Panel Session

Where We are in Disclosure and Aggregate Spend Implementation After the Final Sunshine Rule

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Panellists

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- **Rore Middleton, Esq.**
  - Senior Manager, Corporate Compliance, Purdue Pharma LP, Stamford, CT
- **Trudy J. Seeley**
  - Senior Manager, Transparency Operations, Sanofi US, Bridgewater, NJ
- **David Wysocky**
  - Director, Pharmaceutical and Life Sciences Advisory Services, PricewaterhouseCoopers, Florham Park, NJ (Moderator)

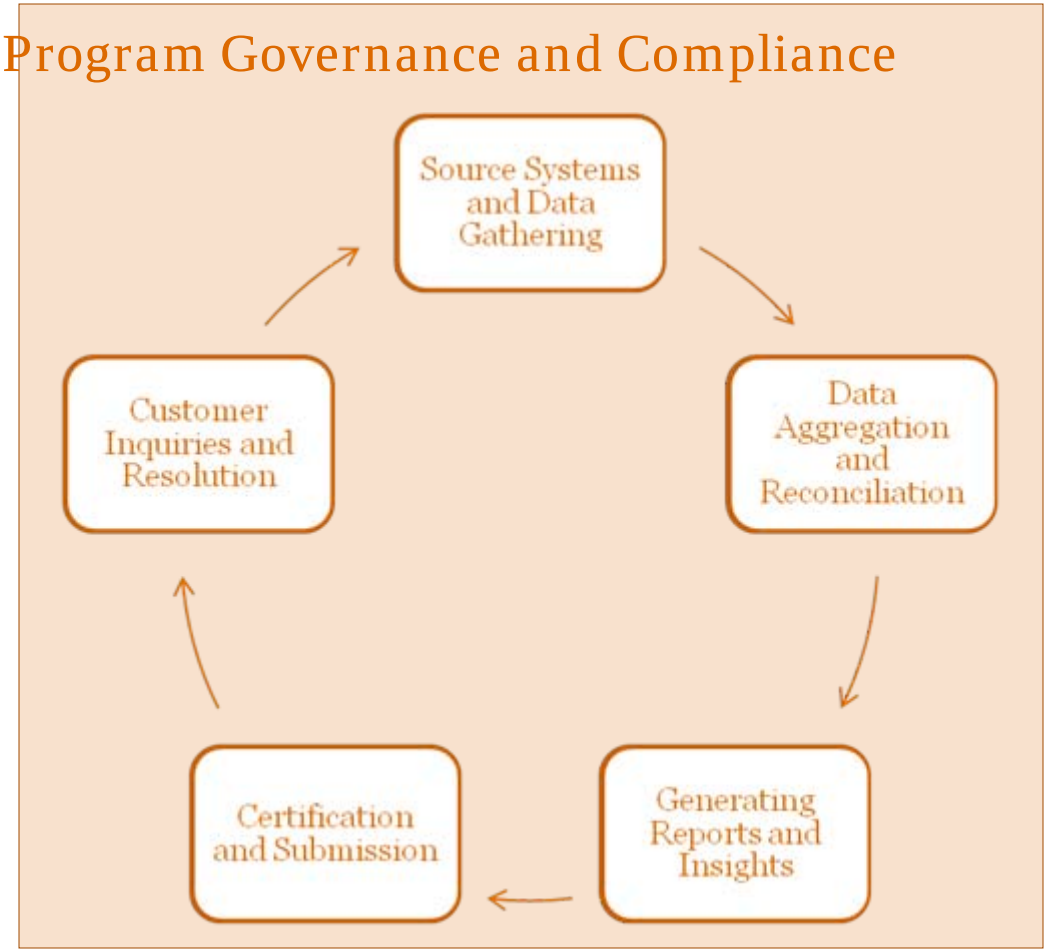
Agenda

The Final Rule provides numerous definitions, updates, and clarifications. Today's panel will focus on the following discussion points:

- Legal Interpretation
- Covered recipients
- Payments or other transfers of value
- Research payments
- Report submission, review, and content
- Dispute resolution
- Stakeholder Management and Communications

