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# Measuring and Addressing Regulatory Burden

## Committee on Federal Regulations and Reporting Requirements

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Regulatory Counsel  
February 13, 2015



Association of  
American Medical Colleges

# Click to add a title

- Identifying the Problem: Unlikely Sources of Regulatory Burden
- Measuring Effect and Effectiveness: A Model for Evidence Based Regulation
- Responding to a Call for Action: Convening Stakeholders Develop Systems that Decrease Burden

# Sources of Regulatory Burden

- Lack of harmonization leads to overlapping regulatory schemes
- Unequal balance of cap on recovery of administrative costs with exponential increase in regulatory requirements
- “Knee jerk” regulatory responses
- No provisions for re-evaluating or recalibrating regulations
- Institutional misinterpretation or over-interpretation

# Sources of Regulatory Burden

Unexpected and Unpredictable:

- Legislation written as regulation
  - Physician Payments Sunshine Act
- Ambiguous guidance
  - OHRP's Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care
- Legislative regulatory interpretation

“Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations... For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.” P.L. 113-240, signed 12-18-2014

# 2011 PHS FCOI Regulations

## Investigator Responsibilities



## Institutional Responsibilities



Yellow star = Changes from 1995

# PHS FCOI Regulations : Impact on Institutions and Faculty

“We had to revise our policies and processes to assure compliance with the regulations. We continue to review our administrative processes, which takes time away from other projects that could be more helpful to our faculty.”

“The new regulations have added to the feeling that the scientific enterprise has become a bureaucratic endeavor which has a negative impact on faculty morale.”

“There has been a significant increase in work load for existing staff and there are no funds to support additional staff.”

“Researchers regularly complain about the PHS requirements but, to our knowledge, none have decided to forego a relationship with industry specifically to avoid the PHS reporting.”

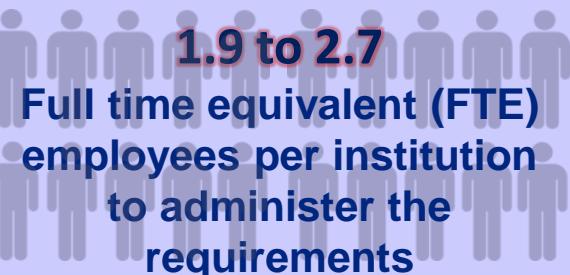
# AAMC Conflict of Interest (COI) Metrics Project: Measuring the Cost, Effect, and Effectiveness of the PHS FCOI Regulations

- 74 AAMC member institutions provide aggregate data to AAMC
  - Baseline – year before implementation
  - 3 years after implementation
- Data include
  - One-time and ongoing administration costs
  - Financial Interests reviewed and FCOIs reported (including assessment of \$10K - \$5K threshold change)
  - Resources needed
- Benchmarking data provided to institutions, de-identified data provided to NIH for retrospective review

71 institutions spent  
**\$22.6 million**  
to implement the rule  
Capital Expenditures  
\$9.7M

