



Tomorrow's Doctors, Tomorrow's Cures

The "Sunshine" Final Rule

What Medical Schools and Teaching Hospitals Need to Know

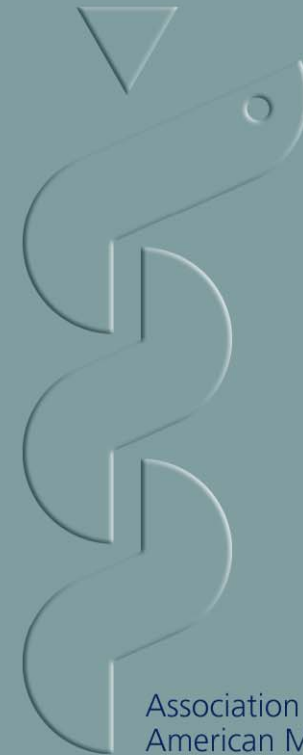
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Learn

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Association of
American Medical Colleges

Today's Agenda

- **Purpose, History and Timeline**
- **Who reports to CMS?**
- **What information is reported?**
- **What is excluded from the reports?**
- **What happens after the annual reports?**
- **How should teaching hospitals and medical schools prepare?**

Transparency Reports and Reporting of Physician Ownership or Investment Interests

- “Sunshine” rule from Physician Payments Sunshine Act
 - Now Sec. 6002 of Affordable Care Act
- Drafted to provide access to information about payments and other financial arrangements between manufacturers and providers
- Data is provided to CMS, then made publicly available on a website

Implementation Timeline

- **110th Congress (2007-2008): Physician Payment Sunshine Act**
- **March 23, 2010: Affordable Care Act**
- **January 1, 2012: Data collection required by statute**
 - Hearings, delays
- **December 19, 2011: Proposed Rule**
 - Hearings, delays
- **February 8, 2013: Final Rule**

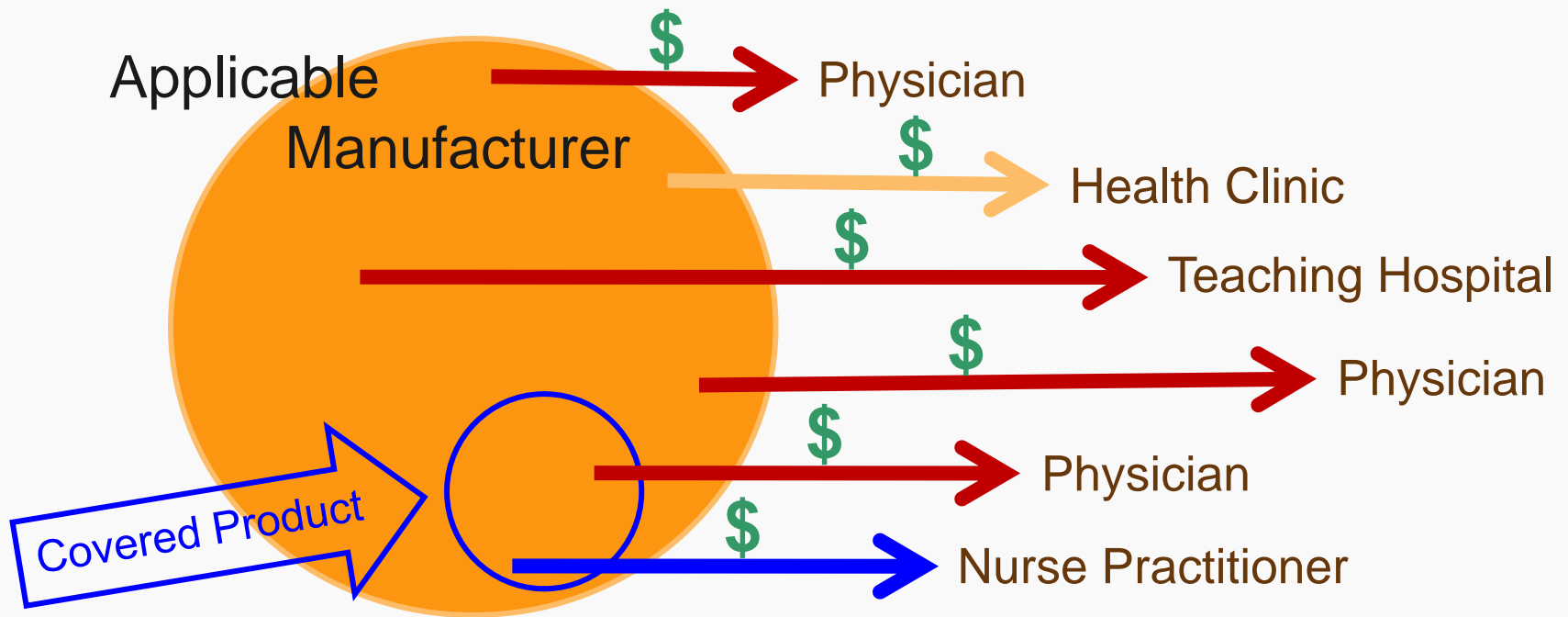
Who Reports Information to CMS?

