



Sunshine and Aggregate Spend

Challenges and Leading Practices in Reporting Clinical Spend

Sixth Annual Summit on Disclosure, Transparency and
Aggregate Spend for Drug, Device and Biotech Companies

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How did we get to this point?

Why is physician payment disclosure needed?

To bring about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine

- Source: Press Release by Senator Charles Grassley (February 1, 2013)

94% of U.S. physicians have had a relationship with a life sciences company

- Source: Eric Campbell et al., A National Survey of Physician-Industry Relationships, 356 N Engl. J. Med. 1742, 1746-47 (2007)

Only 78.7% of U.S. physicians believe in putting a patient's interest above their own

- Source: Martin Roland, et al., Professional values and reported behaviors of doctors in the USA and UK: quantitative survey, Brit. Med. J. Quality & Safety at 3 (2011), <http://qualitysafety.bmj.com/content/early/2011/02/07/bmjqs.2010.048173.full>

55% of patients believe their doctor receives industry gifts

- Source: David Grande, et al., Pharmaceutical Industry Gifts to Physicians: Patient Beliefs and Trust in Physicians and the Health Care System, J. Gen. Intern. Med. (Jun. 14, 2011), available at <http://www.ncbi.nlm.nih.gov/pubmed/21671130>

Strong case for disclosure in research

“The case has clearly been made for requiring industry to report payments to physicians, especially those conducting highly influential research, often with taxpayer support. Operating with transparency sends a message that there’s nothing to hide.”

– Source: Press Release by Senator Charles Grassley (October 29, 2009)

“We want our doctors ... to rely on evidence that is real and true and accurate and not partial or affected some way by a money interest behind it.”

– Source: Susan Winkler, AUSA (Boston), 13th Annual Pharmaceutical Regulatory and Compliance Congress (November 5, 2012)

In general, physicians themselves support a higher bar for researchers.

- 64% of surveyed physicians said that disclosure for doctors should be mandatory, while 83% supported mandatory disclosure for researchers.

– Source: David Hodgson, Seth Whitelaw, Physician Payment Sunshine Act: Physicians and life sciences companies coming to terms with transparency?, Deloitte/ Forbes Insights (2012); https://www.deloitte.com/assets/Dcom-Global/Local%20Assets/Documents/LSHC/dttl_lshc_ForbesInsightsLSHCTransparencyReport.pdf

The academic debate

Point:

Because of the difficulty in determining when financial interactions between life sciences companies and researchers interject an inappropriate level of bias, all financial interactions between companies and researchers should be banned.

— Jerome Kassirer, *Medicine's Obsession with Disclosure of Financial Conflicts: Fixing the Wrong Problem*, in *Science and the Media: Delgado's Brave Bulls and the Ethics of Scientific Disclosure*, 79, 79 (Peter Snyder, et al., eds., Academic Press 2009)

Counterpoint:

“Doctors paid by pharmaceutical companies are ‘leaders in their fields,’ and patients should want to see their physician among them.”

— Charles Ornstein and Tracy Weber, *In Minnesota, Drug Company Reports of Payments to Doctors Arrive Riddled With Mistakes*, ProPublica (Dec. 10, 2010, 9 a.m.), <http://www.propublica.org/article/in-minnesota-drug-company-reports-of-payments-to-doctors-mistaken>



It all comes down to this —
Physicians have to please sponsors to get funded...
that doesn't mean sponsors don't want them to aspire to truth.”

— Thomas Sullivan, *David Korn: Financial Conflicts of Interest In Academic Medicine – Why is He So Vexed?*, *Policy and Med.* (Dec. 29, 2010 at 06:17 a.m.); see also Norman Kachuck, *Managing conflicts of interest and commitment: academic medicine and the physician's progress*, 37 *J. Med. Ethics* 2 (2010)

The Challenging Areas

Some of the Most Challenging Areas



Equipment Loans



Scope of “written agreements”



Meals, Travel & Lodging Expenses



“Pass Through” Costs to Research Sites

Let's ask the audience

Other Areas of Challenge



Organizational

- Understanding responsibilities
 - Role of clinical contracting
 - Authority for the final decision
 - “Flagging” data
 - Interfacing with Compliance



Third Parties

- Understanding the chain
 - CRO’s
 - CRO’s using SMO’s or other CRO’s
- Receiving data
 - CMS format
 - Company format

And More . . .



