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Analysis of the Proposed Sunshine Rule: Implementation Issues

Katherine Cartwright Norris
Director, Corporate Compliance
The Spectranetics Corporation

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We have a Proposed Rule…now what?

- Review and revision of current SOPs and business practices:
  - Tracking clinical trial payments
  - Addressing Direct/Indirect payments
  - Confidence of your FMV assessment and payment arrangements
    - Legitimate business needs
    - Appropriate utilization levels
  - Assessment of 3rd Party competencies
  - Revised approach to state reporting requirements

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Scrutinizing the Rule … and staying current at home

- What falls into the "Other" category?
- Health check:
  - Are we capturing everything we need to report?
  - What about possible slip-throughs?
- Continuous identification of payments & transfers of value
  - New or evolving business practices
  - Total cross-functional integration

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Cross-company training and field based communications

- Personnel training:
  - Revisions to business process
  - Described product identification
    - Multi-product bags and multi-product therapies
  - Materials classification: education and patient benefit
  - Communications with customers
    - Deflecting the “hostile customer”
  - Emphasizing the need to remain flexible in a dynamic world

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Information outputs

- Data review & dispute resolution
  - 45 day review & error correction
  - Fielding inquiries
  - Coordinated response to HCPs
- Error identification & reporting
- Managing appearances
  - Complex relationships with customers
  - Public appearances
  - Other stakeholders (government investigators)
- Identifying potentially bad facts
  - Corrective and preventive actions
  - Evaluating the need to disclose