

Bundled Payments: An Overview of the Antitrust, Regulatory, Contracting and State Law Issues

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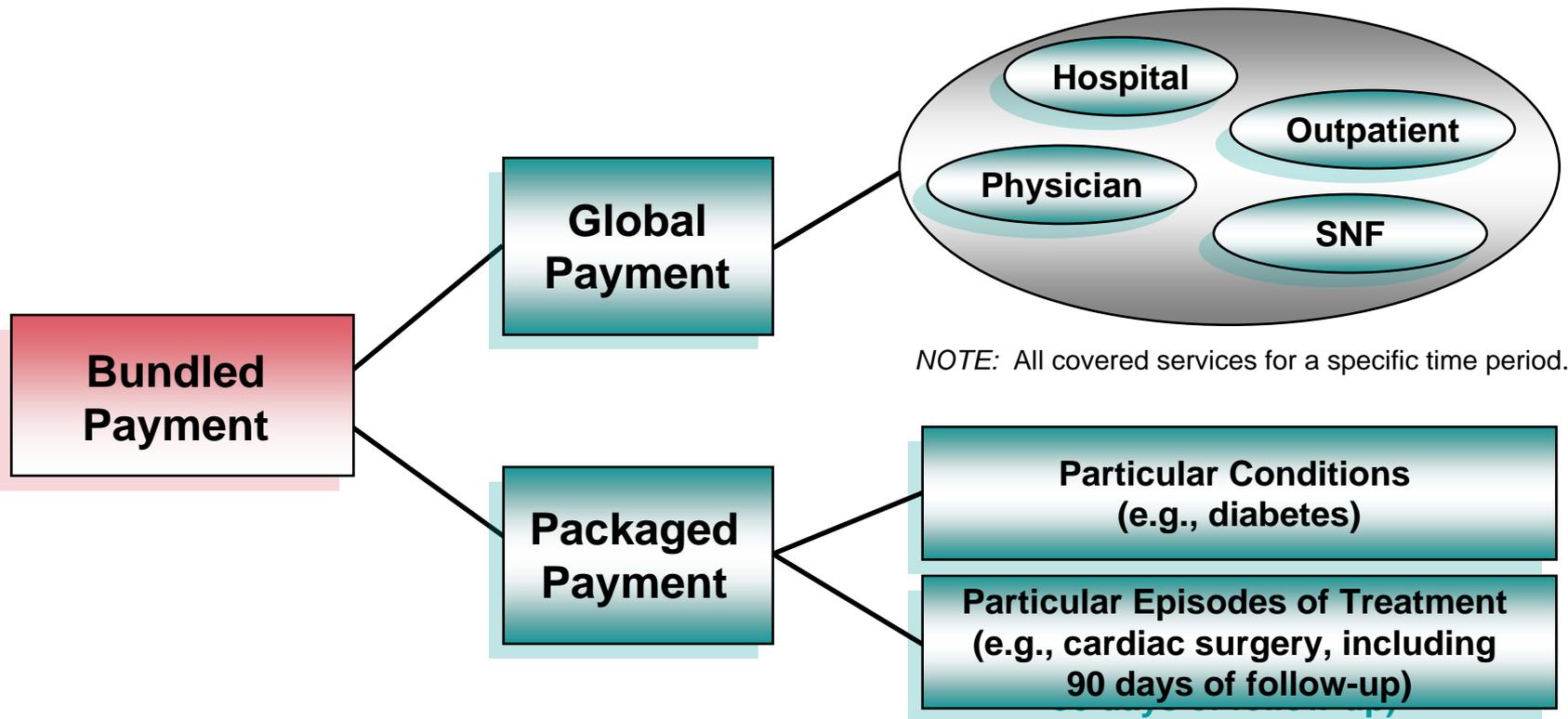
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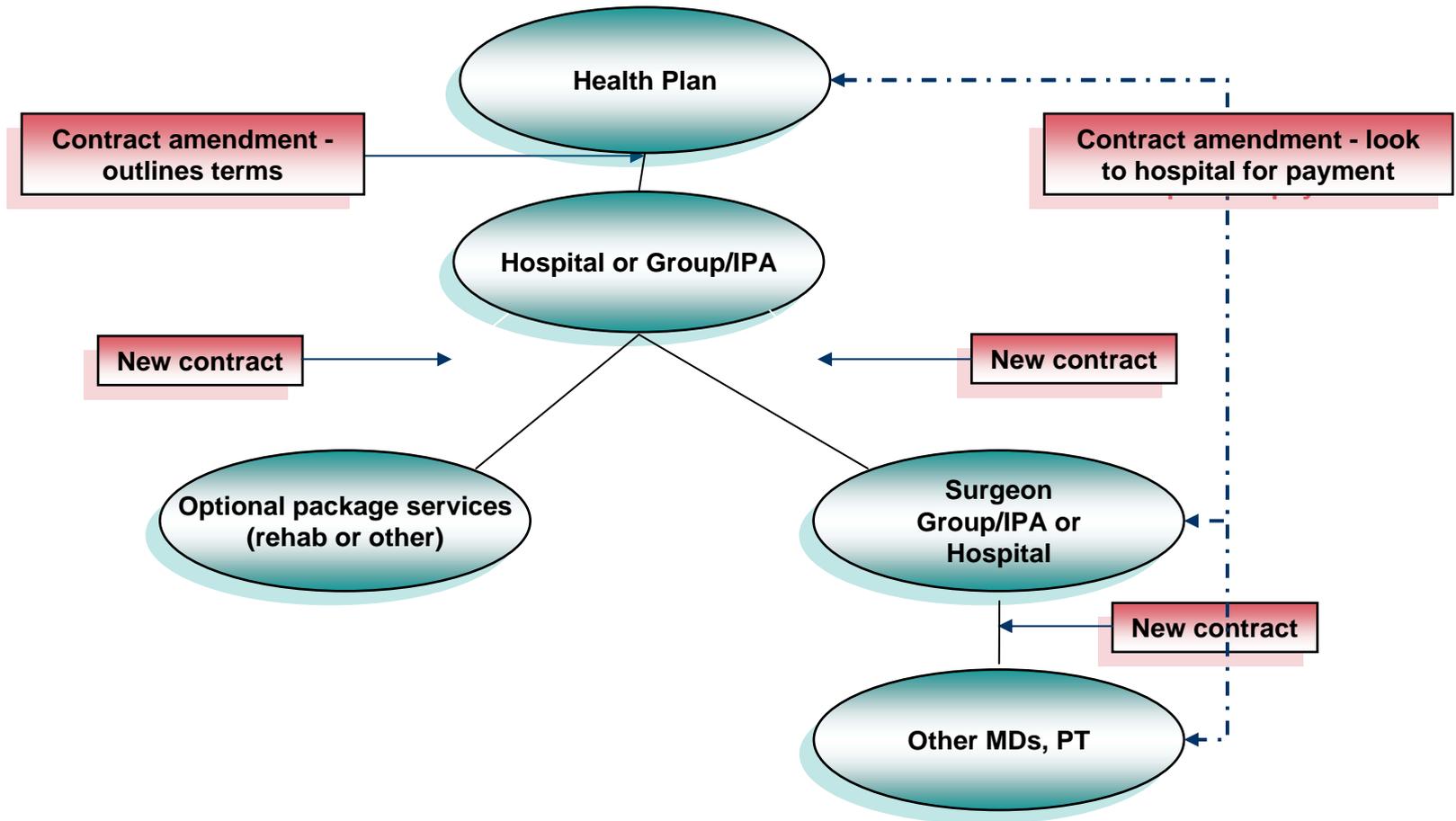


