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Compliance Challenges Raised by Value-Based Purchasing

Health Care Compliance Association
New York Regional Meeting

May 11, 2018

What Is Value-Based Purchasing?

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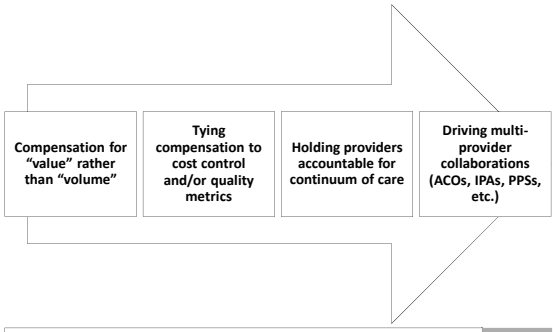

Examples of Government VBP Programs

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Delivery System Reform Incentive Payment Program (DSRIP)	▪ NY Medicaid program operating under CMS waiver ▪ Funds performing provider systems to achieve quality and cost containment goals
Medicare Shared Savings Program (MSSP)	▪ Total cost of care model with caps on shared savings and losses ▪ NextGen model allows providers to take greater financial risk
Bundled Payments for Care Improvement (BPCI)	▪ Procedure-based reimbursement for "episode of care" ▪ Bundles Medicare reimbursement for hospital, physician and post-acute care into single payment
Medicare Access and CHIP Reauthorization Act (MACRA)	▪ Alternative Medicare Part B reimbursement for physician services ▪ Rising portion of compensation tied to quality and cost efficiency metrics

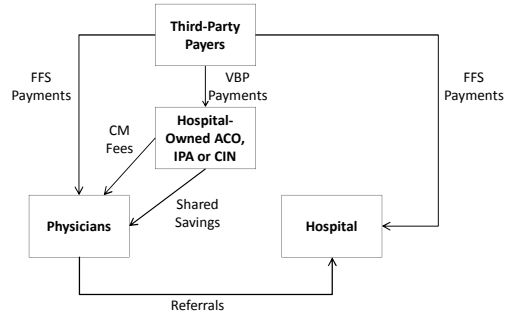
How Does VBP Change Focus of Compliance Programs? 3

Type of Risk	Fee-For-Service Payments	Value-Based Payments
Utilization Risks	Monitor over-utilization driven by volume-based payments	Monitor under-utilization driven by cost containment bonuses
Coding Risks	Monitor upcoding under CPT and other billing methodologies	Monitor HCC and other clinical coding that drives risk scores tied to medical budget targets
Data Integrity Risks	Ensure medical records support billed services	Ensure calculation of quality metrics is accurate
Hospital-Physician Relationships	Assess whether services are FMV based on amount of time/labor required	Assess whether physician share of network benefits aligns with value of contribution
Patient Inducement Risks	Evaluate whether remuneration fits within exceptions/safe harbors	Evaluate whether waivers or VBP rationale support innovative incentive programs

Fraud and Abuse Laws Implicated by VPB Collaborations 4

Statute	Key Restriction
Stark Law	Prohibits a physician from referring a patient for inpatient, outpatient or other "designated health services" covered by Medicare to a hospital or other entity with which the physician has a financial relationship, unless the relationship satisfies a Stark exception.
Anti-Kickback Statute	Makes it illegal for any person to knowingly and willfully exchange remuneration for the referral of a patient for items or services covered by a federal health care program.
Anti-Inducement Law	Prohibits a person from providing remuneration that he or she knows is likely to influence a patient's selection of a provider or supplier for services covered by Medicare or Medicaid.
Gainsharing Law	Prohibits a hospital from knowingly making any payment to induce a physician to reduce or limit medically necessary services covered by Medicare or Medicaid.

