psychiatric hospitals IME during the most recent calendar year.*
    - *CMS to publish a list on an annual basis.*

CMS Final Rule – Applicable Definitions

42 C.F.R. § 403.902

- **"Covered Drug, Device, Biological, or Medical Supply" is defined as:**
  - Any drug, device, biological, or medical supply for which payment is ***available*** under Medicare, Medicaid, SCHIP (or a waiver of such a plan) either separately, or as part of a bundled payment.
  - Drug or biological is limited to those products that, by law, require a prescription to be dispensed; thus excluding over-the-counter drugs.
  - Device or medical supply is limited to those products that, by law, require premarket approval by or premarket notification to the FDA.
  - If a manufacturer has at least **one** product that qualifies under the above guidance, payments/transfers for **covered recipients** must be reported as outlined.

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(a)(1)

- **What to Report**:
  - Direct and indirect payments or other transfers of value made in the preceding year to **covered recipients**.
  - Direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year.
  - "Payments or other transfers of value" do not include transfers made indirectly, through a third party, in connection with an activity or service, where the applicable manufacturer is unaware of the identity of the covered recipient.

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(b)(1)-(4)

- **Limitations on Scope of Reporting –** The following entities need only report payments and other transfers of value that are specifically related to a covered product:
  - An applicable manufacturer with less than 10 percent (gross) revenues from covered products during the previous fiscal year.
  - Entities that are applicable manufacturers based only on common ownership.
  - Operating divisions of applicable manufacturers that do not manufacture any covered products (e.g., an animal health division).
  - Contracted manufacturers of covered products that do not hold the FDA approval, licensure, or clearance and are not involved in the sale, marketing, or distribution of the covered products.

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(c)

- Name and business address of the **covered recipient** including identifying information for physicians such as:
  - Specialty
  - National Provider Identifier (NPI)
  - State license number(s) and the state(s) in which the license is held
- Amount of the *payment or other transfer of value.*
- Date on which the *payment or other transfer of value* was provided.

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(c)

- Description of the form of the *payment or other transfer of value*, indicated as:
  - Cash or cash equivalent
  - In-kind item or service
  - Stock, stock option, or other ownership interest
  - Dividend, profit, or other return on investment

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(c)

- Description of the nature of the payment or other transfer of value.
  - Consulting fee
  - Compensation for services other than consulting (including serving as faculty or as a speaker at an event other than a continuing education program)
  - Honoraria
  - Gift
  - Entertainment
  - Food and beverage
  - Travel and lodging (including the specified destinations)
  - Education
  - Research

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(c)

- Description of the nature of the payment or other transfer of value.
  - Charitable contribution
  - Royalty or license
  - Current or prospective ownership or investment interests
  - Compensation for serving as faculty or as a speaker for an unaccredited and noncertified continuing education program
  - Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
  - Grant
  - Space rental or facility fees (teaching hospital only)

CMS Final Rule – Reportable Information

42 C.F.R. § 403.904(c)

- Name(s) of the related covered drug, device, biological, or medical supply, if applicable.
- Indication of whether the payment or other transfer of value is eligible for delayed publication.
- Name of entity that received the payment or other transfer or value, if not provided to the covered recipient directly.
- Indication of whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in an organization.
  - This is also meant to be a yes/no field in the report submitted.
- Additional information or context for payment.

CMS Final Rule – Special Rules for Research Payments

42 C.F.R. § 403.904(f)

- Name of the research institution, individual, or entity that received the payment
  - Directly from the applicable manufacturer
  - Indirectly through a CRO or SMO, **regardless** of whether the individual or entity is **itself a covered recipient**.
- If the payment is made **directly to a physician covered recipient**, identifying information
  - NPI
  - State license number(s) for at least one state in which the physician maintains a license and state(s) in which the license is held
  - Specialty
  - Primary business address

CMS Final Rule – Special Rules for Research Payments

42 C.F.R. § 403.904(f)

- If the payment is made to a **teaching hospital**
  - Name of teaching hospital
  - Primary business address
- If paid to a **non covered recipient** (non teaching hospital or clinic)
  - Name of the entity
  - Primary business address

CMS Final Rule – Special Rules for Research Payments

42 C.F.R. § 403.904(f)

- Amount of the research payment
- Name of the study
- Name of the related covered drug, device, biological, or medical supply and the National Drug Code, if any
- Name of the principal investigator (including identifying information)
- Context for research (optional)
- ClinicalTrials.gov identifier (optional)
- For pre clinical research, it is **not required** to include the name of the related covered drug, device, biological, or medical supply or the study name since early-stage research is often not connected to a specific product