- **“Applicable Manufacturers”**
 - Have a physical presence or conduct activity in the U.S.
 - Manufacture a covered product:
 - Prescribed drugs and biologicals
 - Devices that require premarket approval
 - Medical Supplies
 - Does not include entity that manufactures a covered product for internal use or for its own patients

Physicians and teaching hospitals have no reporting obligations under the sunshine rule

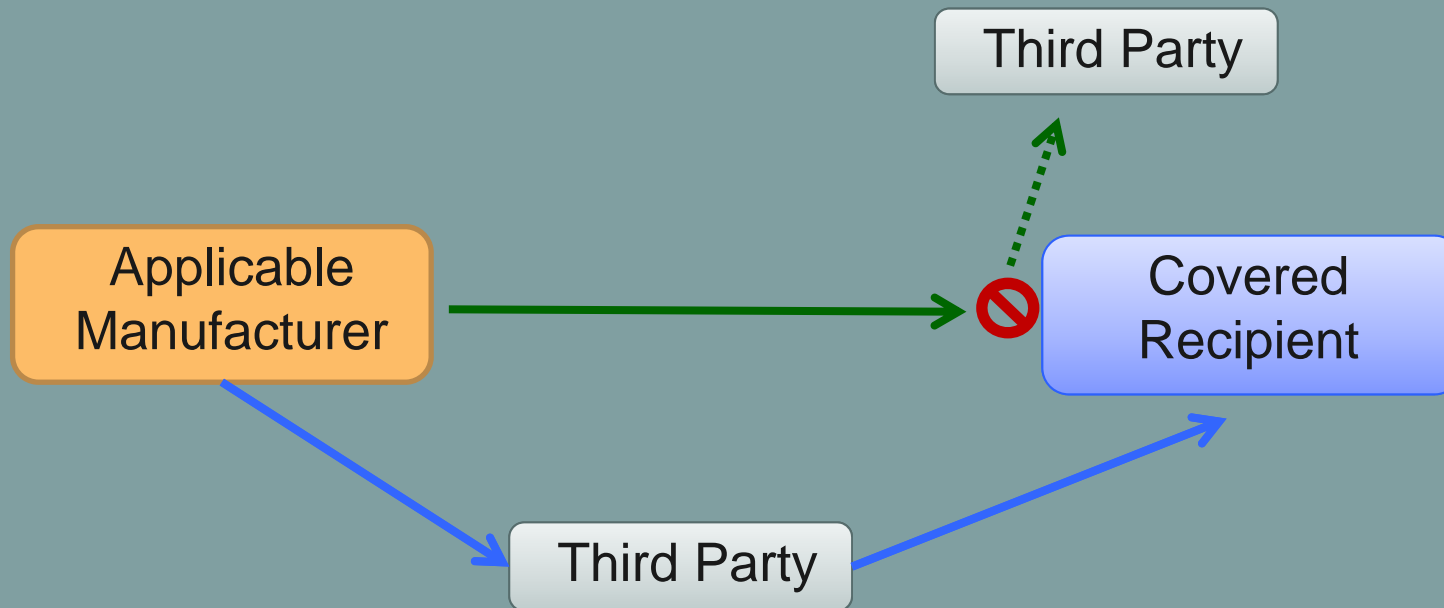
What Gets Reported?

