

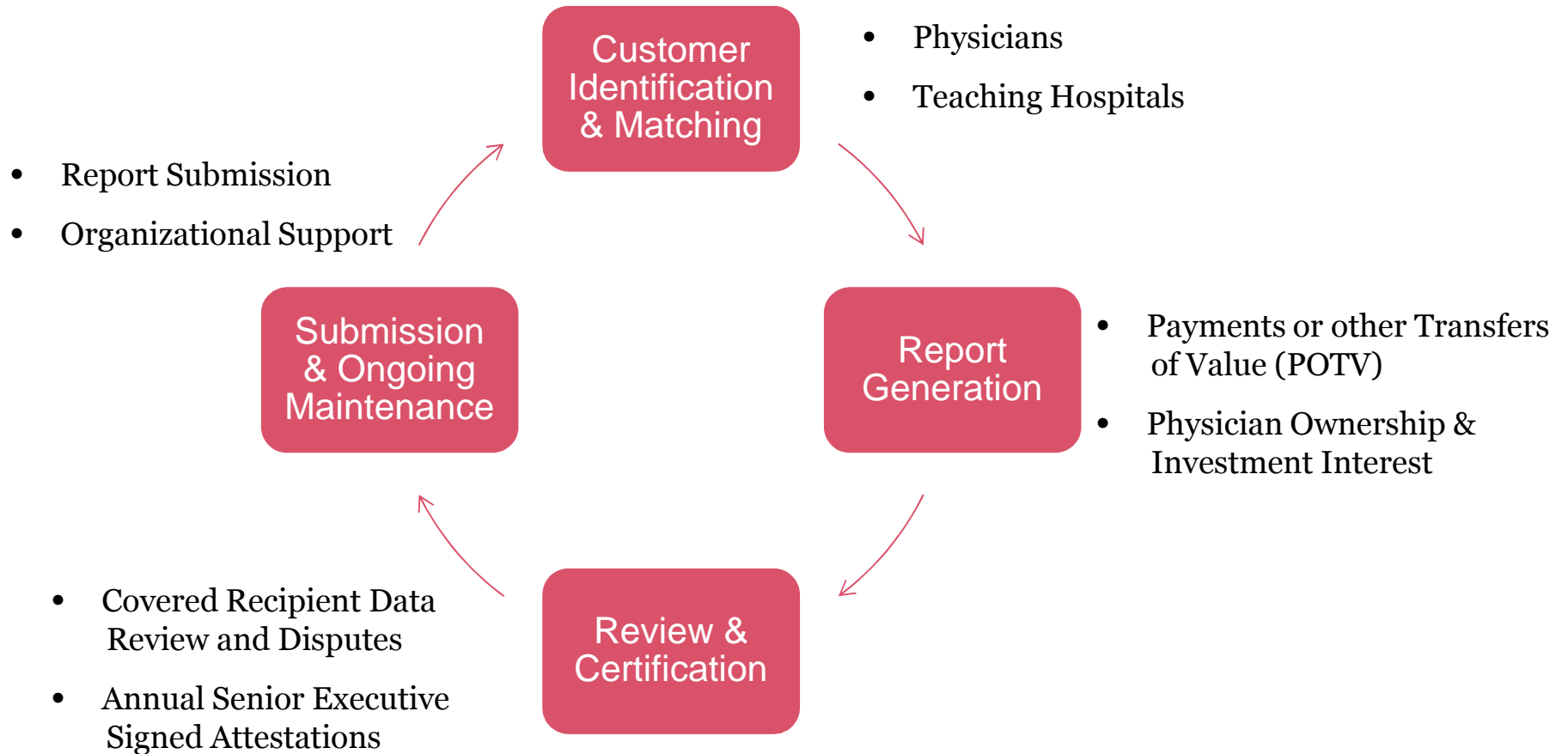
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Analysis of the Proposed Sunshine Rule

Operational Issues
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Operational Issues