Process

- Improving Existing
 - Equipment loans
- Creating New
 - Delayed Payments
- Communication
 - Internal (among departments)
 - External (with physicians and institutions)



Systems & Data

- Multiple Sources
 - Clinical Trial Management System
 - Customer & Vendor Masters
 - CMS inputs (teaching hospital list)
- Manual vs. automated systems
 - Documentation
 - Business case for automation

Some Leading Practices

Setting external customer expectations

- Avoiding surprise

Establishing 3rd party expectations

- Clearly establishing what needs to be tracked and reported
- Ensuring that they “have skin in the game.”
- Exercising oversight

Working with internal research stakeholders

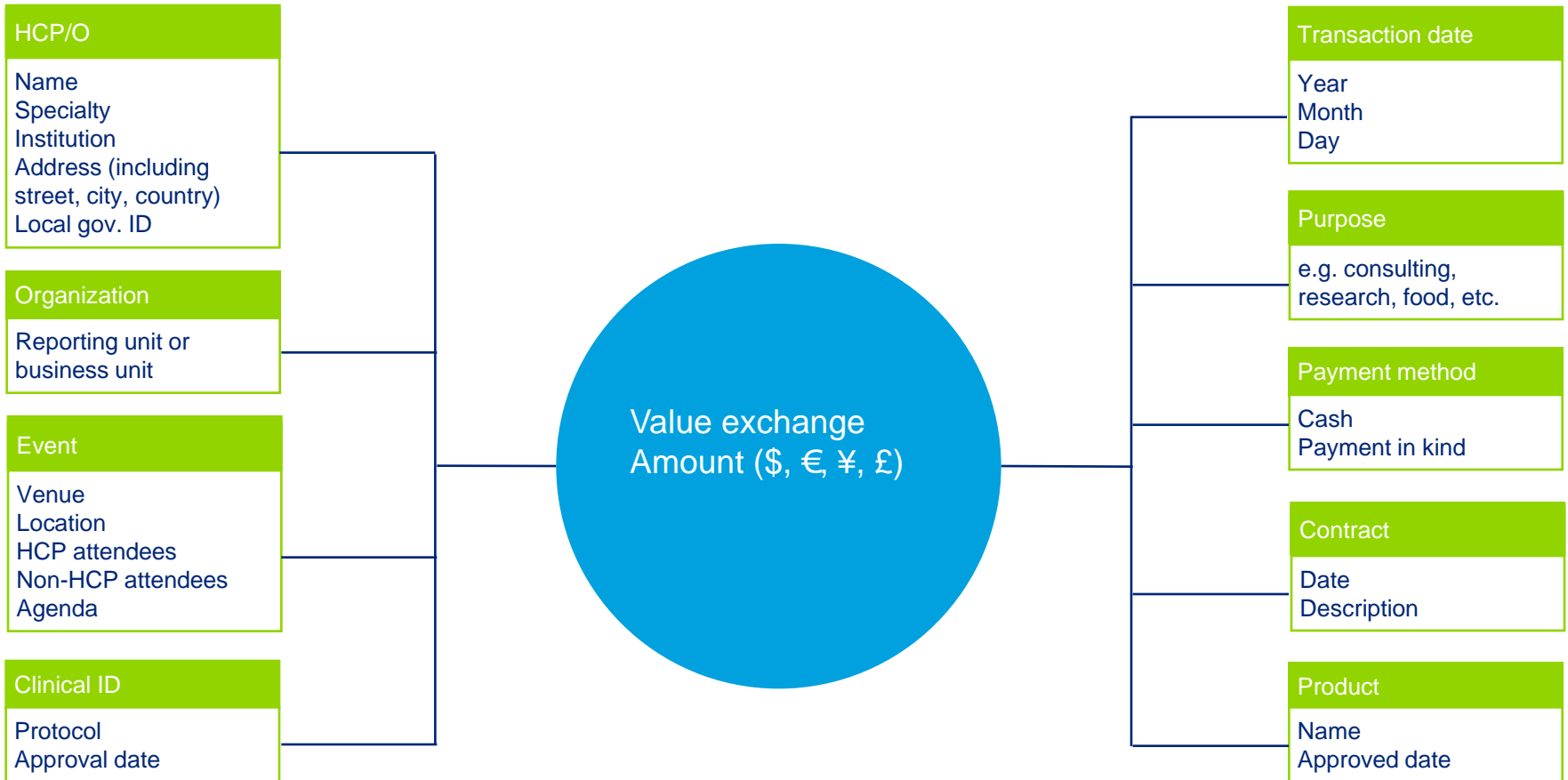
- Providing education and training on data collection and reporting requirements
- Establishing “Sunshine liaisons” within business groups/lines/departments to assist with communication and help escalate issues for timely resolution

