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# Assumptions and Context Boxes: To Do or Not to Do; That is the Question

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# Agenda

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- Regulatory Overview
- Potential Uses of Assumptions and Context Boxes
- Potential Risks
- Strategies for Documenting?
- Sword or Shield?
- Wait-and-See...? The Pros and Cons

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## Assumptions Documents: Regulatory Overview

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- Procedures for electronic submission of reports.

*“Assumptions document. Applicable manufacturers and applicable group purchasing organizations 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.**”*

42 C.F.R. § 403.908(f)

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## Context Boxes: Regulatory Overview

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- CMS agreed to adopt suggestions from commenters that applicable manufacturers be allowed to report free text contextual information about individual payments.

“We believe it could help the public better understand the relationships between the industry and covered recipients. In addition to consumers, we believe contextual information will be useful for covered recipients when reviewing the payments or other transfers of value. Hopefully, the context will provide information to help the covered recipient assess the accuracy of the payment.”

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## Assumptions Documents: Potential Uses

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- CMS plans to use the assumptions documents to determine whether additional guidance would help applicable manufacturers to fulfill their reporting duties, in particular to accurately classify nature of payment categories
- Specific Uses Identified by CMS:
  - Document the **method used to estimate the value** of ownership or investment interests
  - Clarify **assumptions made to determine the nature of the payment** category, *e.g.*, where a payment fits into multiple possible categories, describing how the reporter defined the categories and why one was selected as the best fit
  - Explain assumptions used to determine the **value of journal reprints** provided to covered recipients
  - Explain the **date of payment methodology** used for payments that span multiple years or are bundled

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## Assumptions Documents: Potential Uses

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- Other Potential Uses:
  - Describe how **royalty rates** were calculated
  - Explain criteria for **CME grant** decisions
  - Set forth **corporate structure** for purposes of categorization as a paragraph 1 or paragraph 2 applicable manufacturer
  - Define the company's **employees**, for purposes of whether **recruiting** payments must be reported
- Likely Not a Means of Dispute Resolution:
  - CMS refused commenters' requests to make assumptions documents available to covered recipients as a mechanism to mitigate disputes, because it "would be difficult for the agency to track and would greatly reduce the confidentiality of the documents"
  - However, applicable manufacturers are free to provide assumptions documents to covered recipients should they wish to do so

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## Assumptions Documents: Potential Uses

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- CMS may issue guidance in response to assumptions
- Explaining assumptions can help establish good faith and avoid misunderstandings with CMS, other government agencies, prosecutors, or the media (or it could have the opposite effect...)
- Assumptions documents could be helpful in resolving disputes with covered recipients (but consider organization and structure of your assumptions if you are willing to disclose select assumptions to resolve such disputes)

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## Context Boxes: Potential Uses

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- **Uses Identified by CMS:**

- Unlike assumptions letters, CMS has not identified specific types of contextual information that would be appropriate for context boxes
- Instead, the reporting template indicates that reporting entities should include: “Any free text which the reporting entity deems **helpful or appropriate** . . . .”
- CMS has indicated, however, that context information can “**help the public** better understand the relationships between the industry and covered recipients” and will “be **useful for covered recipients** when reviewing the payments or other transfers of value”

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## Context Boxes: Potential Uses

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### ▪ Other Potential Uses:

- Payments that, without additional information, may invite scrutiny, from the public or otherwise, such as:
  - Large payments
  - Repeat payments to the same covered recipient
  - Payments to covered recipients of an unexpected specialty
- Brief contextual information enabling the public to understand the purpose of a payment, such as:
  - For **consultants** → a description of the **legitimate need** for the consulting services
  - For **CME speakers** → the **content** of the program
  - For **royalties or licenses** → a summary of the **basis** for these payments
  - For **grants** → a **description of the work** the covered recipient will conduct with the funding

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## Context Boxes: Potential Uses

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- Minimize disputes with covered providers:
  - Covered recipients have 45 days to review data prior to publication
  - Covered recipient can dispute any reported payments, and applicable manufacturers must report the results of all disputes
  - If the dispute is not resolved by the end of the resolution period (60 days from release), CMS publishes the information and marks disputed data accordingly
  - Providing context to covered recipients may help preempt disputes

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## Context Boxes: Mechanics of Reporting

