connecticut innovations

Smart Strategies for Addressing Medical Device Reimbursement

A Connecticut Innovations webinar featuring:

Edward E. Berger, Ph.D.
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Smart Strategies for Addressing Medical Device Reimbursement

Edward E. Berger, Ph.D.

Larchmont Strategic Advisors

Connecticut Innovations Webinar

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THE REIMBURSEMENT CHALLENGE

- Critically important element in
  - Opportunity assessment
  - Business plan development
  - Investor due diligence
  - Commercial success
- Requires early and careful analysis and planning

THE GOOD NEWS

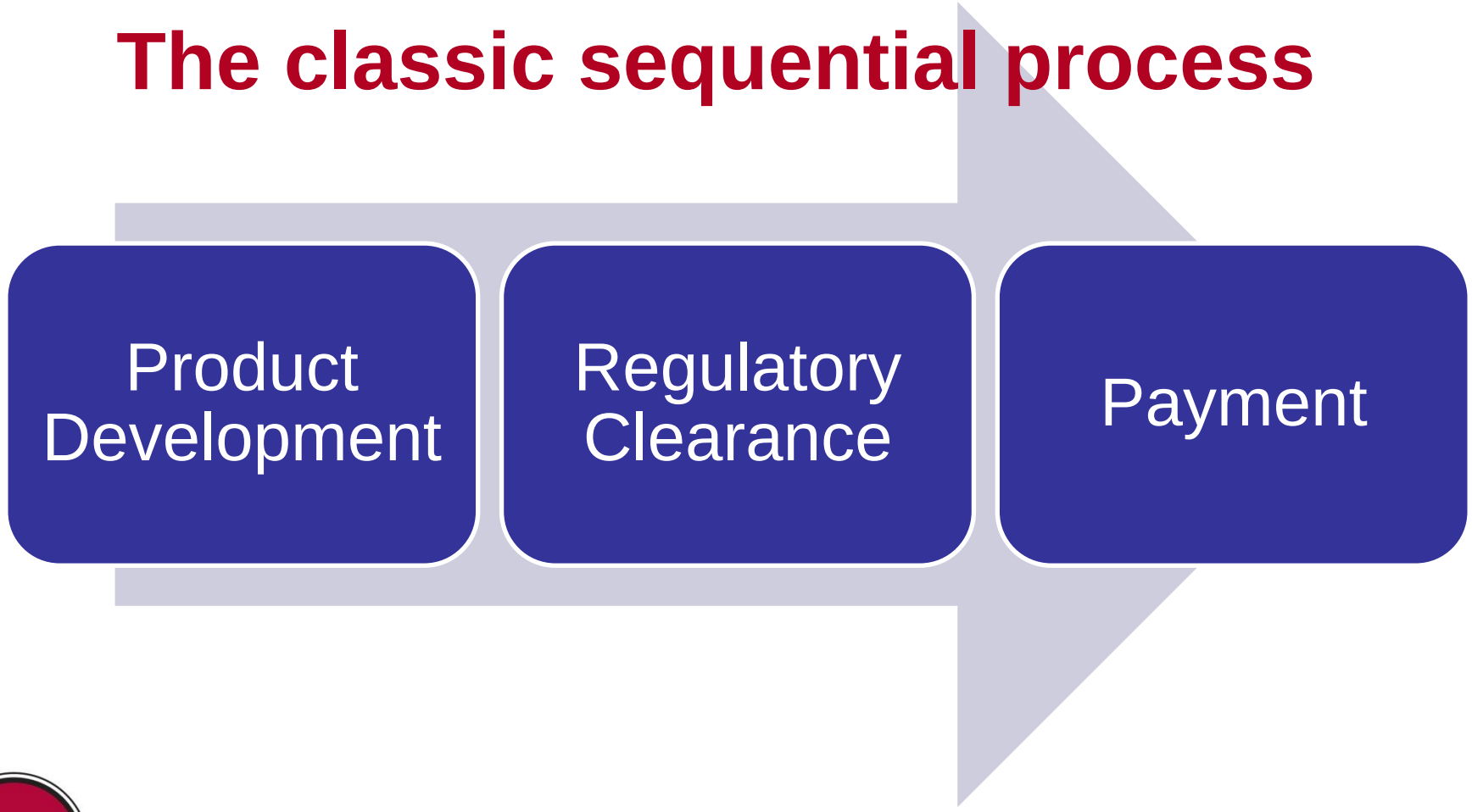
- Medical technologies or therapeutics that effectively address unmet clinical needs, or that clearly improve outcomes, always get reimbursed in the U.S. …

Counter-examples?

