

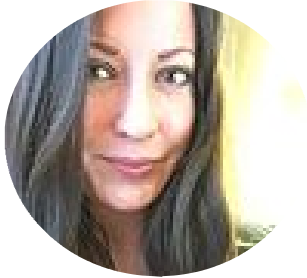


Preconference 4: Government Pricing Compliance After an Acquisition

18th Annual Pharmaceutical and Medical Device Compliance Congress
November 6, 2017

Preconference 4:

Government Pricing Compliance After an Acquisition
Monday, November 6 from 10:00 am – 12:00 pm



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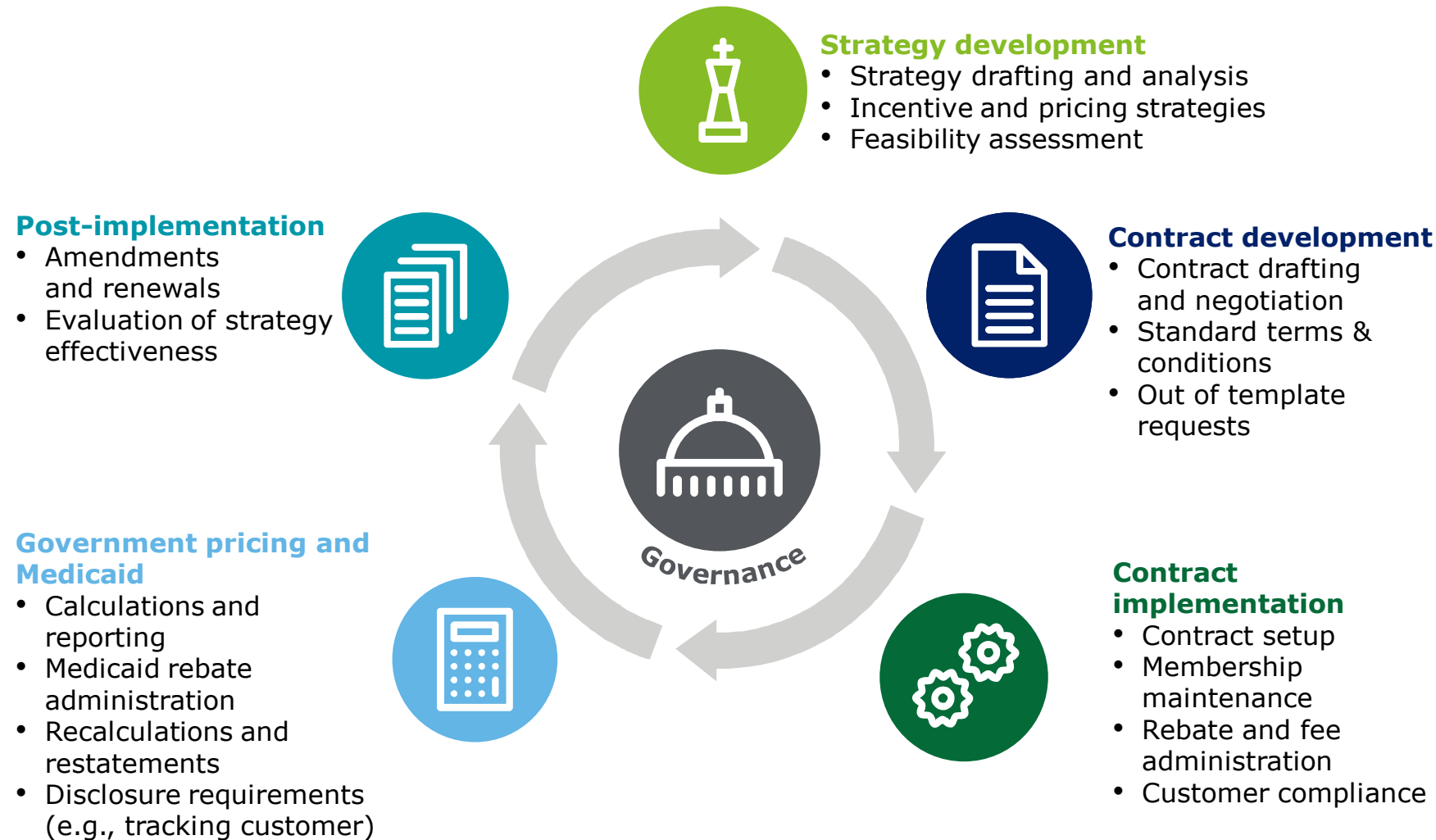


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What is the government and commercial contracting lifecycle?



Government payors represent a significant and growing area of contracting for manufacturers



- By 2024, federal, state, and local **government health care spending** is projected to be nearly **47 percent** of national health expenditures, up from 43 percent in 2013.
- Currently nearly **66 million Americans in the Medicaid Program**.
- Medicaid spending is projected to grow an average of **5.9%** per year for 2015 through 2024 reflecting more gradual growth in enrollment as well as increased spending per beneficiary due to aging of the population.
- **Medicare spending** is projected to **grow an average of 7.3%** per year for 2017 through 2024 due to increased enrollment by baby boomers, greater utilization of care, and higher payment rates.
- There are approximately **9 million dual eligibles**, meaning people who are both Medicare and Medicaid eligible, and can account for up to 30% of Medicare and Medicaid spend.
- This growth can generally be attributed to various socio-economic and political factors