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- A report must contain all of the following information for each payment or other transfer of value:

*“Additional information or context for payment or transfer of value. May provide a **statement with additional context** for the payment or other transfer of value.”*

42 C.F.R. § 403.904(c)(12)

- Special rules for research payments

*“Research-related payments or other transfers of value to covered recipients . . . must be reported to CMS separately from other payments or transfers of value, and must include . . . **[c]ontextual information for research (optional).**”*

42 C.F.R. § 403.904(f)(1)(vi)

# Context Boxes: Mechanics of Reporting (cont'd)

- General Payments Reporting Template: Line 44

DE #	Data Element Name	Definition / Description	Data Type	Format	Required?	Field Size	Validation	Publicly Displayed
<b>General Record Information</b>								
41	Physician Ownership Indicator	If Recipient type = "Physician", does the physician hold ownership or investment interest in the applicable manufacturer?  This indicator is limited to physician's ownership, not physician's family members' ownership.	Boolean	"Y" = Yes; "N" = No	Yes IF  Line 6 Covered Recipient Type = "1" (Physician)	1 Char	Limited to characters "Y" or "N"	Yes
42	Third Party Payment Recipient Indicator	Indicates if a payment or transfer of value was paid to a third party entity or individual at the request of or on behalf of a covered recipient (physician or teaching hospital).	Enumeration	"1" = "Entity" "2" = "Individual" "3" = "No Third Party Payment"	Yes	1 Char	Limited to numeric characters "1," "2," or "3"	Yes
43	Name of Third Party Entity Receiving Payment or Transfer of Value	The name of the entity that received the payment or other transfer of value.	Text	Free form text	Yes IF  Line 42, Third Party Payment Recipient Indicator = "1" (Entity)	≤ 50 Char		Yes
44	Charity Indicator	Indicates the third party entity that received the payment or other transfer of value is a charity.	Boolean	"Y" = Yes; "N" = No	No	1 Char	If reported, Third Party Payment	Yes
45	Third Party Equals Covered Recipient Indicator	Indicator showing the "Third Party" that received the payment or transfer of value			Yes IF  Line 42, Third Party Payment Recipient Indicator = "1" (Entity) or "2" (Individual)	1 Char		Yes
46	Contextual Information	Any free text which the reporting entity deems helpful or appropriate regarding this payment or transfer of value.	Text	Free form text	Yes IF  the Delay in Publication of Research Payment Indicator equals "1" or "2"	≤ 500 Char		Yes

**Required?**  
Yes IF the Delay in Publication of the Research Payment indicator equals "1" or "2"

**Publicly Displayed**  
Yes

**Date Element Name**  
Contextual Information

**Definition / Description**  
Any free text which the reporting entity deems helpful or appropriate regarding the payment or transfer of value.

**Field Size**  
≤ 500 Char

# Context Boxes: Mechanics of Reporting (cont'd)

- Research Payments Reporting Template: Lines 40, 42

DE #	Data Element Name	Definition / Description	Data Type	Format	Required?	Field Size	Validation	Publicly Displayed
36	Expenditure Category	Contextual category for this research payment or transfer of value. There can be multiple contextual categories for this research reported; however, for every Expenditure Category reported, an Expenditure Category percentage must also be reported.  Category and percent represented as a single number for the category followed by the 2 or 3 digit percentage value (eg. 1-90 or 1-100)	Enumeration	Format: X-XXX "1" = Professional Salary Support; "2" = Medical Research Writing or Publication; "3" = Patient Care; "4" = Non-patient Care; "5" = Overhead; "6" = Other	No	≤ 5 Char		Yes
<b>Research Related Information</b>								
37	Pre-clinical Research Indicator	Indicator showing if payment or transfer of value is related to research, which is pre-clinical.	Boolean	"Y" = Yes; "N" = No	Yes	1 Char		Yes
38	Delay in Publication of Research Payment Indicator	Indicator showing if an Applicable Manufacturer/GPO is requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply).	Enumeration	"1" = R & D on New Product "2" = Clinical Investigation on New Product "3" = No Delay Requested	Yes	1 Char		Yes
39	Study	The textual name of the study for which the payment or transfer of value.	Text	Free form text	No	≤ 37 Char	Pre-clinical Research Indicator = "N"	Yes
40	Context of Research	Textual description of research context or research objectives.	Text	Free form text	No	≤ 500 Char		Yes
41	ClinicalTrials.gov Identifier	Identifier assigned if research study is registered on clinicaltrials.gov.	Alphanumeric	11 character alphanumeric, first 3 characters alpha	No	11 Char		Yes
42	Research Information Link	Optional link to information relevant to the research study for which this payment or transfer of value is being reported (there can be a maximum of five links reported).	Web URL	Free form text	No	≤ 2083 Char		Yes

Data Element Name  
Context of Research

Definition / Description  
Textual description of **research context** or **research objectives**.