- **All payments or other transfers of value from an applicable manufacturer to a physician or teaching hospital**
 - Does not have to be related to the covered product
 - Exceptions: certain manufacturers with limited revenue from covered products
 - Data is collected on a calendar year cycle and reported once annually



What Gets Reported?

- All payments or **transfers of value** to a physician or teaching hospital
 - Includes in-kind, equipment
- “Payment on behalf of a covered recipient” vs. “indirect payment to a covered recipient”



What Gets Reported?

All payments or transfers of value to a **physician** or teaching hospital

- **Includes:**

- Physicians as defined in Social Security Act
- Must be “legally authorized” to practice
- Identified by NPI and state professional license number

- **Does not include:**

- Residents
- Allied health professionals
- Non-physician prescribers
- Bona fide employees of the applicable manufacturer

What Gets Reported?

All payments or transfers of value to a physician or **teaching hospital**


- **Includes:**
 - Entities that received indirect medical education (IME) or direct graduate medical education (GME) payment
- **Does not include:**
 - Non-healthcare departments of universities affiliated with teaching hospitals
- **CMS will publish a list of teaching hospitals deemed to be covered recipients**

What Information is Reported?

For each payment or other transfer of value:

- Name of Covered Recipient
- Address
- Identifiers (for Physicians)
- Amount
- Date
- Form
- Nature
- Related covered product (if applicable)
- Eligibility for delayed publication
- Payments to third parties
- Whether physician is owner or investor
- Additional information/context (optional)

Categories for Reporting

1. Consulting fee
 2. Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
 3. Honoraria
 4. Gift
 5. Entertainment
 6. Food and beverage
 7. Travel and lodging
 8. Education
 9. Research
 10. Charitable contribution
 11. Royalty or license
 12. Current or prospective ownership or investment interest
 13. Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
 14. Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
 15. Grant
 16. Space rental or facility fees
- [Other]**
- 

Reporting Categories: Food and Beverage

- **Final Rule clarifies reporting of food and beverage in group settings or at large events**
 - Group settings (e.g. a group practice):
 - Divide total cost of meal by number of individuals who actually partook in the meal, and report that amount for covered recipients only (if > \$10)
 - Does not attribute meals eaten by support staff to physicians
 - Conferences and large events
 - When setting would make establishing the identities of covered recipients difficult (e.g. buffet meals at conferences), not reported

Reporting Categories: Research

- **Proposed Rule required distinction between “direct and “indirect” research payments and attributed full amount of research grant to each PI**
- **Final Rule makes substantial changes in identifying, reporting, and publishing research related payments**
- **Identifying Payments Related to Research**
 - Defines research using Common Rule definition
 - Assumed to cover preclinical, FDA Phases I-IV, investigator-initiated, behavioral, social sciences
 - Requires research to be subject to a written agreement *or* research protocol

Reporting Categories: Research

- **Reporting Payments Related to Research**
 - Must be reported if ultimately paid to a covered recipient
 - Even if paid through CRO or SMO
 - Manufacturers will use a different reporting template
 - Single research payment is only reported once
 - Information provided:
 - Name of institution receiving payment (even if not a covered recipient)*
 - Total amount of research payment*
 - Name of study
 - Name of related covered product
 - Principal investigator(s)*
 - ClinicalTrials.gov identifier (optional)