Bundled Payment Models

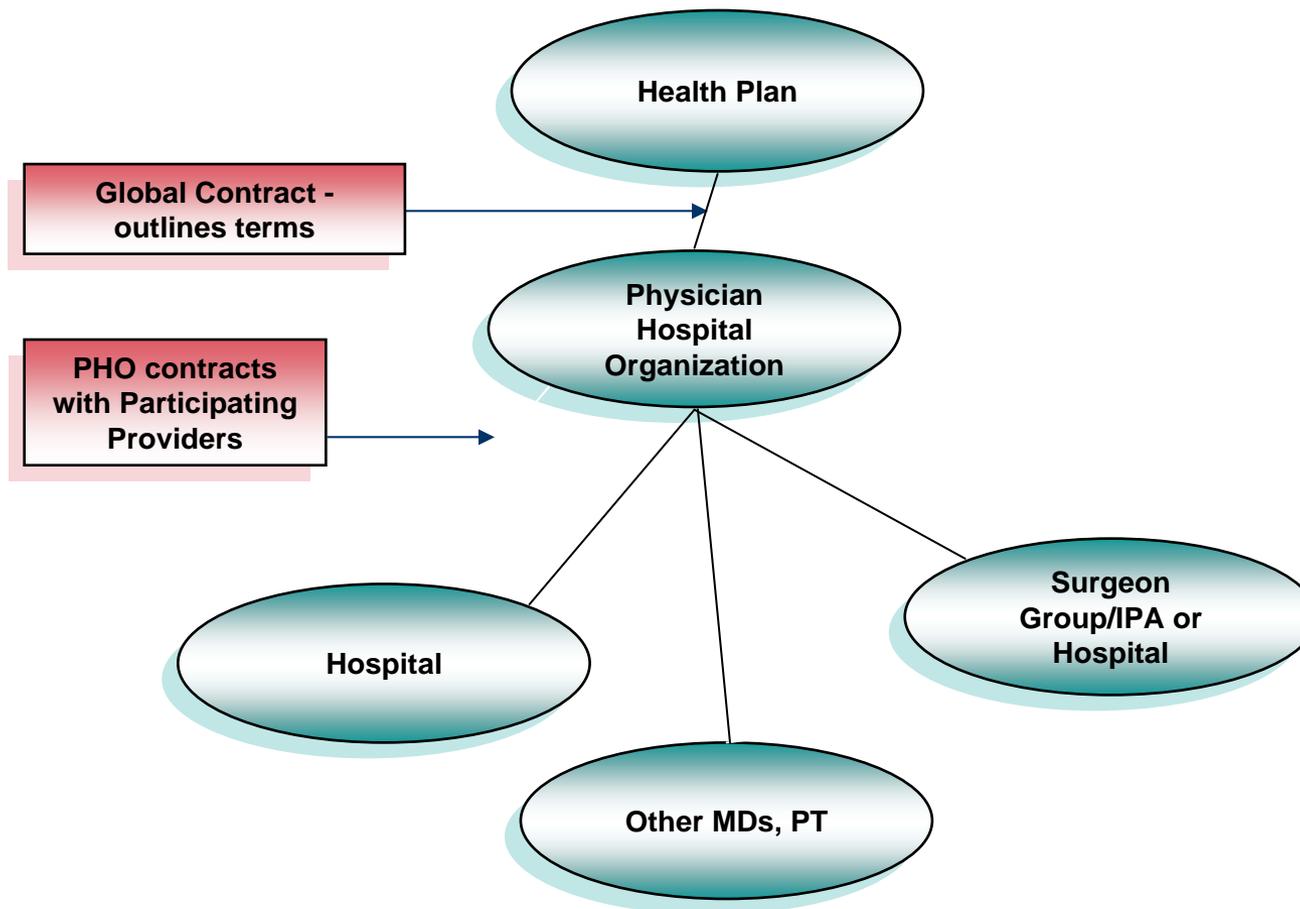
The term “bundled” describes a wide range of payment models. It often refers to a payment that encompasses more than one provider’s services or an entire patient encounter, including global and packaged payments.