Required?  
No

Publicly Displayed  
Yes

Field Size  
≤ 500 Char

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## Assumptions Documents: Potential Risks

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- FOIA Requests:

- Despite being confidential, the information could potentially be acquired through a Freedom of Information Act (“FOIA”) request
- “To the extent an assumptions document is requested under the FOIA, we would follow our predisclosure notification procedures at 45 CFR 5.65(d) and seek the submitter’s input on the **applicability of FOIA Exemption 4**, which protects **trade secrets and commercial or financial information** that is obtained from a person and is privileged or confidential.”

78 Fed. Reg. 9482

- Audit and/or Prosecution:

- Although CMS has stated that it does “not intend to use the assumptions document for prosecution,” it admitted that assumptions documents could serve as the basis for prosecution
- “**Other HHS divisions**, the **Department of Justice** (DOJ), or the **Office of the Inspector General** (OIG) could request access to the documents as part of an **audit or investigation** into an applicable manufacturer or applicable GPO.”

78 Fed. Reg. 9482

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## Context Boxes: Potential Risks

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- The risk of reporting a payment in this type of vacuum is that the raw data can be misconstrued
- Transactional-level detail that you may not be able to get with assumptions
- Explaining the context of payments can help prevent others from inventing context
- Given the proven risks associated with negative press coverage—namely a lengthy government investigation—incorporating contextual information into annual disclosure reports can be a low-cost measure to mitigate the risks associated with Sunshine Act reporting.

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## Assumptions Documents and Context Boxes: Strategies for Successful Use

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- Compliance with law and company policy
- Ensure consistency; consider internal cross functional team, including coordination with Legal
- Internal v. external assumptions
- Coordination across the corporate family
- Nail down your corporate communications strategy

# Cautionary Tales: Disclosure Without Context

Recipient Name(s) <sup>1</sup>	Activity Title	Funding Amount <sup>2</sup>
Alaska Pharmacists Association	Differentiating Type 1, 1.5 and 2 Diabetes	\$2,000.00
American Academy of Family Physicians MedEd Architects LLC	AAFP LearningLink.org - Newer Treatment Options in Diabetes Mellitus	\$349,824.00
American Academy of Physician Assistants Medical Loqix, LLC	State of the Art Diabetes Management - Overcoming Barriers in the Use of Early Insulin Therapy	\$61,440.00
American Association of Diabetes Educators Diabetes Association of Atlanta, Inc.	18th Annual Diabetes University	\$5,000.00

Payee	Physician	Payee Location	Training and Education	Research and Development	Advisory Services	Royalties
American Diabetes Association 8 C Llc	Haid, Regia W, MD	Atlanta, Georgia		X		X
American Diabetes Association	Abbed, Khalid M, MD	New Haven, Connecticut	X	X	X	
American Diabetes Association	Abell, Thomas, MD	Louisville, Kentucky	X	X		
American Diabetes Association	Abelseth, Jill, M, MD	Albany, New York	X	X		
American Diabetes Association	Abodeely, Adam, MD	Saranac Lake, New York	X		X	
American Health Resources Abraham Rivera Md Llc	Rivera, Abraham, MD	Tampa, Florida	X			
American Pharmacists Association Advanced Pain Management Center	Park, Joe Je-Woo	Victorville, California	X			
	Al-Ahmad, Amin, MD	Stanford, California	X			
	Alastra, Anthony, MD	Staten Island, New York		X		
	Alan Levi Inc	Key Biscayne, Florida	X			
	Levi, Alan D, MD					
	Ames, Christopher P, MD	San Francisco, California	X			
	Amir Saffarian Md Inc	Morgan Hill, California	X			
	Saffarian, Amir, MD					
	Anand, Neel, MD	Los Angeles, California	X	X		X
	Anderson, D Greg, MD	Egg Harbor Township, New Jersey				X