CMS Final Rule – Delayed Publication

42 C.F.R. § 403.910

- Delayed publication is allowed for research-related services as indicated below:
  - Research on or the development of **new** drugs, devices, biologicals, and medical supplies
  - Research for a **new** application of a product already on the market provided that the research **does not meet** the definition of a "clinical investigation"
- Applicable manufacturers must continue to report annually on delayed publication data and any updated information. Failure to continue to report data as eligible for delayed reporting will result in the data being published on the next publication date.
- Following FDA approval, licensure, or clearance, applicable manufacturers will indicate in their next annual reports that the payment(s) should no longer be granted a delay and should be published.

CMS Final Rule – Special Rules for Continuing Education Payments

42 C.F.R. § 403.904(g)

- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education event
  - Includes all accredited or certified continuing education payments where the following applies:
    - *Program **meets** accreditation or certification requirements (ACCME, AOA, AMA, AAFP or ADA CERP)*
    - *Applicable manufacturer **does not pay** the covered recipient speaker directly*
    - *Applicable manufacturer **does not select or suggest** covered recipients as speakers*
  - Accredited or certified continuing education payments that meet the above requirements are not considered indirect payments for purposes of the U.S. Sunshine reporting requirements.

CMS Final Rule – Special Rules for Continuing Education Payments

42 C.F.R. § 403.904(g)

- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education event
  - Not intended to capture attendance at CME events where registration fees have been subsidized through the CME organization by applicable manufacturers
  - Any travel or meals provided by an applicable manufacturer must be reported under the appropriate nature of payment category

CMS Final Rule – Special Rules for Continuing Education Payments

42 C.F.R. § 403.904(g)

- Compensation for servicing as faculty or as a speaker for an unaccredited and noncertified continuing education program
  - Applies to all payments for compensation to a covered recipient for serving as faculty/speaker – regardless of whether the payment was provided directly or indirectly
- Compensation for services other than consulting
  - Explicitly includes payments for speaking engagements that are not for continuing education

CMS Final Rule – Reporting Exclusions

42 C.F.R. § 403.904(i)

- For CY 2013, a transfer of value less than $10, as long as the aggregate amount to a covered recipient **is less than $100** during the calendar year.
  - $10 and $100 thresholds to be CPI adjusted for CY 2014 and subsequent years.
  - Transfers of value under the $10 threshold provided at large-scale conferences and seminars do not need to be reported or included in determining aggregate transfers.
- Indirect payments or other transfers of value, where the applicable manufacturer is **not aware** of the identity of the covered recipient.
- Product samples, including coupons and vouchers, that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use, including the value of an applicable manufacturer's services to educate patients regarding a covered product.

CMS Final Rule – Reporting Exclusions

42 C.F.R. § 403.904(i)

- The loan of a **covered device** or a device under development or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed 90 days or a quantity of 90 days' average daily use, to permit evaluation of the **covered device or medical supply** by the **covered recipient**.
- Items or services provided under a contractual warranty, including service or maintenance agreements (whether or not the warranty period has expired) if the terms of the warranty are set forth in the agreement.
- A transfer of anything of value to a **covered recipient** when the **covered recipient** is a patient, research subject, or participant in data collection for research and not acting in the professional capacity of a **covered recipient**.
- Discounts (including rebates).

CMS Final Rule – Reporting Exclusions

42 C.F.R. § 403.904(i)

In-kind items used for the provision of charity care.

- "Charity care" is defined as items provided to a **covered recipient** for one or more patients who cannot pay or for whom payment would be a significant hardship, where the **covered recipient** neither receives nor expects to receive payment because of the patient's inability to pay.
- Provision of items to a **covered recipient** for the care of all of its patients (both those who can and cannot pay) are not excluded.
    - *For example – the donation of an imaging machine to a **covered recipient** that would be used for both paying and nonpaying patients would not be excluded – even if the covered recipient is a charitable organization.*

CMS Final Rule – Reporting Exclusions

42 C.F.R. § 403.904(i)

A dividend or other profit distribution from, or ownership or investment interest in, a publicly-traded security or mutual fund.