Common Financial Relationships in VBP Arrangements 5



Stark Exceptions and AKS Safe Harbors Relevant to VBP

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Stark Risk Sharing Exception	AKS Managed Care Safe Harbor	AKS Health Plan Discount Safe Harbor
Covers any "risk-sharing arrangement" between an MCO or IPA and a physician (either directly or through an intermediary such as a hospital) for services provided to enrollees of a health plan.	Covers payments made by Medicare Advantage or Medicaid managed care contractor (such as hospital or IPA) to providers for delivering or arranging for health care items and services.	Covers discounts on fees offered by providers to health plans or contracting intermediaries.
Should protect shared savings or similar risk-sharing payments from VBP entity to physicians.	Does not protect commercial health plan payments.	Protects only discounts from providers, not shared savings or similar risk-sharing payments.
Does not protect VBP investment relationships or care management fees.	Does not protect VBP investment relationships.	Does not protect VBP investment relationships or care management fees.

Do ACO/IPA/PPS Payments to Physicians Create Indirect Compensation Arrangement Under Stark?

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Indirect Compensation Arrangement Definition	Application to Payments to Physicians
▪ An unbroken chain of financial relationships running from the physician to the DHS entity. ▪ The physician receives aggregate compensation from the entity closest in the chain that varies with, or takes into account, the volume or value of referrals or other business generated by the physician. ▪ The DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physician receives such compensation.	▪ There may be unbroken chain but aggregate compensation test will generally not be met. ▪ Care management fees and FFS payments usually do not vary with volume or value of DHS referrals. ▪ If shared savings is tied to volume or value of DHS referrals, it could create indirect compensation arrangement but should be covered by risk sharing exception.

Unique AKS Fair Market Value Challenges Raised by VBP

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- How is FMV measured when paying for a physician's effectiveness in achieving value-based purchasing goals rather than paying for a physician's time? Are valuation experts adept at performing this type of analysis?
- Will FMV be benchmarked against what health plans pay for comparable services? For example, if a plan pays an IPA a care management fee of $5 PMPM, can the IPA pay a fee of $10 PMPM to physicians?
- Does the IPA's compensation arrangements with physicians have to track the arrangement between the IPA and the health plan? For example, can the IPA assume downside risk from the plan but have a shared savings only arrangement with physicians?

VBP "Preferred Provider" Arrangements

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	Participants Required to Refer Within Network With Limited Exceptions	Participant's Compensation Tied to % In-Network Referrals
Medicare ACOs	Under MSSP rules, ACO participants may not interfere with beneficiary's freedom of choice of providers	MSSP rules do not directly address participant compensation; MSSP waivers may protect these payments
DSRIP PPSs	No targeted rules	No targeted rules
Commercial ACOs and IPAs	Arguably consistent with clinical integration guidance from FTC/DOJ	Emerging trend of tying compensation to cost being replaced by direct tie to in-network referrals?

Beware of "pull through" of referrals outside scope of VBP arrangement

Medicare Shared Savings Program Fraud and Abuse Waivers

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Waiver	Key Terms
Pre-participation Waiver	1. Covers "start up arrangements" pre-dating MSSP participation agreement 2. Good faith intent to participate in MSSP 3. Diligent steps to develop ACO in target year 4. Bona fide determination by ACO governing body that arrangement "reasonably related to purposes of MSSP" 5. Documentation 6. Public disclosure
Participation Waiver	1. ACO participates in MSSP 2. ACO satisfies MSSP governance and management rules 3. Same as items 4-6 in pre-participation waiver
Shared Savings Waiver	Covers distribution of shared savings by Medicare ACO to its participants

Ambiguity Regarding When MSSP Waivers Apply to Other VBP Arrangements

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"Although we are not providing a specific waiver for private payer arrangements at this time, we believe avenues exist to protect flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements 'downstream' of commercial plans (for example, arrangements between hospitals and physician groups) from qualifying for the participation waiver ... The participation waiver does not turn on the source of the funds for the arrangement."

"Arrangements with similar purposes but that are unrelated to the Shared Savings Program are not covered by the term 'purposes of the Shared Savings Program.' Arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waiver."