Bundled Payments: Contract



Bundled Payments: PHO



Bundled Payments

- **Pay for Performance**

(e.g., quality, patient satisfaction, good citizenship)

- **Pay for Savings**

(sometimes referred to as “gainsharing;” e.g., cost savings, standardization, efficiency)

Gainsharing

Hospital pays percentage of resulting savings to physicians

- Product substitution - routine use of less costly agents, medications, etc.
- Product standardization - routine use of specified devices and supplies, e.g., stents, catheters, diagnostic devices, contrast agents, etc.
- Elimination of routine use of specified products or services (“use as needed”)

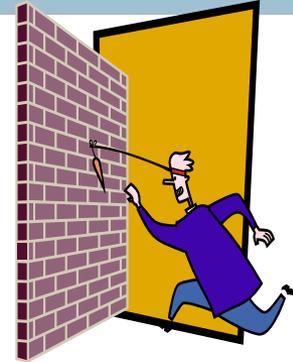
And the law...

- Physician Incentive Plan Law— “Gainsharing CMP”
- Stark Law
- Anti-Kickback Statute
- State Law Restrictions
 - Corporate Practice of Medicine
 - Fee Splitting
 - Insurance/Risk Regulation
 - State Self-Referral and Kickback Statutes
 - Tax
- Antitrust

Gainsharing CMP: The Hospital “PIP law”

- Prohibits a **hospital** from knowingly paying, directly or indirectly, a physician **to reduce or limit services** provided to Medicare or Medicaid patients under the physician’s direct care
- Penalty of \$2,000 for each affected Medicare or Medicaid patient
- Gainsharing CMP has been broadly interpreted by OIG—applies to payments to induce reduction of medically unnecessary care
- Payments to reduce costs have been equated with payments to reduce care
- **HOWEVER:** Gainsharing CMP applies only to Medicare and Medicaid FFS
- For managed care there is a separate PIP law that applies at the health plan level

Gainsharing - Regulatory Review



- 1999 OIG Special Advisory Bulletin on Gainsharing
 - <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.ht>
 - Effectively halted the development of gainsharing programs in the short run
- In a series of subsequent Advisory Opinions the OIG identified the characteristics of acceptable Gainsharing programs
 - Transparency
 - Clinical Support
 - Uniform application subject to cap
 - Protections against inappropriate reductions in care
 - Written disclosure to patients
 - Reasonable compensation
 - Per capita distributions

OIG Advisory Opinion No 08-16

The professional limited liability corporation (PLLC) model allowed the hospital to pay select physicians for attaining hospital quality targets.

Key Elements of OIG Advisory Opinion No. 08-16

- The PLLC participation was open to a broad group of medical staff members
- Participating physicians were required to be members of the medical staff for at least 1 year
- Participating physicians equally capitalized the new entity, although costs were minimal
- The hospital paid the PLLC to meet predetermined quality targets
- Payments were capped at 50% of base-year P4P dollars (with inflation adjuster)
- Quality targets and payments renegotiated annually
- Monitoring in place to protect against inappropriate service reduction
- Physicians who change referral patterns to meet targets could be terminated
- The program maintained records of performance
- Patients informed of the program in writing
- The PLLC set physician participation criteria that did not induce referrals or incentivize more volume at the hospital

Stark Law

The Basic Prohibition:

- Stark prohibits a Physician from referring Medicare patients for certain “designated health services” to an entity with which the physician has a financial relationship unless an exception applies . . .
- If a physician makes a referral prohibited by Stark then the entity providing designated health services pursuant to the referral may not bill the Medicare program for such services



Stark Law – Possible Exceptions

- Bona Fide Employment
- Personal Service Arrangements (physician incentive plan)
- Fair Market Value Arrangements
- Indirect Compensation Arrangements
- Prepaid Plans
- Risk Sharing Arrangements

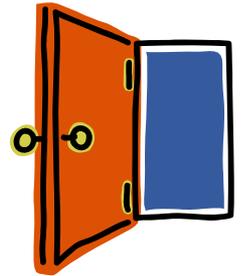
Volume or Value Of Referrals

- Many Stark exceptions require that the compensation not vary with the volume or value of referrals or other business generated between the parties
- This requirement often makes it difficult to pay based on reductions in cost of services or the achievement of efficiencies
- Note, however, payments on a per service or per patient basis are deemed not to be based on the volume or value of referrals



Favorable Exceptions

- The Stark exceptions most likely to be helpful in establishing a bundled payment program:
 - Employment
 - Indirect Compensation Arrangements
 - Risk Sharing Arrangements



Anti-Kickback Statute

Broad Criminal Prohibition on Payment for Referrals

Applies to person receiving kickback:

“(b)(1) Whoever knowingly and willfully **solicits or receives** any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

- (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program”

Anti-Kickback Statute (cont'd.)