Payments for the provision of healthcare to employees and their families under a self-insured plan or through direct reimbursement of healthcare expenses by an **applicable manufacturer.**

A transfer of value if the transfer is payment solely for nonmedical professional services provided by a **covered recipient** who is a licensed nonmedical professional.

A transfer of value if the transfer is payment solely for services, provided by a **covered recipient** who is a physician, with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

CMS Final Rule – Physician Ownership or Investment Interest

42 C.F.R. § 403.906

"Ownership or Investment Interest" is defined as:

- An ownership or investment interest that may be direct or indirect and through debt, equity, or other means.
- Includes, but is not limited to:
  - *Stock, stock options (other than those received as compensation, until they are exercised);*
  - *Partnership shares;*
  - *LLC memberships; and*
  - *Loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue.*

CMS Final Rule – Physician Ownership or Investment Interest

42 C.F.R. § 403.906

"Ownership or Investment Interest" does not include:

- An ownership or investment interest in a publicly traded security or mutual fund;
- An interest in an **applicable manufacturer** or **applicable GPO** that arises from a retirement plan offered by that **applicable manufacturer** or **applicable GPO** to the physician (or immediate family member) through his or her employment with that **applicable manufacturer** or **applicable GPO**;
- Stock options and convertible securities received as compensation, until the stock is exercised or the convertible securities are converted to equity; and
- An unsecured loan subordinated to a credit facility.
- An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

CMS Final Rule – Physician Ownership or Investment Interest

42 C.F.R. § 403.906(a)

"Ownership or Investment Interest" by whom:

- Physicians
  - *Defined as <u>any</u> physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO*
- Physician's immediate family member
  - *Defined as:*
    - Spouse
    - Natural or adoptive parents, child, or sibling
    - Stepparent, stepchild, stepbrother, or stepsister
    - Father-, mother-, daughter-, son-, brother-, or sister-in-law
    - Grandparent or grandchild
    - Spouse of a grandparent or grandchild

CMS Final Rule – Physician Ownership or Investment Interest

42 C.F.R. § 403.906(b)

Information that must be reported:

- The dollar amount invested by each physician.
- Whether the ownership or investment interest is held by the physician or an immediate family member.
- The value and terms of each ownership or investment interest.
- Physician-specific identifier information (e.g., name, business address, specialty, NPI number, state license number).
- Direct and indirect payments or other transfers of value provided to a physician holding such ownership or investment interest (or to a third party on behalf of the physician) must be reported in accordance with the requirements for reporting payments and other transfers of value.

Implementation, Tracking & Reporting – Annual Reporting Requirement

42 C.F.R. §§ 403.904(a)(2), 403.906(a)(2), 403.908(a)

When to Report:

- First report due March 31, 2014.
- Data collection must begin on August 1, 2013.
- First report will cover the time period of August 1, 2013 to December 31, 2013.
- For all other years, reports are due within 90 days of the end of the calendar year for which a report is required.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(c)

Registration:

- Any **applicable manufacturer** or **applicable GPO** that has reportable payments/transfers of value (for applicable manufacturers only) or reportable ownership/investment interests must register within 90 days of the end of the calendar year for which a report is required.
- Must designate two points of contact (a primary and a backup) to receive detailed information from CMS on the report submission process.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(d)(1)

Consolidated Reporting:

- Applicable manufacturers under common ownership may, but are not required to, file a consolidated report.
- If an organization is submitting consolidated reporting, it must still register each entity name under common ownership.
- The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(e)

Attestation Requirement:

- Each report, or subsequent correction to a filed report, must include a certification as to its accuracy.
- The certification must be signed by the chief executive officer, chief financial officer, chief compliance officer, or other officer.
- *"information submitted is true, correct, and complete to the best of his or her knowledge and belief."*
- Applicable manufacturers for which covered products represent less than 10 percent of total (gross) revenue for the preceding year that have payments or other transfers of value to report must attest that less than 10 percent of total (gross) revenue in the immediately preceding year came from covered products.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(f)-(g)

Data Submission:

- **Applicable manufacturers** and **applicable GPOs** should submit their data electronically.
- **Applicable manufacturers** and **applicable GPOs** can submit an "assumptions" document with annual reporting.