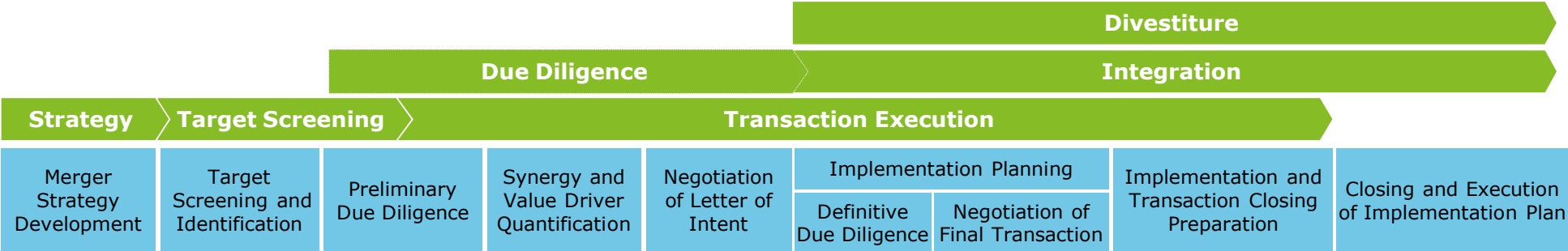
Source: www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html

Mergers, acquisitions, and divestitures introduce government pricing compliance challenges

Mergers and acquisitions (M&A) are a strategic focus for many manufacturers, and industry trends and market forces will likely keep M&A in the forefront of strategic importance for years to come.

Whether a transaction includes buying, selling, or partnering there are some key legal, financial, and strategic alignment considerations required to identify and resolve compliance risks related to Government Pricing (GP).

M&A Life Cycle



Government pricing compliance leading practices



Demonstrating the appropriate level of **due diligence** to reflect program integrity and having an effective plan in place to ensure **ongoing compliance**



Understanding the **regulations and guidance** that define requirements under the various **Federal health care programs**



Evaluating the guidance and developing **appropriate reasonable assumptions** applicable to the client's business



Establishing and maintaining **policies, procedures and controls** to ensure ongoing compliance, specifically including the accuracy and integrity of required statutory pricing



Developing and maintaining **"audit readiness"** to define GP compliance based upon the company's ability to demonstrate its program compliance and integrity and preparedness for an external audit

What are the right questions to ask during the pre-close evaluation phase?

Which areas of the integration can be the most challenging and why?

What lessons can we draw from some of the most complex and challenging integrations?

Drawing from our collective experience, we have identified considerations to be evaluated based on your perspective in the transaction (acquisition vs. divestiture)



Product Attributes

- UOM, package size, material id and other critical attributes
- Identifiers (pseudo-NDCs)
 - WAC vs. list pricing



Customer Attributes

- Class of trade and “view” of the customer (parent/child, retail vs. non-retail)
- Identifier and 3rd party data



Commercial Contracting

- Complex strategies and/or bundled arrangements
- Non-standard terms/conditions
 - Completeness of data in source systems
 - Contractual notification requirements (e.g., bid award)



Government Pricing

- Aligning methodology and processes
- Consolidating programs (VA/FSS, State, etc.)
- Managing new/changing regulatory guidance
- Open disputes/claims



Governance

- Pre- vs. post-deal (e.g., clean room)
- System of record considerations
- Aligning approval authority and thresholds



Systems

- Manual processes
- Prior system upgrades and conversions
- Archival and decommission strategy



Historical Data

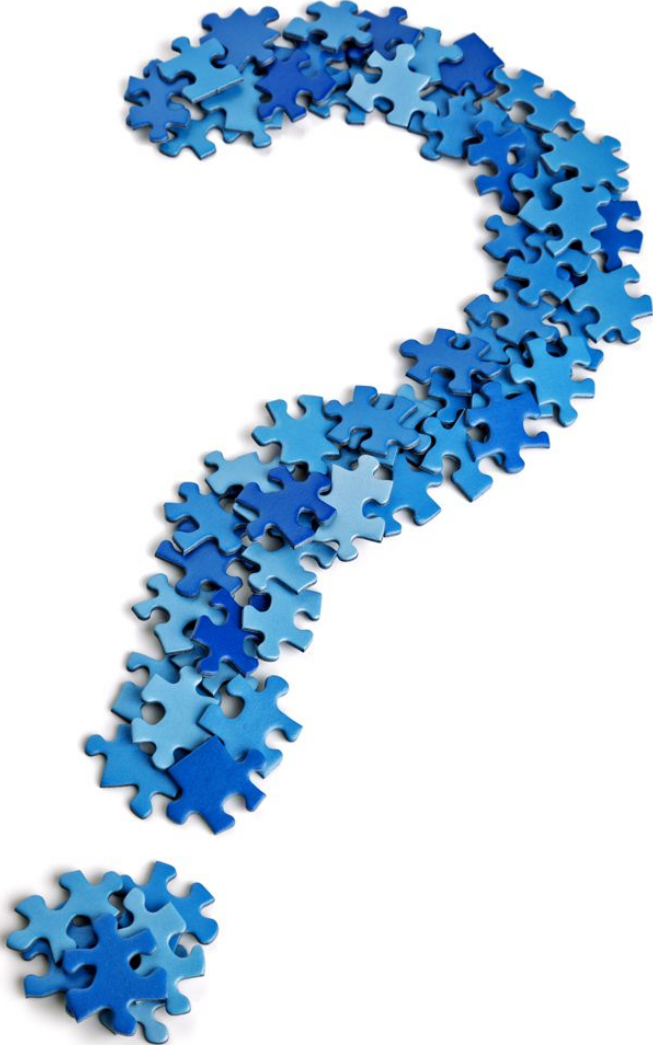
- Amount of data required for conversion, dual maintenance and “moving targets”
- Implications for master data requirements
 - Cross references (1:1 vs. 1:Many)



Stakeholders

- ERP, Finance, Trade, Legal
 - Aligning to other teams’ milestones (e.g., go live, data conversion)

Q&A





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