*Pre-clinical
research

Reporting Categories: Research

- **Publishing Payments Related to Research**

- In public database, research studies will be listed separately from all other payments
 - Generally, aggregated amount of payment (non-itemized) will be reported if included in agreement or protocol
 - Separate payments made directly to physician (e.g. additional fees for study steering committee) reportable
- Research payments will not be aggregated on database as personal payments to physicians

Reporting Categories: Note on Delayed Publication

- **Certain payments made under a “product research or development agreement” must be reported to CMS in appropriate year but will not be shown on public website**
 - Research on or development of new drug, device, biological or medical supply or new application of existing
 - Clinical investigations regarding a new drug, device, biological or medical supply
- **Delay until (1) FDA approval, licensure or clearance or (2) Four years after date of payment**

Reporting Categories: Consulting, Speaking, and CME

Proposed Rule Categories	Final Rule Categories
Consulting fee	Consulting fee
Compensation for services other than consulting	Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
Direct compensation for serving as a faculty or as a speaker for a medical education program	<p>Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program</p> <p>Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program</p>

Reporting Categories: Continuing Medical Education

Certain compensation to speakers at CME programs is not reportable

All three criteria must be met:

1. Event is accredited or certified
2. Applicable manufacturer does not pay the speaker directly
3. Applicable manufacturer does not chose the speaker or submit a list of speakers to consider

Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program

Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program

Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program

What is Not Reported?

Other exclusions from reporting include:

- Indirect payments where the applicable manufacturer is unaware of recipient
- Payments under \$10, unless over \$100 in aggregate
- Samples
- Educational materials for patients
- Short term loans (devices) or trials (medical supplies)
- Items or services under warranty
- Transfers of value to a physician who is a patient or research subject

What is Not Reported?

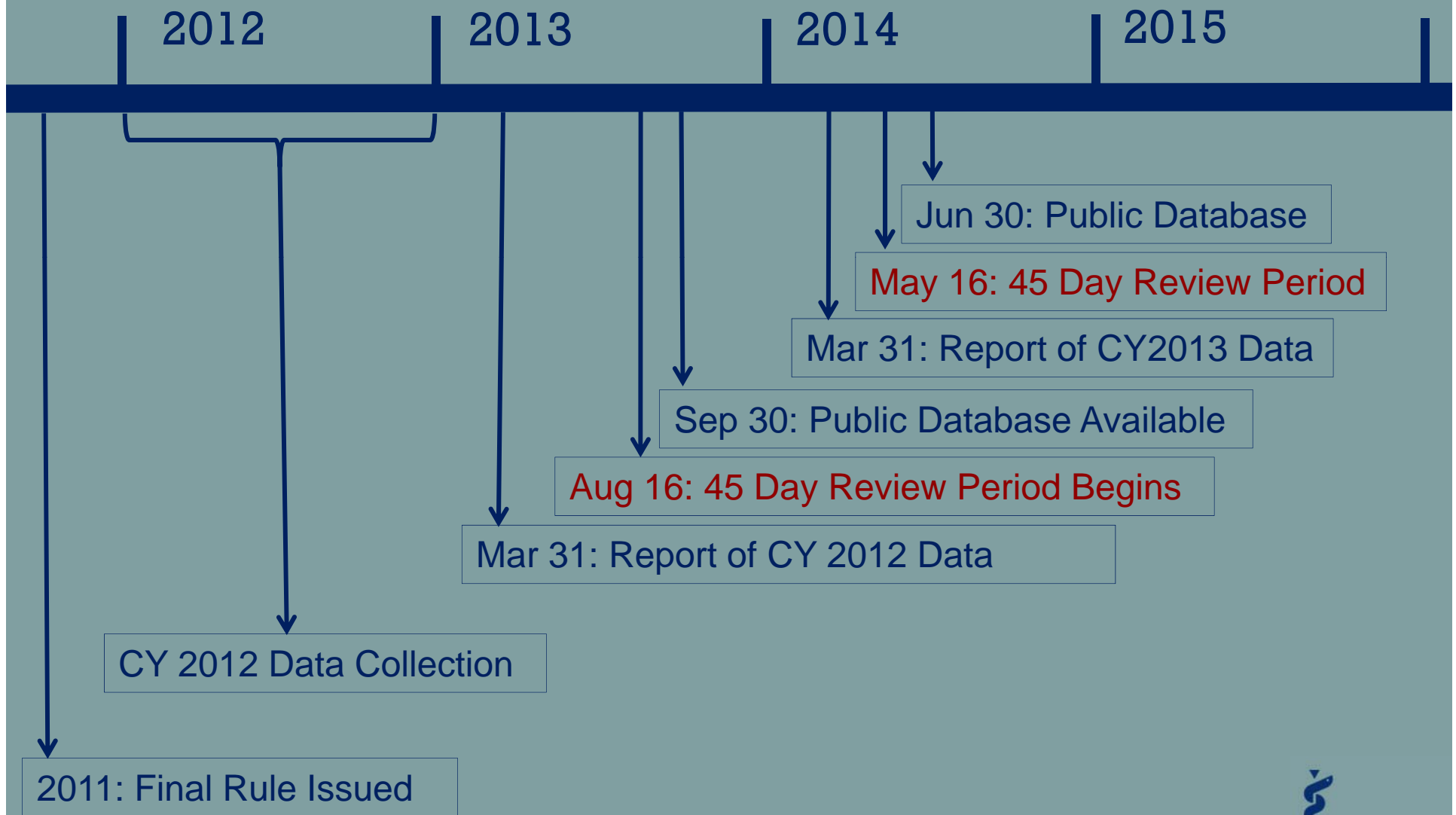
- Discounts and rebates
- In-kind items for use in charity care
- Dividends from publicly traded securities or mutual funds
- Payments to provide healthcare for employees/families
- Non-medical professional services of a physician
- Legal services of a physician
- Personal, non-business related transfers of value