Notification:

- CMS notifies applicable manufacturers and applicable GPOs through the points of contact identified during the registration process.
- Physicians and teaching hospitals will be notified using an online posting as well as through CMS's distribution lists. Physicians and teaching hospitals may also register to receive direct notification.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(g)

45-Day Review Period:

- Data will be aggregated by individual **covered recipients** and **physician owners or investors**.
- CMS will notify **applicable manufacturers**, **applicable GPOs**, **covered recipients**, and **physician owners and investors**.
- Disputes must be handled directly between parties. If not resolved, CMS will show the data as disputed but will include in the public reports the applicable manufacturer's or applicable GPO's original data.

Data Disputes:

- Following the 45-day review and correction period, applicable manufacturers and applicable GPOs will have an **additional 15 days** to correct data for purposes of resolving disputes.
- Only data disputed during the 45-day review and correction period **and** resolved within the 15-day period for dispute resolution will be captured in the initial publication of data for the current reporting year.

Implementation, Tracking & Reporting – Report Submission & Certification

42 C.F.R. § 403.908(h)

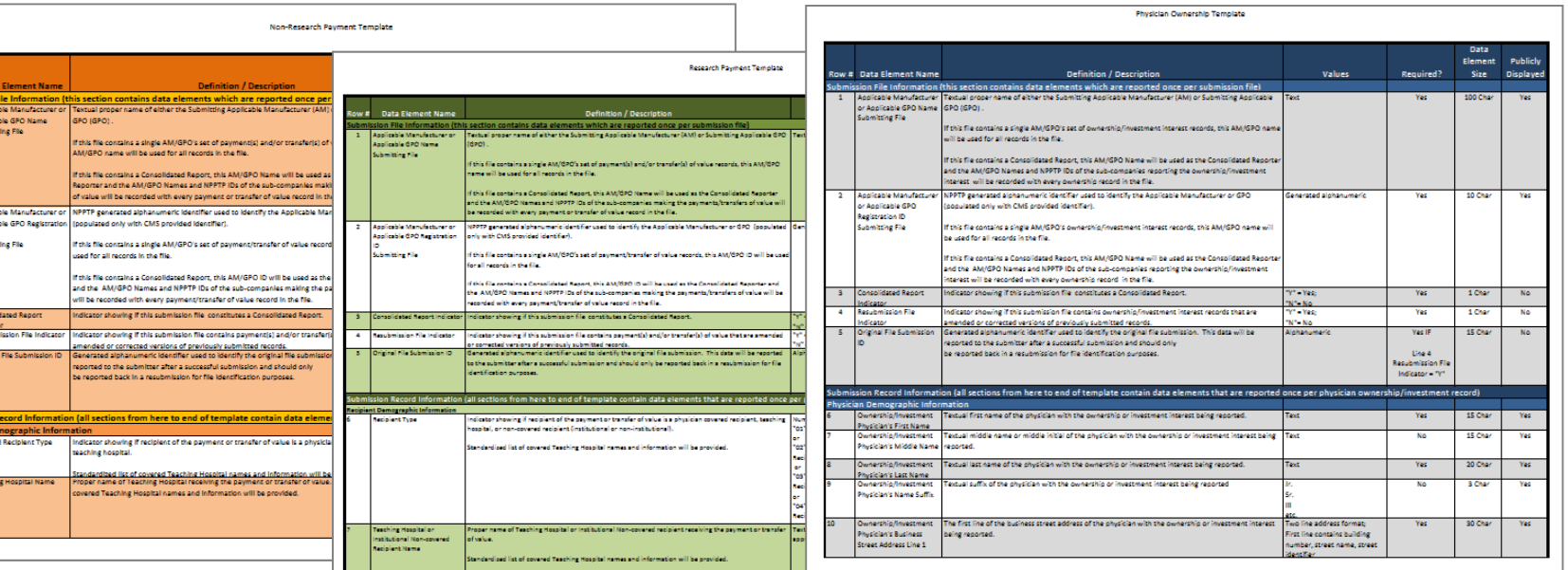
Errors and Omissions:

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

Implementation, Tracking & Reporting – CMS Proposed Templates

Proposed templates available on CMS.gov website

- CMS Form Number: CMS-10419
- Separate templates for Research, Non-Research, and Physician Ownership
- Provide detailed description of the various data elements (e.g., character length, numeric, alpha-numeric, yes/no values)