- …***If the case is made effectively***
  - Understanding of payers' wants/needs
  - Effective execution of a well-constructed plan
  - Compelling empirical demonstration of value

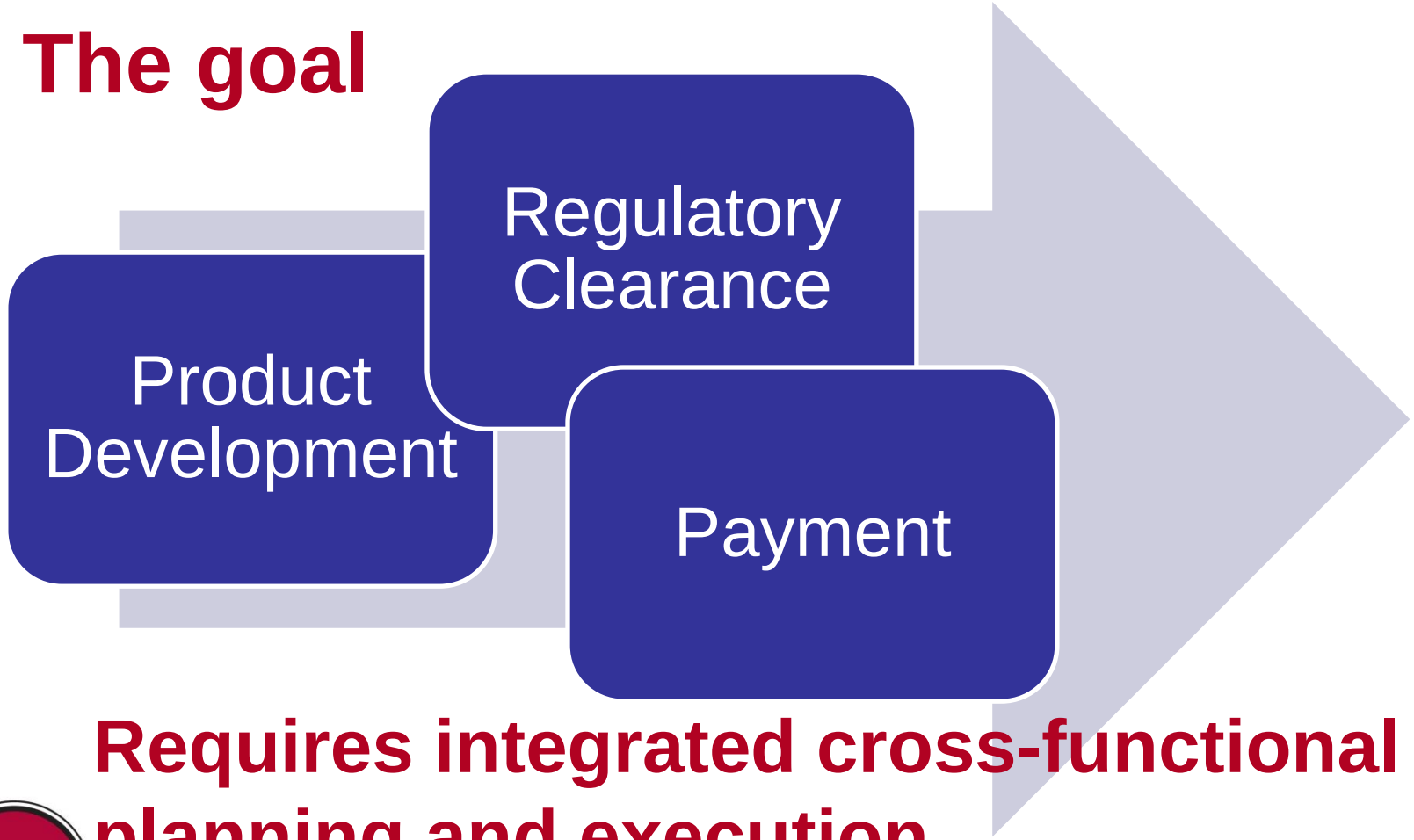
BUT TIME TO REVENUE IS CRITICAL TO SUCCESS