And to the person offering kickback:

- “(2) Whoever knowingly and willfully **offers or pays** any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
 - (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program”

Anti-Kickback Safe Harbors

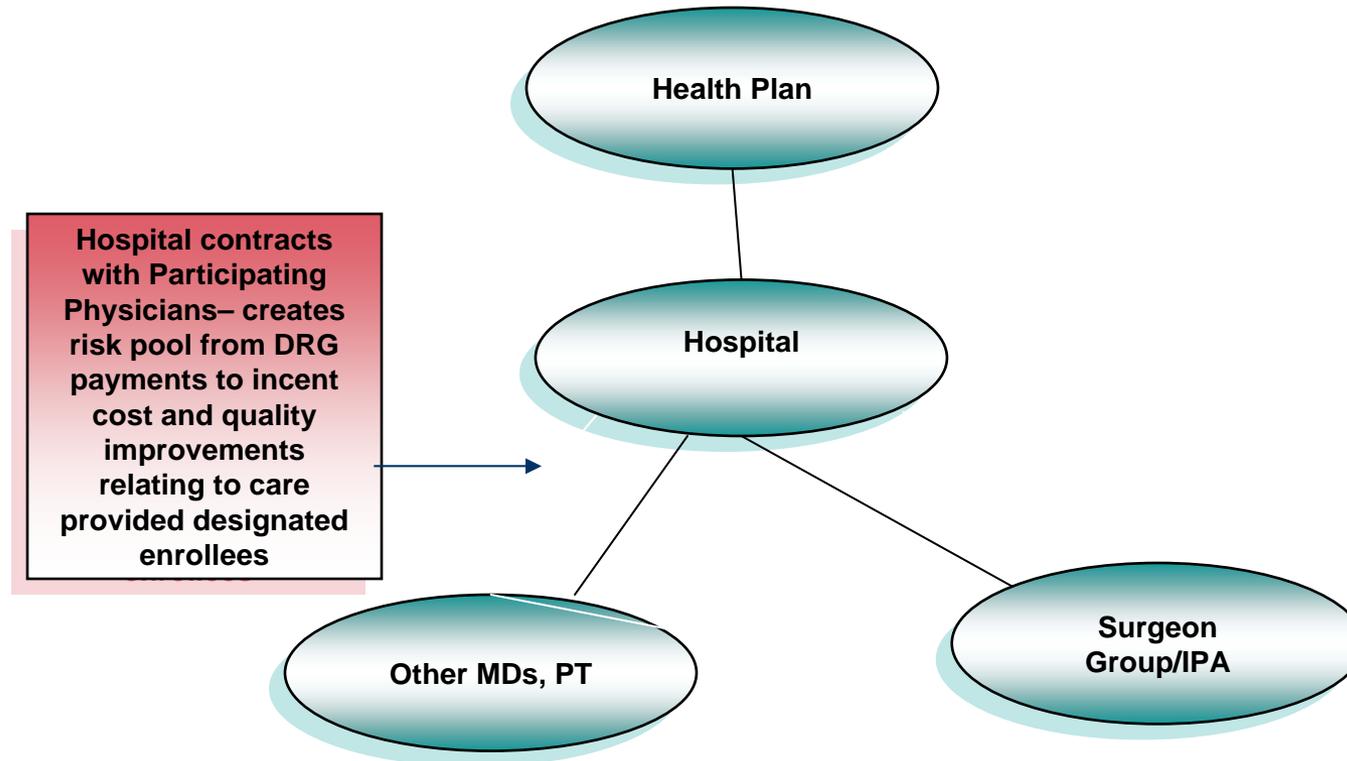
- Bona fide Employment Relationships
- Personal Services Arrangements
- Provider Discounts to Health Plans
- Provider Discounts to Managed Care Plans
- Risk Sharing Arrangements
- NOTE: Unlike Stark compliance with safe harbors not required