Non-Research Payment Template

Element Name	Definition / Description
le Information (this section contains data elements which are reported once per	
ble Manufacturer or ble GPO Name ing File	Textual proper name of either the Submitting Applicable Manufacturer (AM) GPO (GPO) . If this file contains a single AM/GPO's set of payment(s) and/or transfer(s) of AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies maki of value will be recorded with every payment or transfer of value record in th
ble Manufacturer or ble GPO Registration ing File	NPPTP generated alphanumeric identifier used to identify the Applicable Mar (populated only with CMS provided identifier). If this file contains a single AM/GPO's set of payment/transfer of value record used for all records in the file. If this file contains a Consolidated Report, this AM/GPO ID will be used as the and the AM/GPO Names and NPPTP IDs of the sub-companies making the pa will be recorded with every payment/transfer of value record in the file.
dated Report	Indicator showing if this submission file constitutes a Consolidated Report.
ission File Indicator	Indicator showing if this submission file contains payment(s) and/or transfer(s)
File Submission ID	amended or corrected versions of previously submitted records. Generated alphanumeric identifier used to identify the original file submissio reported to the submitter after a successful submission and should only be reported back in a resubmission for file identification purposes.
ecord Information (all sections from here to end of template contain data eleme	
nographic Information	
Recipient Type	Indicator showing if recipient of the payment or transfer of value is a physicia teaching hospital. Standardized list of covered Teaching Hospital names and information will be
g Hospital Name	Proper name of Teaching Hospital receiving the payment or transfer of value. covered Teaching Hospital names and information will be provided.

Research Payment Template

Row #	Data Element Name	Definition / Description
Submission File Information (this section contains data elements which are reported once per submission file)		
1	Applicable Manufacturer or Applicable GPO Name Submitting File	Textual proper name of either the Submitting Applicable Manufacturer (AM) or Submitting Applicable GPO (GPO) . If this file contains a single AM/GPO's set of payment(s) and/or transfer(s) of value records, this AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies making the payments/transfers of value will be recorded with every payment or transfer of value record in the file.
2	Applicable Manufacturer or Applicable GPO Registration ID Submitting File	NPPTP generated alphanumeric identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file contains a single AM/GPO's set of payment/transfer of value records, this AM/GPO ID will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO ID will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies making the payments/transfers of value will be recorded with every payment/transfer of value record in the file.
3	Consolidated Report Indicator	Indicator showing if this submission file constitutes a Consolidated Report.
4	Resubmission File Indicator	Indicator showing if this submission file contains payment(s) and/or transfer(s) of value that are amended or corrected versions of previously submitted records.
5	Original File Submission ID	Generated alphanumeric identifier used to identify the original file submission. This data will be reported to the submitter after a successful submission and should only be reported back in a resubmission for file identification purposes.
Submission Record Information (all sections from here to end of template contain data elements that are reported once per		
Recipient Demographic Information		
6	Recipient Type	Indicator showing if recipient of the payment or transfer of value is a physician covered recipient, teaching hospital, or non-covered recipient (institutional or non-institutional). Standardized list of covered Teaching Hospital names and information will be provided.
7	Teaching Hospital or Institutional Non-covered Recipient Name	Proper name of Teaching Hospital or Institutional Non-covered recipient receiving the payment or transfer of value. Standardized list of covered Teaching Hospital names and information will be provided.

Physician Ownership Template

Row #	Data Element Name	Definition / Description	Values	Required?	Data Element Size	Publicly Displayed
Submission File Information (this section contains data elements which are reported once per submission file)						
1	Applicable Manufacturer or Applicable GPO Name Submitting File	Textual proper name of either the Submitting Applicable Manufacturer (AM) or Submitting Applicable GPO (GPO) . If this file contains a single AM/GPO's set of ownership/investment interest records, this AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies reporting the ownership/investment interest will be recorded with every ownership record in the file.	Text	Yes	100 Char	Yes
2	Applicable Manufacturer or Applicable GPO Registration ID Submitting File	NPPTP generated alphanumeric identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file contains a single AM/GPO's ownership/investment interest records, this AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies reporting the ownership/investment interest will be recorded with every ownership record in the file.	Generated alphanumeric	Yes	10 Char	Yes
3	Consolidated Report Indicator	Indicator showing if this submission file constitutes a Consolidated Report.	"Y" = Yes; "N" = No	Yes	1 Char	No
4	Resubmission File Indicator	Indicator showing if this submission file contains ownership/investment interest records that are amended or corrected versions of previously submitted records.	"Y" = Yes; "N" = No	Yes	1 Char	No
5	Original File Submission ID	Generated alphanumeric identifier used to identify the original file submission. This data will be reported to the submitter after a successful submission and should only be reported back in a resubmission for file identification purposes.	Alphanumeric	Yes IF Line 4 Resubmission File Indicator = "Y"	15 Char	No
Submission Record Information (all sections from here to end of template contain data elements that are reported once per physician ownership/investment record)						
Physician Demographic Information						
6	Ownership/Investment Physician's First Name	Textual first name of the physician with the ownership or investment interest being reported.	Text	Yes	15 Char	Yes
7	Ownership/Investment Physician's Middle Name	Textual middle name or middle initial of the physician with the ownership or investment interest being reported.	Text	No	15 Char	Yes
8	Ownership/Investment Physician's Last Name	Textual last name of the physician with the ownership or investment interest being reported.	Text	Yes	30 Char	Yes
9	Ownership/Investment Physician's Name Suffix	Textual suffix of the physician with the ownership or investment interest being reported	Jr. Sr. III etc.	No	3 Char	Yes
10	Ownership/Investment Physician's Business Street Address Line 1	The first line of the business street address of the physician with the ownership or investment interest being reported.	Two line address format; First line contains building number, street name, street identifier	Yes	30 Char	Yes