Appendix

- Requirements for Research Spend

Standard data elements for transfers of value

While the necessary data elements for research transfers of value are fundamentally the same, capturing those for research present their own unique challenges



All Health Care Professional (HCP) Transparency Disclosure Regulations can be met using just 10 data attributes

General rules for research payments

- Research Payments are reported separately on a different template
- SCOPE: Includes,
 - **Pre-clinical research,**
 - **FDA Phases I-IV research, and**
 - **Investigator-initiated trials**
- Must report all payments, direct and indirect (thru CRO, SMO)
- Research payments are to be reported as a single payment (i.e., milestone payment) and need to include entity paid (regardless if recipient is a covered recipient), as well as the PI(s)
- “Regarding reporting of research-related payments which do not meet the definition of research, applicable manufacturers should report using the other categories available.”
 - Example: Grant

Defining applicable manufacturer in a research context

FAQs

- *Are entities currently in the research and development phase for drugs which, are at the time not approved by the FDA, subject to Open Payments reporting requirements?*
 - An applicable manufacturer, as defined by 42 CFR 403.902, is an entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or is under common ownership with an applicable manufacturer and 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. A covered drug is any drug for which (1) payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP), either separately (such as through a fee schedule or formulary) or as part of a bundled payment, and (2) requires a prescription to be dispensed. The question of whether you fall within the definition of an “applicable manufacturer” depends in part on whether payment is available for any of your products under Medicare, Medicaid, or CHIP. While most products for which payment is available under these programs will have already received FDA clearance or approval, there are some exceptions. See 78 FR 9465. For that reason, we did not set FDA approval or clearance as a bright line test for determining whether a product is considered to be a “covered” product. If payment is not currently available under Medicare, Medicaid, or CHIP for your product at this time, then you would not be considered an applicable manufacturer for purposes of the reporting requirements; however, if payment is available (for example, under the Medicare Clinical Trial Policy), then you would be considered an applicable manufacturer. Note that the preamble addresses the situation where an entity with no covered products becomes an applicable manufacturer because, for example, its only product receives FDA approval. See 78 FR 9463. In that situation, an entity has a grace period of 180 days following its product becoming “covered” to begin complying with the data collection and reporting requirements (FAQ8392)

Defining applicable manufacturer in a research context (cont'd)

FAQs

- *Is a contract research organization (CRO) that performs clinical trials according to protocols for pharmaceutical companies required to report a budgeted amount contracted for medical safety, which is performed by the CRO's employed physician?*
 - A CRO that is not an applicable manufacturer is not required to report information under Open Payments. However, an applicable manufacturer providing a payment that meets the definition of research, as defined at 42 C.F.R. § 403.902, to a CRO which is ultimately paid in whole or in part to a covered recipient (physician or teaching hospital), is required to report, as outlined in §403.904(f), the name of the research institution, individual or entity receiving the payment, total amount of the research payment, name of the research study, names of any related covered drugs, devices, biological, or medical supplies, and information about each physician covered recipient principal investigator. The research agreement may include an unbroken chain of agreements as long as they link the applicable manufacturer with the recipient. If the employee of a CRO who is conducting medical safety for clinical trials for a research study is also a physician covered recipient principal investigator then information regarding the physician is required to be reported by the applicable manufacturer under Open Payments. (FAQ8988)