What Happens After the Annual Reports?

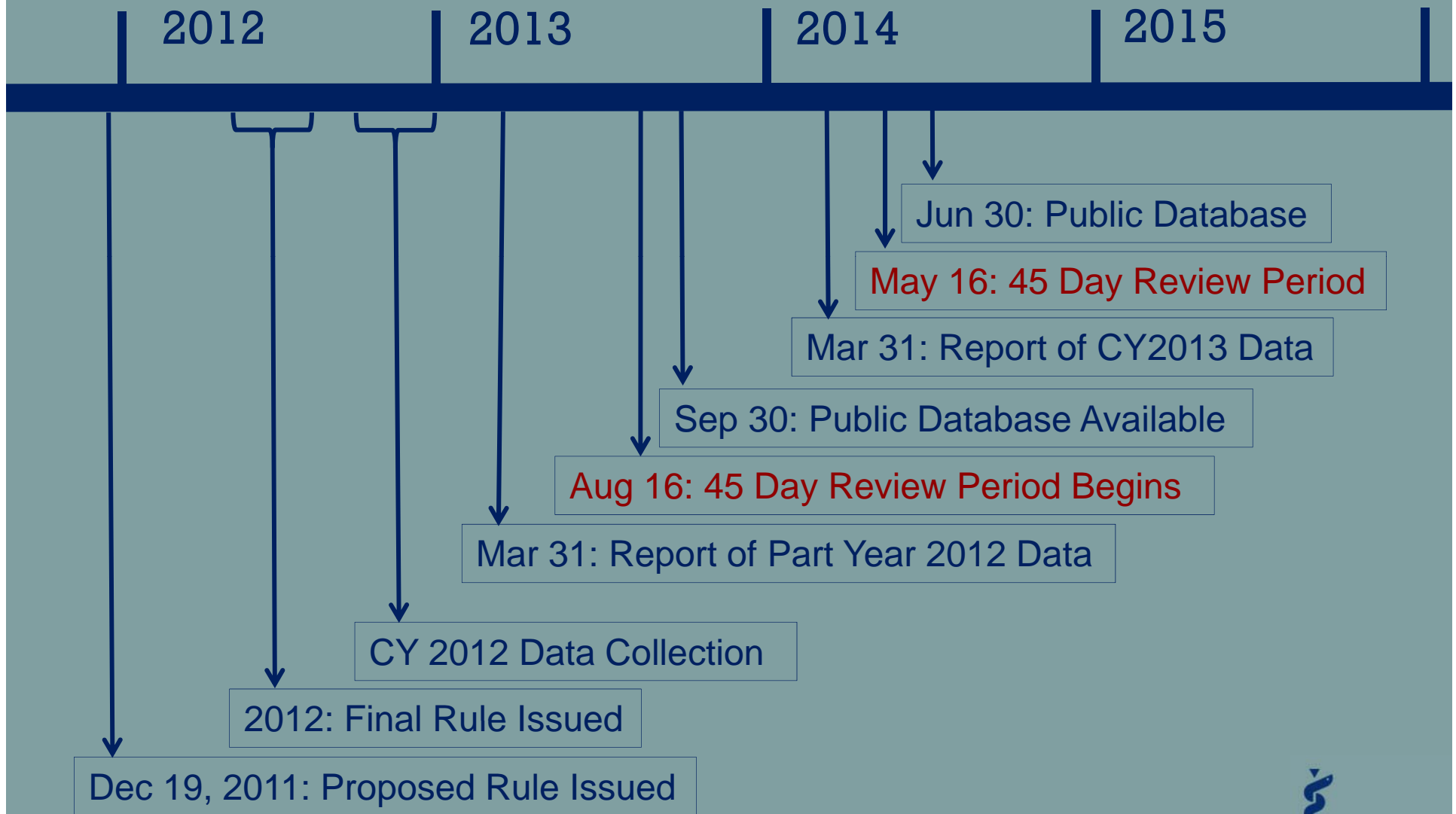
Opportunities for Review and Correction

- **Data provided to CMS are compiled, aggregated, and then made available for review by covered recipients**
 - Access is specific to identified recipient
- **Covered recipients have 45 days to review and notify applicable manufacturers of incorrect payment data**
- **Final rule adds 15 day resolution reporting window**