Discussion Points

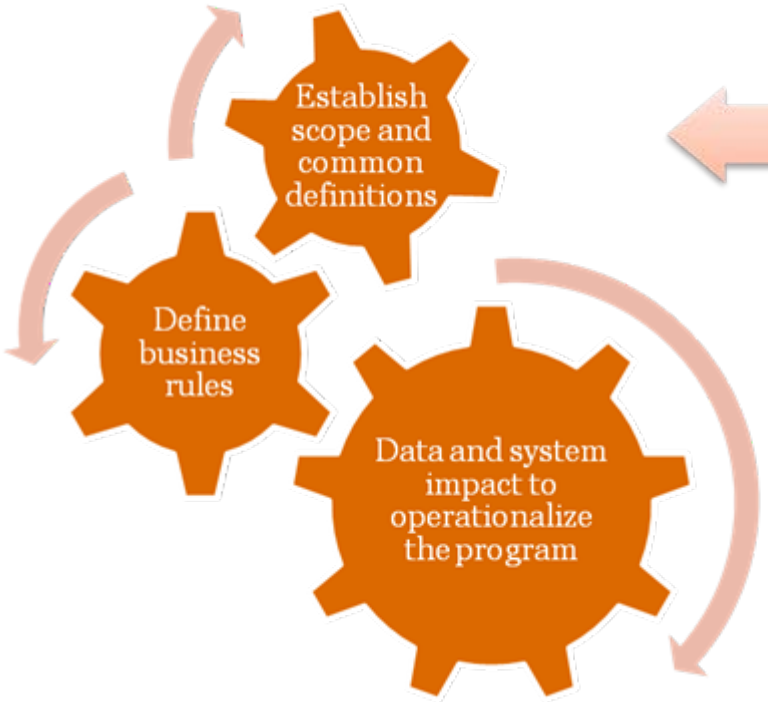
- Panelists' view on the Final Rule through an operational (business process and systems/data) lens
- Focus on the updates and clarifications
- Q&A after each section



Importance of Legal Interpretations

- A formal legal interpretation of the Final Rule, as well as the State reporting requirements, is essential and will serve as the foundation for our operational processes

Operational Impact



Impact on P&Ps

Determine legal interpretation for each provision

Update existing policies to account for new/updated legal interpretations

Draft additional policies, SOPs, processes to cover all legal interpretations if necessary

Covered Recipients

Final Rule Requirements

- Physician: Doctors of medicine & osteopathy, dentists, podiatrists, optometrists, chiropractors, including those who are not actively practicing but still hold a license
- NPPES will be utilized for the NPI
- The unique identifier requirements have been extended to include State professional license
- Determine NPI, including demonstrating a good faith effort to obtain the information
- For common ownership, determine how to align name, NPI, and data across units for reporting

Key Operational Considerations

- Assessing/Updating/Developing Customer Master and Customer Lists
- Differentiating, flagging and excluding residents and other types
- Matching and/or integrating internal Customer Master/Lists with external NPPES and Hospital lists
- Enhancing source systems to assign covered recipients at the point of transaction
- Beginning/ Continuing to capture physician state license numbers and middle initials for reporting
- Create policies and procedures to document good faith effort to capture NPI number if one is not obtained

Covered Recipients

Q&A

Payments or Other Transfers of Value (PoTV)

Final Rule Requirements

- PoTV definition and scope updated, manufacturers responsible for calculation
- "Indirect PoTV" introduced and defined
- PoTV trough a group or practice should be attributed those who requested or are intended to benefit from PoTV
- Meal costs should be reported taking "actual" partake into account
- Include items not directly benefiting patients
- Exclude PoTV related to certain CME programs

Key Operational Considerations

- Determining value of items and other transfers of values
- Building flexibility to allocate costs based on particular situations
- Establishing process to accurately and completely tracking recipients and all attendees at each event
- Modifying business rules to remove excluded PoTV from reporting excluded items (e.g. CME or items for Patient Benefit/Use)

Payments or Other Transfers of Value (PoTV)

Q&A

Research Payments

Final Rule Requirements

- Reporting requirements expanded. Research payments will be captured in a separate report template
- Scope includes pre-clinical research, FDA Phases I-IV research, and investigator-initiated trials
- Must report direct and indirect payments
- Reported as a single payment (i.e., milestone payment) and need to include the entity paid, regardless if recipient is a covered recipient, as well as the PI(s)
- Publication delay granted for research for new products (including generics); no delay granted for new applications of products already on the market
- Need to indicate if POTV should be granted a delay from publication

Key Operational Considerations

- Defining a process to identify payments related to research activities and associated primary investigator(s)
- Developing a mechanism/trigger to indicate eligibility for delayed publication of research payments
- Developing a process to receive payment information from CROs and SMOs in a timely manner at the appropriate level of detail
- Delineating between pre-clinical and clinical research activities
- Aligning primary investigators with profile data from customer master lists

Q&A

Report Submission, Review, and Content

Final Rule Requirements

- Data collection will begin on 1 August 2013
- First reports will be sent electronically to CMS on 31 March 2014 and 90th day of each calendar year thereafter
- Report content for three distinct types: 1) POTV, 2) Research -related POTV, and 3) Physician ownership or investment interest
- No format specified for reports
- Federal rule pre-empts any state or local laws requiring reporting of the same type of information concerning PoTV, unless information is being collected for public health surveillance, investigation, or other public health purposes or health oversight