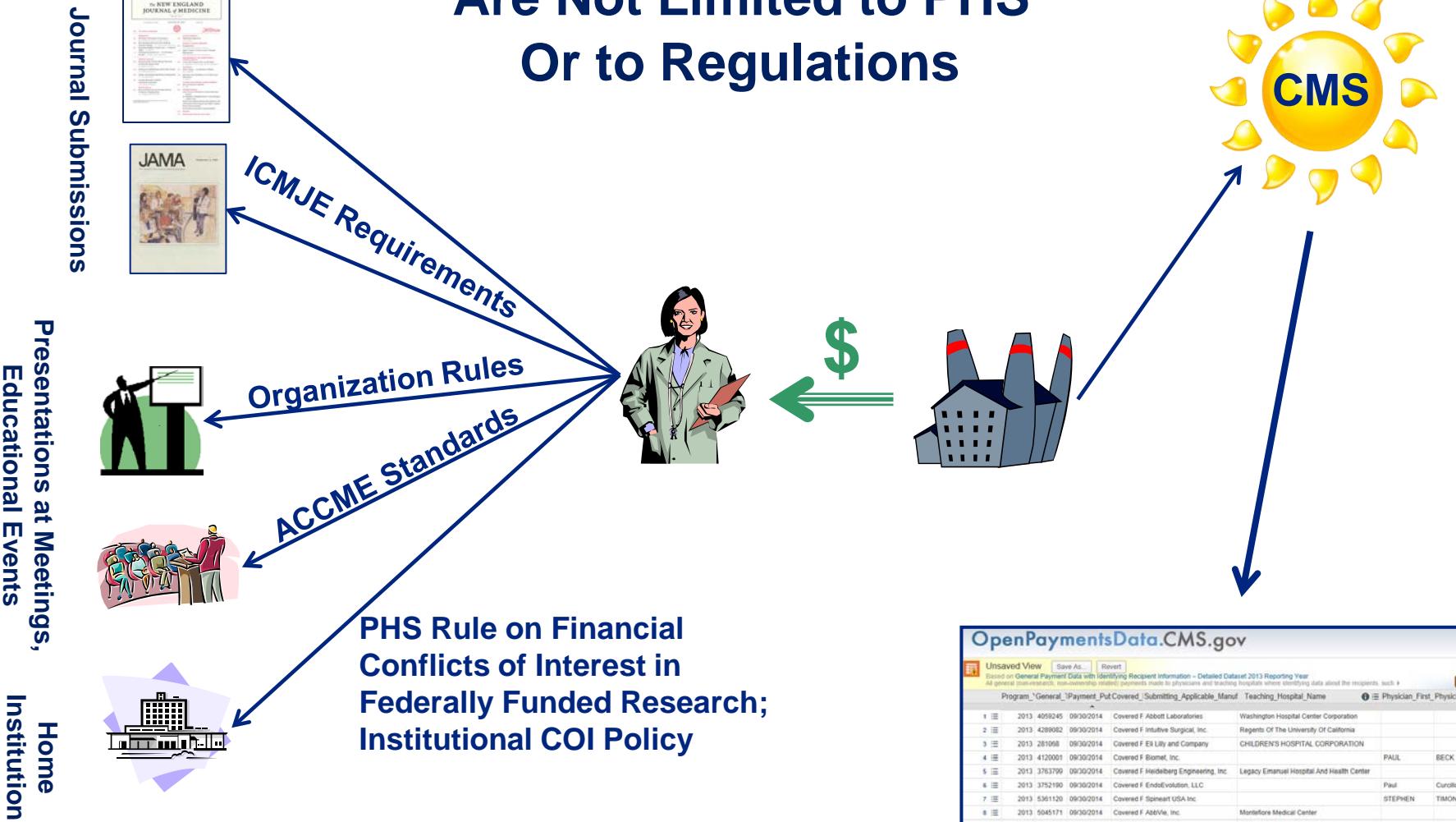
Personnel Costs  
\$11.6M

Other costs  
\$1.2M



1.9 to 2.7  
Full time equivalent (FTE)  
employees per institution  
to administer the  
requirements

# Disclosure and Reporting Obligations Are Not Limited to PHS Or to Regulations



OpenPaymentsData.CMS.gov						
Program		General		Submitting_Applicable_Manuf		Teaching_Hospital_Name
1	III	2013	4059240	09/30/2014	Covered F Abbott Laboratories	Washington Hospital Center Corporation
2	III	2013	4289082	09/30/2014	Covered F Intuitive Surgical, Inc.	Regents Of The University Of California
3	III	2013	281098	09/30/2014	Covered F Eli Lilly and Company	CHILDREN'S HOSPITAL CORPORATION
4	III	2013	4120001	09/30/2014	Covered F Biomet, Inc.	PAUL BECK
5	III	2013	376379	09/30/2014	Covered F Boston Scientific	2111 N
6	III	2013	3752190	09/30/2014	Covered F Endevolution, LLC	2800 N
7	III	2013	5361120	09/30/2014	Covered F Spineart USA Inc.	Paul Curollo
8	III	2013	5045171	09/30/2014	Covered F Abbott, Inc.	STEPHEN TIMON
9	III	2013	281248	09/30/2014	Covered F Eli Lilly and Company	910 E
10	III	2013	1854538	09/30/2014	Covered F Smith & Nephew, Inc.	1500 E
11	III	2013	5216698	09/30/2014	Covered F Covidien Sales LLC	535 E
12	III	2013	3396261	09/30/2014	Covered F Novartis Pharmaceuticals Corp. MONTEFIORE MEDICAL CENTER	124 C
13	III	2013	2619105	09/30/2014	Covered F Alcon Research Ltd	111 E
14	III	2013	4963380	09/30/2014	Covered F AstraZeneca, Inc.	243 CP
15	III	2013	5704074	09/30/2014	Covered F Allergan Healthcare Corporation	150 EA
16	III	2013	4008568	09/30/2014	Covered F Pfizer Inc.	101 th
17	III	2013	5193074	09/30/2014	Covered F Covidien LP	2301 E
18	III	2013	1415430	09/30/2014	Covered F Bristol-Myers Squibb Company	MARTIN PAUL
19	III	2013	3047103	09/30/2014	Covered F Pfizer Inc.	3301 N
20	III	2013	4675989	09/30/2014	Covered F Olympus Corporation of the Am	ABHIMANYU GARG
21	III	2013	5017842	09/30/2014	Covered F Abbott, Inc.	111 E
						Montefiore Medical Center

# A Single Repository Could Maintain Individual Financial Interests for All Disclosure Purposes

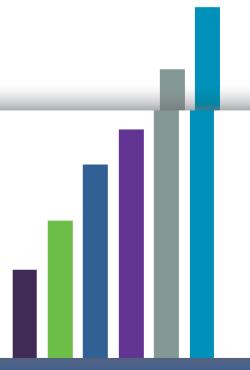


# From IOM Recommendation to Prototype

- Secure, user-controlled
- Draws from single source of financial interests
- Interoperable with COI management systems – based on data standards
- Intuitive and easy to use for both individuals and subscribing organizations
- Provides relevant disclosure information based on organization criteria and user assessment

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