Implementation, Tracking & Reporting – CMS Proposed Templates

Non-Research Payment Template

lement Name	Definition / Description	Values	Required?	Data Element Size	Publicly Displayed
Information (this section contains data elements which are reported once per submission file)					
Manufacturer or GPO Name g File	Textual proper name of either the Submitting Applicable Manufacturer (AM) or Submitting Applicable GPO (GPO) . If this file contains a single AM/GPO's set of payment(s) and/or transfer(s) of value records, this AM/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO Name will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies making the payments/transfers of value will be recorded with every payment or transfer of value record in the file.	Text	Yes	100 Char	Yes
Manufacturer or GPO Registration g File	NPPTP generated alphanumeric identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file contains a single AM/GPO's set of payment/transfer of value records, this AM/GPO ID will be used for all records in the file. If this file contains a Consolidated Report, this AM/GPO ID will be used as the Consolidated Reporter and the AM/GPO Names and NPPTP IDs of the sub-companies making the payments/transfers of value will be recorded with every payment/transfer of value record in the file.	Generated alphanumeric	Yes	10 Char	No
ed Report	Indicator showing if this submission file constitutes a Consolidated Report.	"Y" = Yes; "N" = No	Yes	1 Char	No
ion File Indicator	Indicator showing if this submission file contains payment(s) and/or transfer(s) of value that are amended or corrected versions of previously submitted records.	"Y" = Yes; "N" = No	Yes	1 Char	No
e Submission ID	Generated alphanumeric identifier used to identify the original file submission. This data will be	Alphanumeric	Yes IF	15 Char	No

Report Submission & Certification – Public Availability

Except where confidentiality applies (delayed publication), data reported will be made publicly available through an Internet website that:

- Is searchable and in a format that is clear and understandable;
- Contains key reportable information; and
- Is easily aggregated and downloadable.

Data will not include a physician's NPI number.

Report Submission & Certification – Penalties

42 C.F.R. § 403.912

Failure to submit the required information may result in:

- a civil monetary penalty (CMP) of $1,000 to $10,000 for each payment or other transfer not reported.
- not to exceed $150,000 annually.

A knowing failure to submit the required information may result in:

- a CMP of $10,000 to $100,000 for each payment or other transfer of value not reported.
- CMP not to exceed $1,000,000 annually.

Additional Questions

u have any questions, or would like more information on any of the issues
ssed today, please contact:

Kathleen McDermott *at 202.739.5458; kmcdermott@morganlewis.com;*

Michele Buenafe *at 202.739.6326; mbuenafe@morganlewis.com;*

Becky Osowski *at 202.739.5009; rosowski@morganlewis.com; or*

Jonathan Havens *at 202.739.5952; jhavens@morganlewis.com.*

Additional Resources

ditional Resources

Morgan Lewis Transparency Compliance Team email:
TransparencyCompliance@morganlewis.com

Transparency Compliance Resource Center website:
http://www.morganlewis.com/topics/transparencycompliance

- Final Rule
- Morgan Lewis Memorandum
- Health Industry Transparency Chart
- CMS Proposed Data Templates
- Historical Information, Including the Proposed Rule

Transparency Compliance Team

Kathleen McDermott is a partner in the Washington, D.C. office of Morgan Lewis and has been involved in government enforcement and compliance matters for 20 years. She has served as an Assistant U.S. Attorney and DOJ Health Care Fraud Coordinator, and is a recipient of the HHS-OIG Inspector General's Integrity Award for her work in government healthcare fraud matters.