Commercial Bundled Payment Model: A way forward

- Program Limited to Commercial Enrollees—
 - But can use single structure for all commercial and self-pay
- Can be implemented by hospital and physicians without payor cooperation—
- Can use a PHO or administer through contracts
- Lots of flexibility on incentives, terms, structure
- Problem: Potential “spill over” effect for Medicare/Medicaid business?
- Problem: Medicare Secondary Payor issues?

Commercial Bundled Payment Model



Legal Constraints?

- Anti-kickback Statute
 - No Medicare/Medicaid fee for service
 - Some risk of a “pull through” claim—use of arrangement to pull through federal program referrals
 - Can minimize exposure by adopting some of the OIG advisory opinion safeguards
- Gainsharing CMP
- Inapplicable b/c no Medicare/Medicaid
 - Caution---Spill over effect?
- Stark - ??

Stark Risk Sharing Exception

Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians' association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan...

Enrollee is an individual who has entered into a contractual relationship with a health plan . . .

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees . . .

CMS Broadly Interprets Exception

CMS Commentary:

The new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or Independent Practice Association (IPA), provided the arrangement relates to enrollees and meets the conditions set forth in the exception. All downstream entities are included. We purposefully declined to define the term “managed care organization” so as to create a broad exception with maximum flexibility.

Stark Analysis for Commercial Bundled Payment Model

- Hospital is at risk for fixed hospital payment from plan
- Hospital is downstream of plan (downstream contractor)
- Hospital is managing hospital care (MCO itself)
- Hospital is sharing risk of its payment with physician for care to plan enrollee
- Payment is a covered bonus

State Law Considerations

- **Corporate Practice of Medicine**
 - Generally prohibits a lay entity from holding itself out as “practicing medicine” or employing a physician to provide professional medical services absent specific authorization
 - May impact whether bundled payment arrangement involves new entity or contractual model
 - Some states’ CPoM prohibition limits physician-hospital ownership of entity that provides or arranges for the provision of care
 - Does arrangement impinge upon professional’s clinical judgment?

State Law Considerations



- Fee Splitting
- In General
 - Prohibits physicians from splitting fees for professional services with any person for referring patients – can be tied to CPoM
 - Bundled payment model may implicate prohibition
- State Variation
 - Broad:
E.g., Florida - prohibits engaging in any split-fee arrangement in any form whatsoever
 - Specific:
 - May prohibit fee-splitting among certain provider types (PTs and MDs; MDs and labs)
 - Non-statutory:
 - Medical Board Advisories or Position Statements, AGOs
- Like CPoM, application will vary broadly state to state

State Law Considerations

- State Insurance/Risk Regulation
 - Does state insurance/managed care law allow the assumption of risk by a provider for services it doesn't provide?
 - Are health plan or managed care organization licensing or registration requirements triggered?
 - Requirements for downstream risk assumption?
 - Are “any willing provider laws” triggered?

State Law Considerations

- State Insurance/Risk Regulation (con't)
 - Regulation of financial solvency (reserves/reporting)
 - Consumer protections / heavy regulation of capitated products
 - Minimum benefit requirements
 - Carve-out for self-funded insurance (ERISA plans)

State Law Considerations

- State Self-Referral, Kickback and Fee Splitting Statutes
 - Does state law apply to the arrangement?
 - Many laws are “all payor” or cover beneficiaries from multiple payor sources
 - May be implicated by services other than Stark “DHS”
 - Does a favorable exception exist under state law?
 - Does state law mirror federal law such that a federal waiver will help?

State Law Considerations

- State Tax Considerations
 - Understand tax treatment of revenue stream
 - State income tax exemption
- Other
 - Scope of practice?
 - Antitrust?
 - Certificate of need?