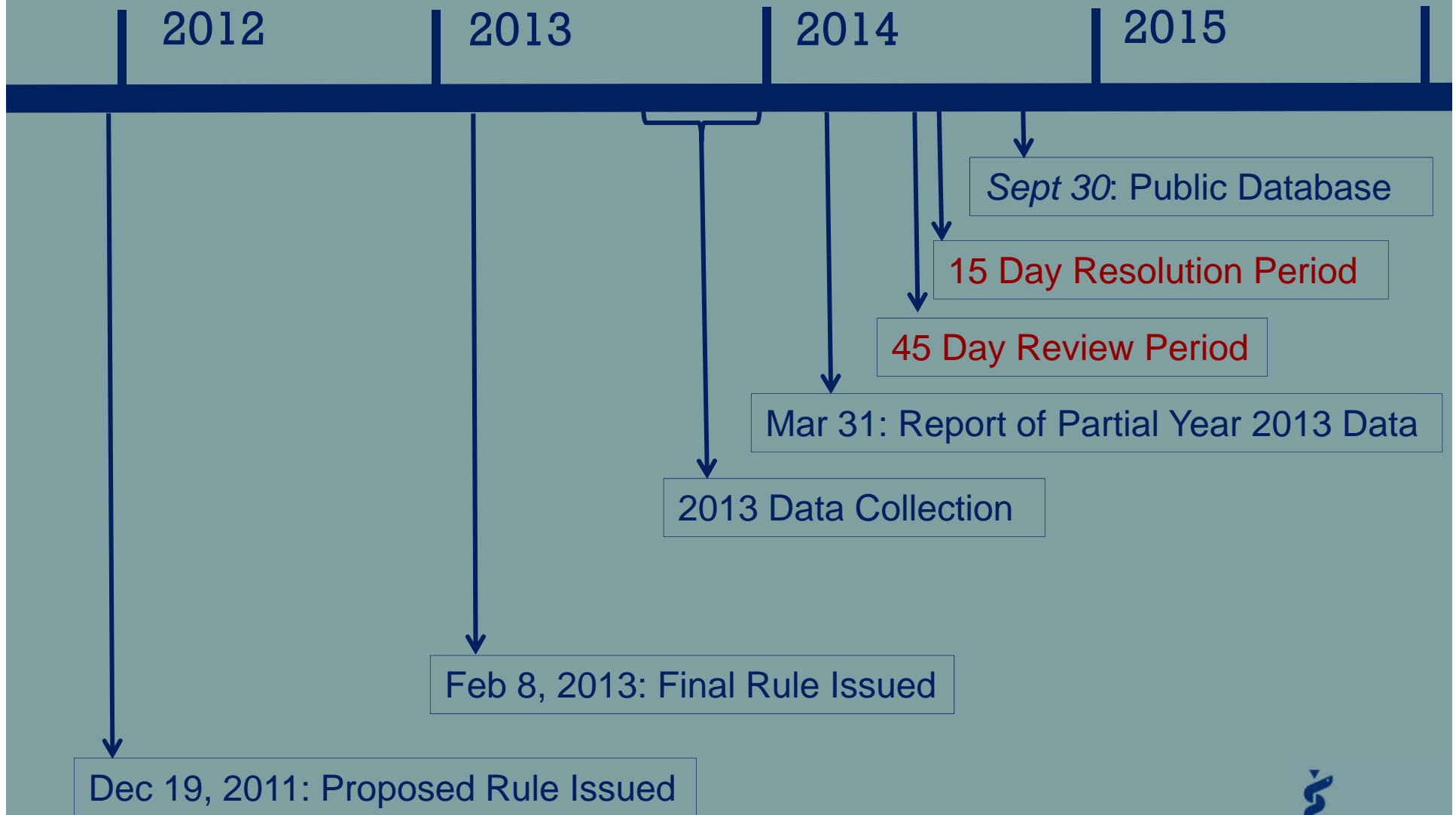
Statutory Data Collection and Reporting Timeline



Proposed Data Collection and Reporting Timeline



Final Payment Collection and Reporting Timeline



Dispute Resolution Process

- **Covered recipients are responsible for engaging applicable manufacturers to resolve disputes**
 - Incentives to avoid *over-reporting*
- **Applicable manufacturers must certify to the accuracy of the information and are subject to penalties for inaccurate information**
 - Incentives to avoid *under-reporting* or failure to report

Dispute Resolution Process

- **Proposed rule**
 - For unresolved disputes, both \$ amounts would be listed
- **Final rule**
 - In case of unresolved disputes, reported amount remains, but indication that payment amount is disputed
- **CMS will monitor dispute and resolution rates by applicable manufacturer**

Medicare

Medicaid/CHIP

Medicare-Medicaid
Coordination

Insurance
Oversight

Innovation
Center

Regulations
and
Guidance

Research,
Statistics, Data and
Systems

Outreach and
Education

[Home](#) > [Regulations and Guidance](#) > [National Physician Payment Transparency Program OPENPAYMENTS](#) > National Physician Payment Transparency Program: OPENPAYMENTS

National Physician Payment Transparency Program OPENPAYMENTS

National Physician Payment Transparency Program: OPENPAYMENTS

Why OPENPAYMENTS is important to you

The National Physician Payment Transparency Program or OPENPAYMENTS makes the financial relationships between manufacturers, group purchasing organizations, physicians, and teaching hospitals transparent and publicly available.