Ms. McDermott has a national corporate defense practice devoted exclusively to health industry matters in a broad array of government enforcement and litigation representations and has handled investigations in diverse jurisdictions, relating to allegations of off-label promotion, anti-kickback, reimbursement, privacy, and quality-of-care violations. She has been recognized as a leading False Claims Act practitioner with both government and defense experience in this unique practice area and designated as one of the top fraud and abuse compliance attorneys in the country by Nightingale's and as a D.C. Super Lawyer in white collar corporate matters.

Ms. McDermott also represents various health industry sectors on government voluntary disclosures, mandated compliance matters, including OIG-CIAs and DOJ consent decrees, compliance policy development for global operations, and fraud and abuse, transparency, and codes of ethics counseling. She frequently conducts training and internal reviews for corporate boards and related corporate operations.

Ms. McDermott teaches and publishes on corporate compliance and enforcement developments and has served as Chair of the American Health Lawyers Association's Fraud and Abuse Practice Group and as a board member for the BNA Medical Devices Law and Industry publication. She has served as faculty for many years for the Seton Hall Health Care Compliance Program and as adjunct faculty for Catholic University Columbia School of Law, teaching on healthcare fraud and compliance issues.

Transparency Compliance Team

Michele L. Buenafe is an associate in Morgan Lewis's FDA Practice. Her practice focuses on FDA regulatory, compliance, and enforcement issues pertaining to medical devices and pharmaceuticals. As part of her practice, Ms. Buenafe regularly advises clients on issues related to the development, manufacturing, and marketing of medical devices, pharmaceuticals, biologics, and combination products; labeling and advertising; post-market requirements; and compliance with FDA's bioterrorism regulations. In addition, Ms. Buenafe has assisted clients in navigating the state regulatory requirements (including licensure requirements) applicable to drug and device manufacturers and distributors, pharmacies, DME suppliers, and healthcare providers. Ms. Buenafe also has experience advising clients on the regulatory requirements and emerging legal issues related to health information technology.

Transparency Compliance Team

Becky Osowski is the director of healthcare compliance for Morgan Lewis's Healthcare Practice. Morgan Lewis's compliance representations encompass HHS OIG corporate integrity agreements for CIA implementation; Board and IRO compliance resources; DOJ deferred prosecution agreements; voluntary corporate compliance effectiveness reviews; healthcare professional arrangement reviews; corporate compliance policy development; and federal and state transparency and marketing compliance.

Ms. Osowski's corporate compliance engagements focus on assisting clients in developing and implementing practical and sustainable global compliant business practices, complying with government mandated requirements under CIAs and DPAs, voluntary arrangements reviews, compliance effectiveness assessments, and corporate policy development. Ms. Osowski has deep industry knowledge, including involvement within AdvaMed, to help shape industry guidelines governing interactions between industry and healthcare professionals.

She also has experience in the area of health industry transparency requirements (e.g., Physician Payment Sunshine Act) as well as similar state requirements (e.g., Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct, Vermont Gift Ban and Disclosure Law). Ms. Osowski's compliance career has involved serving as a healthcare compliance officer for a large international device company under both a DPA and CIA and as a consultant assisting clients in the development and implementation of corporate compliance best practices for a broad range of health industry sectors.

Transparency Compliance Team

Jonathan A. Havens is an associate in Morgan Lewis's FDA Practice. His practice focuses on FDA and healthcare regulatory, compliance, and enforcement issues. In this capacity, Mr. Havens assists in the representation of clients in matters relating to FDA regulatory compliance, including marketing, promotion, and advertisement. Mr. Havens has spoken on health industry transparency compliance and is well versed on the procedural and substantive requirements of transparency reporting.

Prior to joining Morgan Lewis, Mr. Havens was a regulatory counsel with the U.S. Food and Drug Administration. While at the FDA, Mr. Havens received an FDA Group Recognition Award for Compliance and Enforcement of Tobacco Product Regulations and a Center for Tobacco Products Team Excellence Award. Before his legal career, Mr. Havens was a legislative aide in the U.S. Senate and U.S. House of Representatives, as well as a legislative specialist with a national law firm.