Bundled Payments

CMS Initiatives

- **Medicare Acute Care Episodes (ACE):**
 - 3 year demonstration projects focusing on episodes of care for specified cardiovascular and/or orthopedic procedures
 - Limited geographic scope
- **Bundled Payments for Care Improvement Initiative (new)**
 - Separate from National Pilot Program on Payment Bundling required by Section 3023 of Affordable Care Act
 - Undertaken by Centers for Medicare and Medicaid Innovation (CMMI)
 - Providers invited to help test and develop four different models of bundling payments (retrospective and prospective)

Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

■ Model 1:

- Episode of Care = inpatient stay in a general acute care hospital
- Hospital will be paid a discounted IPPS rate and physicians will be paid separately under the fee schedule
- Discount rate to be proposed by applicant but CMS requires minimum of 0% in the first six months, rising to 2% in the third year
- Hospital and physicians would be able to share in any savings achieved

Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

▪ Model 2:

- Episode of Care = inpatient stay + post-acute care for a minimum of 30 or 90 days after discharge
 - Episode definition at provider's election but CMS will give preference to applicants proposing an episode definition longer than 30 days
 - Applicants to propose the clinical conditions targeted
- Includes physicians' services, post-acute care services, related readmissions and other services defined in the bundle
- Minimum discount to CMS will be 3% for the 30- to 89-day period after discharge, and 2% on and after day 90
- At the end of the episode, providers share in the amount by which total payments were less than the target price; if total payments exceed the target price, provider will be responsible for paying the overage to CMS

Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

■ Model 3:

- Episode of Care = begins the day the patient is discharged from the hospital and ends no sooner than 30 days after discharge
 - Episode definition at provider's election but CMS will give preference to applicants proposing an episode definition longer than 30 days
 - Applicants to propose the clinical conditions targeted
- The bundled payment methodology is structured as in Model 2
- No specified minimum discount rate

Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

▪ Model 4:

- This model contemplates prospective payment for an inpatient stay
- Payment of a single fixed amount for all services by all providers during the stay
- Hospital (or some designee) pays physicians and all other providers out of the bundled payment and providers submit "no pay" claims to Medicare for record-keeping purposes
- Minimum discount to CMS - 3% of projected total costs for the episode of care

Gainsharing Waiver – to be defined

Bundled Payments

	MODEL 1: Inpatient Stay Only	MODEL 2: Inpatient Stay plus Post-Discharge Services	MODEL 3: Post- Discharge Services Only	MODEL 4: Inpatient Stay Only
Services Included in Bundle	Inpatient hospital services	Inpatient hospital services Physician services Related post-acute care services Related readmissions Other services defined in the bundle	Post-acute care services Related readmissions Other services defined in the bundle	Inpatient hospital services Physician services
Discount to Government	To be proposed by applicant CMS requires minimum discounts increasing from 0% in first six months to 2% in 3 rd year	To be proposed by applicant CMS requires minimum discount of 3% for 30-89 days post-discharge episode, and 2% for episodes of 90 days or longer	To be proposed by applicant	To be proposed to applicant Subject to minimum discount of 3% Larger discount for MS-DRGs in ACE Demonstration
Payment from CMS to Providers	Acute care hospital: IPPS payment less pre-determined discount Physician: Traditional fee schedule payment (not included in episode or subject to discount)	Traditional fee-for-service payment to all providers and suppliers, subject to reconciliation with predetermined target price	Traditional fee-for-service payment to all providers and suppliers, subject to reconciliation with predetermined target price	Prospectively established bundled payment to admitting hospital Hospitals distribute payments from bundled payment
Prospective or Retrospective	Prospective	Prospective	Prospective	Retrospective
Duration	Bundled care agreements will include a performance period of three years, with the possibility of extending an additional two years, beginning with the respective program date. The program start date may be as early as the first quarter of CY 2012 for awardees in Model 1.			

Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

- Letter of Intent (LOIs)
 - Model 1: October 6, 2011 (date changed)
 - Models 2-4: November 4, 2011
 - Can submit one LOI if proposing more than one of Models 2-4
- Application deadlines
 - Model 1: November 18, 2011
 - Models 2-4: March 15, 2012



Bundled Payments

CMMI Bundled Payments for Care Improvement Initiative

▪ Helpful links

- Bundled Payments for Care Improvement Initiative Request for Application
 - http://www.innovations.cms.gov/documents/payment-care/Request_for_Application_v2.pdf
- Bundled Payments for Care Improvement Initiative FAQs
 - http://www.innovations.cms.gov/documents/payment-care/Bundled%20Payments-FAQs_updated_09-09-11_revised_Final_Compliant.pdf



Antitrust Issues

- Potential concern: joint price negotiations among competitors
 - Naked price fixing = per se illegal
 - Civil penalties
 - Criminal penalties
- Solution: Integration

Antitrust Solutions

- Integration
 - Financial integration
 - Clinical integration
- Rule of Reason Analysis
 - Balance harm to competition with procompetitive efficiencies
 - Not a “safety zone” or immunity: still fact-dependent

Sources of Guidance

- DOJ & FTC, Statements of Antitrust Enforcement Policy in Health Care, Statements 8 & 9 (1996)
- Agency Review
 - DOJ Business Review Letters
 - FTC Advisory Opinions
 - Obtain review for proposed payment network?

Proposed ACO Regulations

- New antitrust guidelines for ACOs
- Do not discuss bundled payments
- Could provide some guidance
- FTC Chairman Liebowitz to AMA, June 2010:
 - The new health care reform law promotes innovative payment structures that should improve the quality and affordability of patient care. The law addresses the “bundled payments” issue by mandating both Medicaid and Medicare projects which will look at ways to pay when cases involve both hospitalization and related care for a particular diagnosis. The FTC is particularly interested in these projects. In fact, in 1996, we identified bundling as a way a network of competing physicians might share substantial financial risk.

Financial Integration

- Network must assume “substantial financial risk”
 - Capitated rates
 - Percentage of premiums
 - Incentives to achieve specified cost-containment goals
 - Bundled payments

Financial Risk: Incentives

- “Withholding from all provider participants a substantial amount of the compensation due to them, with distribution of that amount to the participants based on group performance in meeting the cost-containment goals of the network as a whole.”
- “Establishing overall cost or utilization targets for the network as a whole, with the provider participants subject to subsequent substantial financial rewards or penalties based on group performance in meeting the targets.”
- Bundled Payment Initiative Models 2 & 3

Financial Risk: Bundled Payments

- “Agreement by the venture to provide a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialities offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors.”
- Bundled Payment Initiative Model 4

What about Model 1?

- Is there “substantial financial risk”?
- Depends on the structure, how much of physician compensation is actually at risk

Clinical Integration

- Alternate route to Rule of Reason analysis
 - does not require financial integration
 - Joint negotiation must be reasonably necessary to obtain efficiencies
- Quality measures likely to require some clinical integration

Clinical Integration

- No “checklist”
- “Can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”
 - Establish mechanisms to monitor and control utilization
 - Selective membership
 - Investment of capital by members
- FTC Advisory Opinions

Market Power

- Ability to raise prices above competitive levels
- Fact-specific inquiry
- Percentage of participating providers
 - Less than 30% = likely little concern
 - Greater than 50% = likely to create concern
 - Count by specialty, not just total provider
 - Preexisting consolidation less of a concern
- Exclusive or not?
 - If exclusive, greater the risk of scrutiny
- New product offering is good

Integration Is Agreement-Specific

- Not a “free-pass” for non-bundled agreements
- No-risk contracts should use messenger model
- Put procedures in place to avoid improper information sharing

Antitrust Compliance Policies

- Independent administrator (i.e., not a participating doctor)
- Keep price information shielded from participants
- Prohibit discussions of certain topics
 - Joint price-setting
 - Market division
 - Refusals to deal with payers

Bundling a Bundle

- Inclusion of bundled payment arrangement in “bundle” of services
- Pricing should not be below cost
 - Predatory pricing
- Availability of bundle should not be conditioned on purchase of other services
 - Tying arrangement