Physicians, teaching hospitals, and industry manufacturers working together can design and deliver life-saving drugs and devices. While working together can be beneficial, payments from manufacturers to physicians and teaching hospitals can also set up conflicts of interest.

What OPENPAYMENTS will do

- Facilitate transparency into the financial relationships between industry and physicians and teaching hospitals
- Help reduce the potential for conflicts of interest that physicians or teaching hospitals could face as a result of their relationships with manufacturers
- Empower informed decision-making for consumers of healthcare

How OPENPAYMENTS works

Applicable manufacturers (AMs) and applicable group purchasing organizations (AGPOs) will tell us every year about:

Working to Ensure the Public Database is Accurate

- **Let faculty/institutional administrators know about the narrow review and correct period**
 - Encourage faculty to register with CMS to receive notification when the data are available to review
 - Establish an institutional process or point of contact for keeping track of the outcome of disputed payments
 - Ensure disputed payments are resolved by the next review period
- **Other methods to review data, resolve disputes prior to submission to CMS**

Other Transparency Considerations

- **Sunshine Database vs. PHS Public Accessibility**
 - Scope of information included
 - Timing of available information
 - Format of accessible data
 - Implications of each reported financial relationship
- **Context is critical**
 - CMS is engaging stakeholders to assist in implementation language and processes
 - Common talking points could create consistent message



Conflicts of Interest in Research

Financial Conflicts of Interest Regulations

Final Rule on Regulations Related to Individual Conflicts of Interest in Federally-funded Research

On August 23, 2011, the Department of Health and Human Services issued a final rule revising the regulations entitled "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors."

- [Federal Register Final Rule \(August 25, 2011\)](#)
- [AAMC Press Release on Final Rule](#)
- [AAMC-AAU-ACE-APLU Comment Letter in Response to NPRM PDF](#)
- [Federal Register Notice of Proposed Rule \(May 21, 2010\) PDF](#)

AAMC COI Metrics Pilot: Measuring the Cost and Outcomes of the Rule on Financial Conflicts of Interest in PHS-funded Research

AAMC is working with member medical schools and teaching hospitals to measure the effects and effectiveness of the rule using annual, aggregate data about conflict of interest review systems, disclosures made by investigators to institutions, and financial conflicts of interest identified and reported to federal funding agencies. More information and registration procedures are available at www.aamc.org/metricsproject. You may direct any questions to COIMetrics@aamc.org.

- [AAMC Report on Institutional Approaches to Implementing the Final NIH Rule on Financial Conflicts of Interest](#)



This report, issued in March 2012 by the AAMC, provides institutions subject to the new rule with some insight into how their peer institutions were thinking about these issues in the first few months after announcement of the new rule, and to provide a range of contemplated approaches. The report captures the contributions of 48 AAMC member institutions that participated in a series of regional working meetings convened in late 2011.

"Sunshine" Regulations on Reporting of Payments to Physicians and Teaching Hospitals

On February 8, 2013, the Centers for Medicare and Medicaid Services (CMS) issued a final rule entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests," (78 FR 9458). This rule implements section 6002 of the Affordable Care Act.

Metrics Project

AAMC COI Metrics Pilot: Measuring the Cost and Outcomes of the Rule on Financial Conflicts of Interest in PHS-funded Research

[Metrics Project >](#)

Responsible Conduct of Research

- ▣ [Beyond the Framework: Institutional Considerations in Managing Allegations of Misconduct in Research](#)
- ▣ [Update on the Requirement for Instruction in the Responsible Conduct of Research](#)

Related Topics

- ▣ [Forum on Conflict of Interest in Academe \(FOCI Academe\)](#)
- ▣ [Clinical Research](#)
- ▣ [Medical Research](#)
- ▣ [Medical Education Initiatives](#)

<http://www.aamc.org/initiatives/coi/>



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