# Cautionary Tales: Disclosure Without Context (I)

Payee	Physician	Payee Location	Training and Education	Research and Development	Advisory Services	Royalties
6 C Llc	Haid, Regia W, MD	Atlanta, Georgia		X		X
Abbed, Khalid M, MD	Abbed, Khalid M, MD	New Haven, Connecticut	X	X	X	
Abell, Thomas, MD	Abell, Thomas, MD	Louisville, Kentucky	X	X		
Abelseth, Jill, M, MD	Abelseth, Jill, M, MD	Albany, New York	X	X		
Abodeely, Adam, MD	Abodeely, Adam, MD	Saranac Lake, New York	X		X	
Abraham Rivera Md Llc	Rivera, Abraham, MD	Atlanta, Georgia	X			

## Atlanta, Georgia

*When Medtronic pays an entity for either services provided or royalties earned by a service provider, Medtronic does not know the amount of payment, if any, the entity makes to the service provider. As such, the payment data presented in this registry may not reflect amounts received by individual service providers.*

### Payments to 6 C Llc

Year to Date July 2011:

Research and Development	\$5,000 - \$9,999
Royalties	\$1,188,000.00

### Physician's Royalties for intellectual property contributions to the following Medtronic products/systems:

- Cervical Spine Arthroplasty Device
- Anterior Cervical Spinal Plating System
- Spinal Surgery Retractor System

**It is Medtronic's practice to not pay royalties to physicians for royalty-earning products they prescribe or products purchased by their institutions.**

# Cautionary Tales: Disclosure Without Context (I)

## Bone-fusion protein raises questions about doctors' financial stakes

Some question whether doctors should be allowed to do clinical trial research involving products that might enrich them or the company they work for.

## Doctors question journal articles

## Medtronic paid surgeons millions for other products

## Trial with questionable results

## Success rate higher for surgeons with financial ties to device maker

## Researchers get royalties, papers omit sterility link

## Doctors receiving funding differ from others on complication

By [John Fauber](#) of the Journal Sentinel

May 25, 2011 | [\(50\) Comments](#)

“[E]arlier this year, Medtronic began listing payments to doctors on its website, a practice that will become law when the Physician Payment Sunshine Act goes into effect . . . *The Journal Sentinel used that database to check payments made this year to a core of prominent doctors who have published research about BMP-2 since its approval. . . . Three of the four authors of a 2004 article . . . are listed as receiving nearly \$4 million this year in royalties*”

“Last year, a Journal Sentinel investigation found that *doctors who had financial relationships with Medtronic produced substantially better results with Infuse in the clinical trial leading to its FDA approval than doctors who did not have financial ties to the company.*”

## Cautionary Tales: Disclosure Without Context (II)

Recipient Name(s) <sup>1</sup>	Activity Title	Funding Amount <sup>2</sup>
Scripps Health	Scripps Cancer Centers Oncology Nurses Symposium	\$15,000.00
Scripps Health	Comprehensive Diabetes Care and Clinical Management Program	\$5,000.00
Scripps Health dba Scripps Clinical Research	2009 VanderLaan Diabetes Lectureship Series (Wednesday)	\$3,102.00
Scripps Memorial Hospital - La Jolla	The Art and Science of Insulin Management and Incretin Therapy	\$3,500.00
Shands Jacksonville	EMS & Community Education on STEMI Awareness and Activation	\$5,000.00
Sharp HealthCare Foundation	5th Annual Antithrombosis Therapy Conference	\$5,000.00
Sinai Hospital	Oncology Grand Rounds	\$3,500.00
Society of Hospital Medicine	Reduce the Likelihood of Patient Harm Associated with the Use of Anticoagulation Therapy	\$9,600.00
Southern Medical Association	13th Annual Conference on Hypertension - Focus on Hypertension,	\$5,000.00