The classic sequential process



A SMARTER PROCESS YIELDS THE SHORTEST TIMELINE TO $$

The goal



Requires integrated cross-functional planning and execution

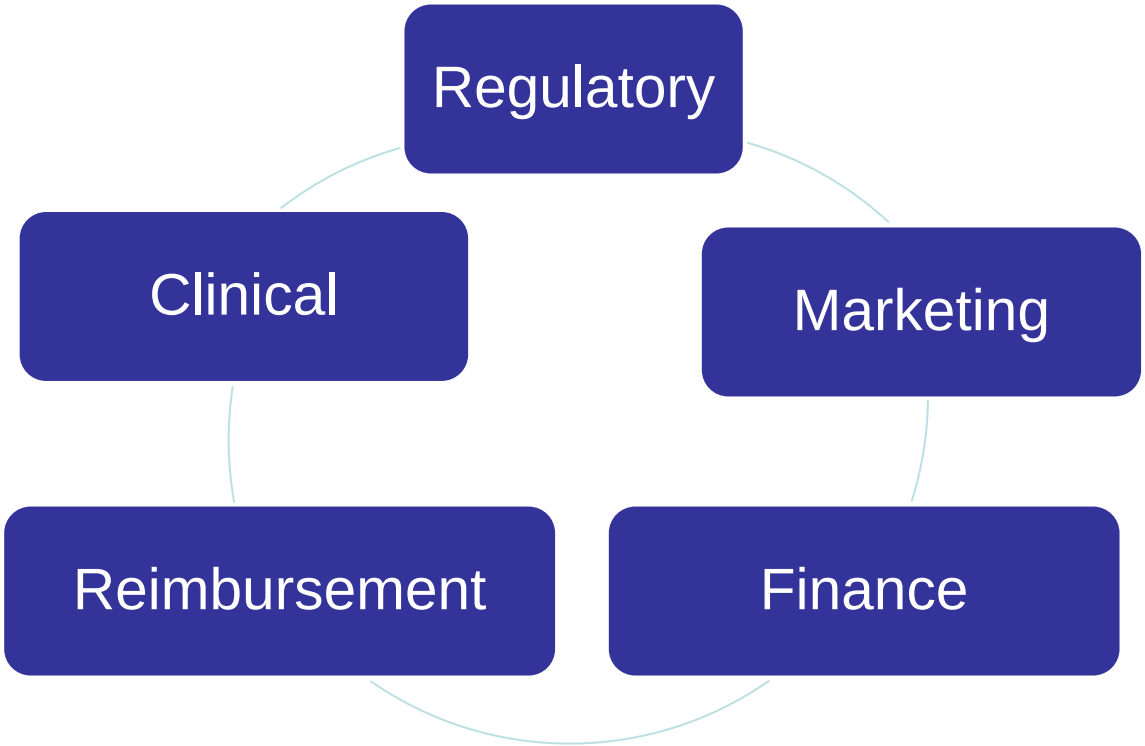
COMMUNICATE EARLY, FULLY AND OFTEN WITH FDA, CMS, KOLs

- Open communication channels are beneficial
  - You won't be surprised by their requirements
  - They'll know what is coming and be appropriately educated and prepared to make decisions
  - A comfortable trusting relationship can only be a good thing
- Treat them as allies, not as adversaries

REIMBURSEMENT REQUIRES MORE THAN "BLOCKING AND TACKLING"

- A good reimbursement expert can
  - Characterize the landscape
  - Develop a reimbursement strategy and plan
  - Execute on all four elements
- But that isn't enough
  - You'll eat up time and run out of money before anyone will pay for your product if reimbursement is an isolated function