Defining "research" and "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)

Further refining the definition of "research"

FAQs

- *Why was research removed as a nature of payment category option from the general data specification? (posted October 2013)*
 - The research nature of payment category was removed from the general data specification because all payments or other transfers of value made in connection with an activity that meets the definition of research, as defined at 42 C.F.R § 403.902, are required to be reported using the research data specification according to § 403.904(f). As discussed in the preamble to the final rule research-related payments, which do not meet the definition of research, should be reported using the other nature of payment categories available. (42 Fed Reg. 9482) (FAQ9130)
- *Are payments for medical research writing and/or publication included in reporting research payments?*
 - Under OPEN PAYMENTS, a payment reported as research falls within a research payment category if it is subject to either: 1) a written agreement; 2) a contract; or 3) a research protocol. Payments for medical research writing and/or publication would be included in the research payment, if the activity (here, medical research writing/publication) was included in the written agreement or research protocol and paid as a part of the research payment. (FAQ8159)

Information to be reported 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
 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 biological, 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

FAQs

- *Should all physician covered recipient principal investigators who perform research for the research institution under a research agreement or research protocol be listed on the research reporting templates when reporting research payments, even if such sub-researchers would not normally be considered "principal investigators" in the normal industry understanding of the word - i.e., the sub-researchers are not directing or in charge of the research overall?*
 - No, applicable manufacturers are only required to report the names of principal investigators, as that term is normally used in industry, not sub-researchers. Applicable manufacturers reporting research payments may report up to five covered recipient principal investigators for each research payment reported. (FAQ8266)
- *Is an applicable manufacturer required to report the name of a third party, such as a clinical research organization (CRO) providing an indirect research payment to a covered recipient? (posted October 2013)*
 - No, applicable manufacturers are not required to report the name of the third party, such as a CRO, that indirectly provides a research payment to principal investigators, teaching hospitals, nonteaching hospitals or clinics. Applicable manufacturers are required to report information regarding recipients of research payments as specified in 42 C.F.R § 403.904(f). (FAQ9136)

Refining what constitutes a research transfer of value

FAQs

- *Is study equipment, implantable devices, instrumentation, or other supplies provided to a covered recipient by an applicable manufacturer in connection with a FDA approved clinical trial for use solely in a research project considered a transfer of value?*
 - Yes, payments or other transfers of value made in connection with an activity that meets the definition of research and that are subject to a written agreement, a research protocol or both should be included in the total amount of the research payment. Payments or other transfers of value that are not included in the written agreement or research protocol should be reported separately in the appropriate nature of payment category. (FAQ8264)
- *What value should an applicable manufacturer assign to clinical study drugs that are provided to principal investigators as part of the research agreement? (posted October 2013)*
 - Applicable manufacturers are not required to assign a specific value to clinical study drugs that are provided to principal investigators, rather applicable manufacturers should report the total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol or both, as specified in 42 C.F.R. § 403.904(f)(1)(ii). (FAQ9118)

Handling military research

FAQs

- *Are research payments provided to a Military Medical Center that is not a teaching hospital covered recipient required to be reported for Open Payments?*
 - Yes, for research payments, the reporting entity must provide the name of the research institution, individual or entity receiving the payment or other transfer of value as outlined in §403.904(f). If the Military Medical Center receives a research-related payment or other transfer of value, which is ultimately paid in whole or in part to a covered recipient (physician or teaching hospital), it must report information on the payment as indicated at § 403.904(f)(1)(i)(C). (FAQ8998)
- *Is information regarding a physician principal investigator required for reporting if he/she is a military physician?*
 - Yes, if a military physician is a physician covered recipient principal investigator for a research study that is identified according to 42 C.F.R. § 403.904(f) then information about the physician covered recipient principal investigator is required to be reported as indicated at § 403.904(f)(1)(v). (FAQ9000)

Information to be reported for pre-clinical research

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



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