Recipient Name(s) <sup>1</sup>	Activity Title	Funding Amount <sup>2</sup>	
St. Vincen			
St. Bernar	The University of Arizona College of Medicine	9th Annual Women's Mental Health Symposium	\$10,000.00
St. Lukes-	The University of Texas M. D. Anderson Cancer Center	Hepatobiliary Surgery Clinical Research Fellowship	\$75,000.00
St. Lukes-	The University of Texas M. D. Anderson Cancer Center	A Comprehensive Board Review in Hematology and Medical Oncology	\$10,000.00
St. Vincen	The University of Texas M. D. Anderson Cancer Center	Living With, Through and Beyond Cancer - Anderson Networks' 21st Annual Patient & Caregiver Conference	\$5,000.00
	The University of Texas M. D. Anderson Cancer Center	Hematologic Malignancies 2009 - Fifth International Conference	\$10,000.00
	JWC Covenant, Inc.		
	The University of Utah School of Medicine	North American Thrombosis Summit 2009	\$30,000.00
	North American Thrombosis Forum		
	TriHealth Seniors Health	TriHealth Seniors Health Symposium	\$2,000.00

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## Sword or Shield? What is your strategy?

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- Would context boxes or an assumptions document have made a difference?
- Would additional information have led to more inquiry or less?
- What value can either bring other than what CMS has suggested?
- Do you have the resources to support the drafting , review and audit?
- Are you indirectly creating an assumptions document through training materials and tracking instructions?
- What is everyone else doing?

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## Case Study for Assumptions Document : Journal Reprints

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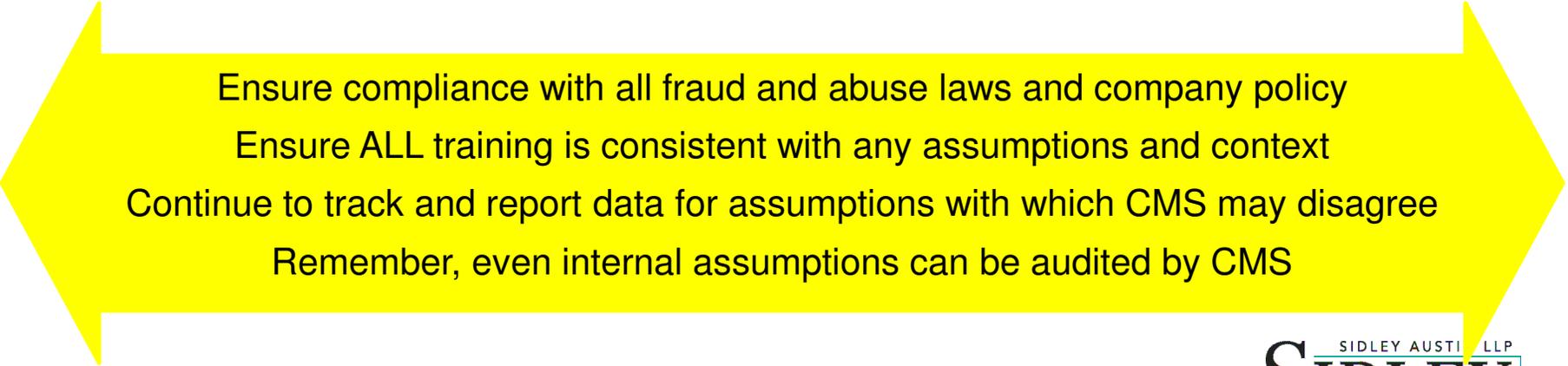
- Do you have a policy or other forms of documented guidance on whether it is permissible to distribute reprints?
- Is there a documented process (or several) for distribution?
- If so, how are they currently being distributed?
  - Email, personal delivery, US Mail
  - Copied on personal computers, corporate office or third party vendor or all
  - Medical Affairs or Commercial
- How are you calculating the value?
  - Cost equally over the course of the year
  - Medical Affairs rate is different than commercial rate
- Is it a gift or educational item?
- What if they are distributed to consultants for preparation purposes?

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## Concluding Thoughts

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Context Boxes	Assumptions Documents
Frame purpose of payments and control messaging to the public	Address transactions or circumstances not addressed by guidance
A possible tool to minimize potential disputes with covered recipients	Explain aggressive stances to avoid any future allegations of fraud
Use for large, repeat, or unusual payments	Use to discuss information that should not be made public but that should be disclosed to CMS



Ensure compliance with all fraud and abuse laws and company policy  
Ensure ALL training is consistent with any assumptions and context  
Continue to track and report data for assumptions with which CMS may disagree  
Remember, even internal assumptions can be audited by CMS