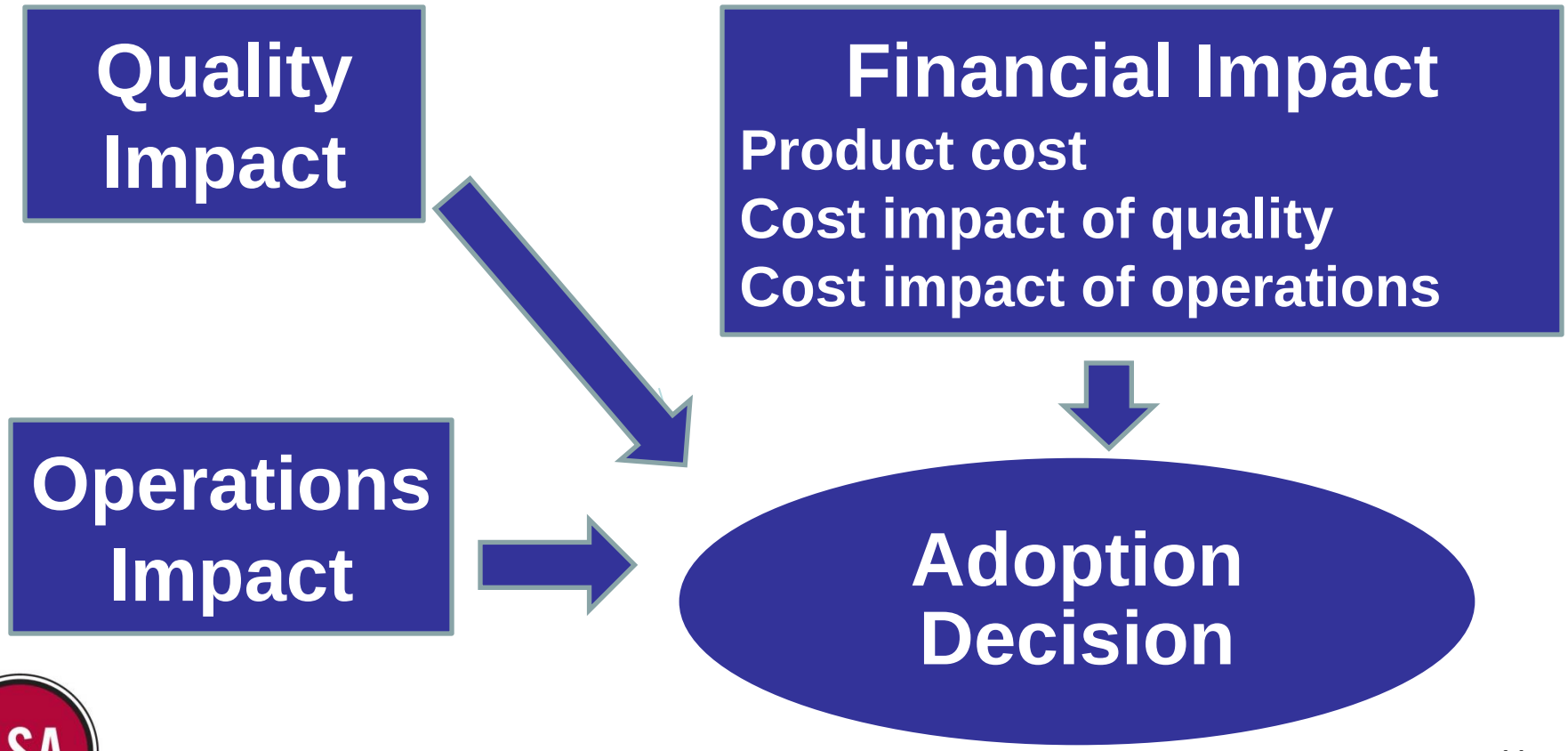
REIMBURSEMENT MUST BE A SEGMENT OF AN INTEGRATED BUSINESS PLAN