Key Operational Considerations

- Utilize flexible reporting tools to allow for specific reporting details to change regularly
- Assign responsibility of attestation and institute program governance and define a process for review and certification by internal stakeholders and data owners
- While States may continue to modify or repeal requirements, companies should maintain separate business rules and system requirements to comply with both State and Federal reporting requirements

Report Submission, Review, and Content

Q&A

Dispute Resolution

Final Rule Requirements

- Covered recipient or physician owner or investor can initiate a dispute by filling out an electronic form to detail the dispute
- Manufacturers are responsible for submitting corrected data and re-attesting to the new data within 15 days after the 45-day review period closes
- For unresolved disputes, CMS will only post the most recent attested data subject to the dispute and will flag the transaction as “disputed”

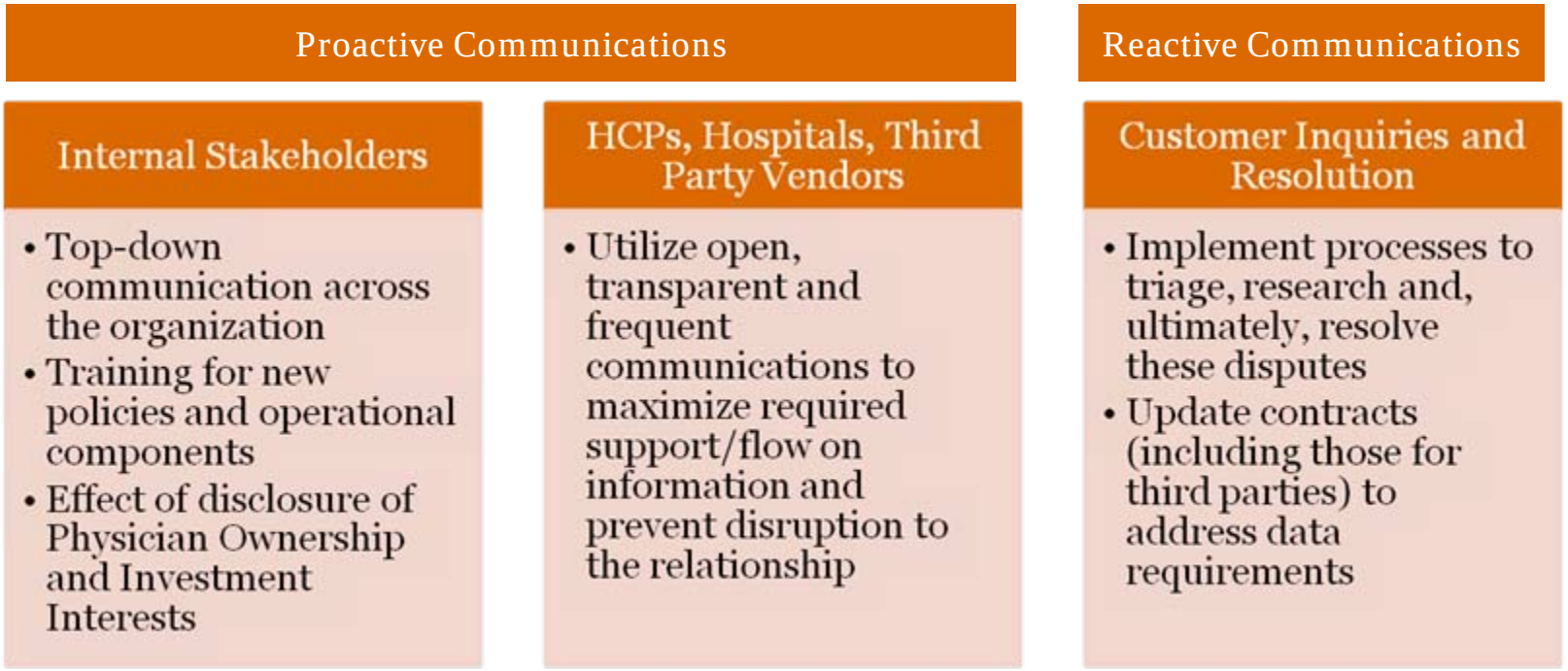
Key Operational Considerations

- Define a process for handling disputes and assign accountability to resources that can efficiently investigate and resolve disputes and route disclosure reports for re-attestation
- Assign data stewardship for triaging disputes to appropriate departments and incorporation of new/updated transactions
- Consider proactive communication strategies with covered recipients throughout the year to resolve disputes prior to reporting due date

Q&A

Stakeholder Management and Communications

- Another key success factor to ensure compliance with the Final Rule is taking the right steps to effectively managing communications and relationships with internal and external stakeholders:



Q&A

Thank You!