Manufacturers should evaluate the impact of the proposed CMS Sunshine rule against their existing organization's interpretations, business processes, systems, and data quality



Customer Identification and Matching

Manufacturers should reassess their Customer Master solution and processes associated with customer identification, profiling, and matching to identify and report required Covered Recipients

Physicians

CMS suggests manufacturers use the National Plan & Provider Enumeration System (NPPES) to identify physician covered recipients

- Manufacturers will need to address the operational challenge of matching their HCP universe to the NPPES source, procuring and incorporating NPIs for those not listed in the registry, and possibly collecting and reporting other identifiers for physicians who do not have a NPI

Teaching Hospitals

CMS proposes to publish an annual list of hospital covered recipients (those who receive Medicare direct and indirect graduate medical education (GME)) on the CMS website

- Manufacturers will need to match hospital covered recipients from their internal systems to the hospital covered recipients on the CMS website (through name/address alone). These institutions may have multiple addresses.

Report Generation

Manufacturers should evaluate their existing Aggregate Spend interpretations, sources, solutions and processes to confirm they can comply with the proposed scope, definitions, and reporting format

Payments or other Transfers of Value

The definition includes all POTVs given to a Covered Recipient (CR) regardless of whether the recipient requested the POTV

- Manufacturers may need to design data capturing and reporting capabilities to allow a single payment to be assigned to multiple entities
 - Report POTVs made to an individual or entity at the request of, or designated on behalf of, a CR
 - Report POTVs to a group practice under each individual physician CR
 - Report only one related product, using the name under which it is marketed
 - Exclude educational materials that directly benefit patients or are intended for patient use
 - Report indirect payments via third-parties if the third-party and/or manufacturers is aware of CR identity

Physician Ownership & Investment Interests

CMS is proposing that manufacturers and GPOs prepare and submit a separate report indicating ownership and investment interest of physicians and their immediate family members as well as value provided to physician owners and investors

- Manufacturers generally do not capture this information and will need to create and implement new policies, processes, systems and controls to comply with this new reporting requirement

Review and Certification

Manufacturers should focus on their data quality and management processes in light of CMS' proposed requirements for customer data review, dispute tracking and reporting, and corporate officer signed attestations

Covered Recipient Data Review and Disputes

It is recommended, but not required, that manufacturers and GPOs provide each CR with a “pre-submission” review of information regarding the information they plan to submit as part of their report

- Manufacturers will need to consider processes, tools and organization support necessary to support CR pre-submission review as well as the impact of CMS' CR review and tracking and reporting of resulting resolved & unresolved disputed data

Annual Senior Executive Signed Attestations

CMS proposes that an authorized representative (CEO, CFO, COO) would provide an attestation of the correctness, truth and completeness of the data

- Manufacturers need to establish an effective senior executive certification process (and sub-certification process) that enables the organization to review and validate the completeness and accuracy of the data from the point of collection to the point of reporting

Submission and Ongoing Maintenance

Manufacturers should assess and redesign their ongoing reporting processes and organizational support to align with the operational implications and level of effort resulting from CMS' proposed rule

Report Submission

All reportable research payments should be reported to CMS annually with other POTV and CMS will delay public publication of the payment(s) based on manufacturers' indication on their reports whether the payment is subject to delayed publication and continued indication if the payment should no longer be granted a delay

- Manufacturers will need to focus on designing and implementing their annual reporting process to account for the proposed reporting format, annual research payment reporting and delayed publication tracking and notification, and 5-year data retention requirements

Organizational Support

CMS offered a perspective on the level of effort and resource needs that manufacturers of different sizes should consider as they build out their respective programs and implement solutions

- Manufacturers should reassess and align their Aggregate Spend organizations, roles and responsibilities in light of the CMS proposed rule, operational impact, and level of effort considerations
- Smaller manufacturers are projected to dedicate 50% of a full-time equivalent employee
- Larger manufacturers are projected to dedicate 5-15 full-time equivalent employees

Questions?

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