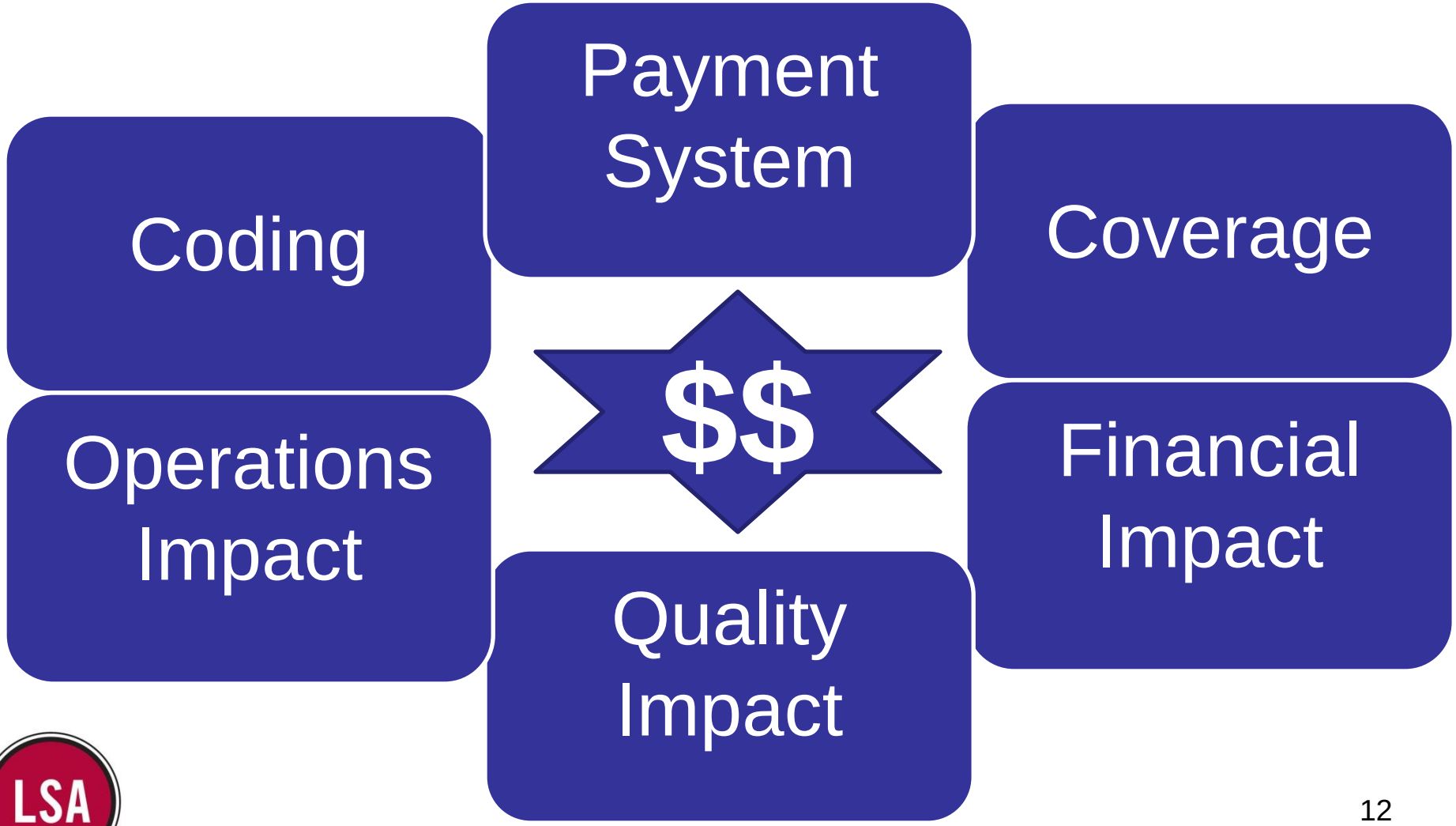
Optimize timeline and resource utilization

BILLABLE PRODUCT/SERVICE OR EXPENSE LINE ?

Expense line considerations



BILLABLE PRODUCT/SERVICE RAISES THE COMPLEXITY LEVEL



INFORMATION IS THE KEY TO OPTIMIZING REIMBURSEMENT

- Understand where your product fits into the health care landscape
  - Reimbursable or expense line
  - Self-pay or insured
  - Dominant payment model
    - Fees-for-service or capitation/quality contract
  - Site of care and applicable payment system and amount
  - Evidence payers and users will require
    - Look to cognate therapies and technologies

INSURER COVERAGE DECISIONS ARE DATA DRIVEN

Health technology assessments (HTAs)

- AHRQ
- Hayes, Inc.
- BCBS TEC
- ECRI
- HealthTech

Online databases of coverage policies, including:

- CMS
- Cigna
- Aetna
- United

PROVIDER ADOPTION/UTILIZATION DECISIONS ARE ALSO DATA DRIVEN

- Empirical data re: clinical effectiveness
- Professional society practice guidelines
- Personal experience
- Financial incentives cannot be discounted
  - Fee-for-service rewards higher volumes
  - Capitation rewards cost efficiencies
  - Penalties or add-ons for protocol adherence and/or quality metrics

CLINICAL UTILITY IS THE TOUCHSTONE FOR COVERAGE AND ADOPTION

- …but there is no common operating definition
  - "Reasonable and necessary" standard is not the same as FDA's "safe and effective"
- Incremental clinical benefit is key
  - Reinforced by recent CER initiatives
- Cost will always enter the equation
  - Overtly or covertly
    - More rigorous analysis for high cost technologies

COVERAGE POLICIES ARE INCREASINGLY REFINED

- Diagnostic tools allow identification of subgroups likely to benefit from specific treatments
  - Companion diagnostics model for drug testing trades off between market size and success probability; Device analogs are emerging
- High-cost therapies getting placed into a sequential hierarchy of interventions…
  - …for patients who fail a trial of…

COVERED SERVICES GET REIMBURSED, BUT HOW MUCH?

- Billing codes translate into payment amounts
- A well-defined and executed coding strategy is essential
  - Identify and evaluate existing codes
    - “fit” and “adequacy of payment”
  - If new code is needed, understand the process - requirements and timelines
  - Use “unlisted procedure” code in interim
    - Administrative burden on company and customers

CODING IS ADMINISTRATIVELY COMPLEX AND RIGID

- Multiple coding systems mandated for different purposes
  - CPT, ICD-9 / ICD-10, HCPCS
  - Each controlled by a different organization
    - Overlapping but not always synched
  - Each with distinct application processes, requirements, lengthy review cycles and implementation schedules
- Careful planning and execution is essential

MEDICARE PAYS UNDER FIXED RULES, CODES DICTATE PAYMENT GROUP / $$

Acute Hospitals
MS-DRGs

Outpatient Hospital
APCs

Physician Fee Schedule
RVUs

Clinical Laboratory
Fee Schedule

Ambulatory Surgery
Centers

DME Fee Schedule and
Competitive Bidding

Capitation Contracts
Medicare Advantage / Pioneer ACOs

LSA

PRIVATE INSURERS HAVE MANY WAYS OF SETTING PAYMENT LEVELS

- Rate schedule mirroring Medicare
- Negotiated rate w/ provider
- Prevailing charge
- Disease-management contract
  - With or without carve-out
- Inclusion in capitated rate

Each method creates distinct incentives

PROVIDERS CAN NEGOTIATE WITH PRIVATE INSURERS

- Need clinical and financial data to support highest attainable payment level
  - Efficacy and safety relative to therapeutic alternatives
  - Cost relative to therapeutic alternatives
  - Impact on total cost of care
    - Complication rates, follow-up care
- Insurers will pay to incent adoption of cost-saving technology

OVERALL FOCUS ON CLINICAL VALUE

- A growing segment of care is subject to per capita or per episode fixed payment
- Increasing rewards for delivering good quality at an attractive price
  - Accountable Care Organizations (ACOs); Medicare Shared Savings; Medicare quality indicator / meaningful use requirements
- Care protocols reflect “Quality ROI” consideration not present in fee-for-service

HOSPITALS AND PHYSICIAN GROUPS KNOW THE FINANCIAL SCORE

- Medicare and total operating margins
  - By department, DRG, APC, or visit type
  - For each identifiable diagnosis, service, surgical procedure, etc.
- They invest in winners, disinvest in losers
  - But $$ benefit of reputation and clinical leadership counterbalance narrow $$ impact
- Successful companies create new winners for hospitals and medical groups

Thank You

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