Preamble from CMS on MSSP Waivers, 76 Fed. Reg. 67992 (11/2/2011)

There are no federal Stark or AKS waivers applicable to DSRIP!

VBP Under-Utilization Risks

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Type of VBP Program	Potential Risk
Total Cost of Care Tied to Shared Savings/Losses	Reduction in medically necessary hospital admissions, lab tests, imaging services, specialty referrals, etc.
BPCI and similar bundled payment arrangements	Improper discharge of patients to home rather than skilled nursing facility
Hospital-physician gainsharing	Medically inappropriate early discharge of patient from hospital by physician
Medical group capitation	Inappropriate diversion of patients from practice to specialists or emergency room

Provider Quality Data Reporting Risks

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- Provider compensation from Medicare increasingly tied to quality metrics
  - Hospital VBP
  - Home health VBP
  - MACRA
- Health plans providing enhanced compensation or bonuses tied to HEDIS and QARR measures
- Inaccurate reporting of quality data can affect payment
  - Inaccurate coding of claims
  - Inaccurate medical chart reviews
  - Data maintenance and integrity issues

Provider HCC Coding Risks Tied to VBP

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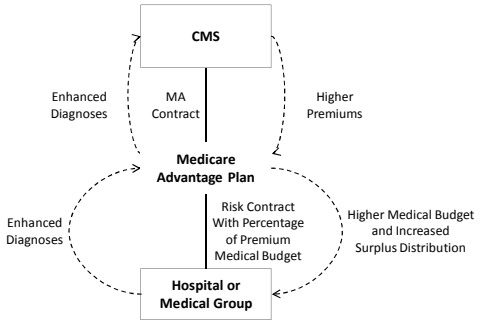

Health Plan VBP Risk Areas

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- **VBP reporting**. Medicaid managed care plans must report amount of payments tied to Level 1, 2 and 3 VBP arrangements, which may lead to premium bonuses or penalties. VBP level of contract and associated VBP dollars may not always be clear.
- **MA quality data reporting**. Reported data drives Star ratings, which impacts payments and convey other benefits to MA plans.
- **PIP rule**. Medicare Advantage and Medicaid managed care plans must ensure that stop loss insurance is in place for physicians who assume "substantial financial risk" for the cost of referral services.
- **HCC coding**. Medicare Advantage plans face primary FCA risk for HCC coding errors. Risk heightened by use of targeted initiatives or outside vendors to identify under (but not over) coding.

Allocation of Compliance Responsibility Under DSRIP

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"PPS Leads are not responsible for network providers' individual compliance programs that may be required in connection with their status as a servicing provider. Likewise PPS Leads cannot be responsible for how network providers use their respective DSRIP distributions, but PPS Leads must have adequate processes in place (such as an effective compliance program) to be able to identify when network providers obtain DSRIP distributions in a way that is inconsistent with approved DSRIP project plans."

OMIG DSRIP Compliance Guidance

PPS Lead Responsibilities for Key Compliance Program Elements Under DSRIP

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Reporting	Training	Policies and Procedures	Auditing and Monitoring
Reporting of compliance issues identified may be made directly to the PPS Lead's Compliance Officer or through compliance liaisons within the network.	PPS Lead is responsible for designing or approving training, but training may be carried out by network providers if provision of training is verified by PPS Lead.	PPS Lead policies must apply to all network providers. Network providers may supplement with policies that do not conflict with those of PPS Lead.	PPS Lead's risk assessment as well as auditing and monitoring must include network providers' performance and progress toward achieving DSRIP milestones.

OMIG DSRIP Compliance Guidance

ACO Compliance Responsibilities Under MSSP

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"Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS …"

42 CFR 425.314(c)

Considerations in Allocating Compliance Program Responsibilities Under VBP Arrangements

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Benefits of PPS/IPA/ACO Assuming Compliance Responsibilites	Risks of PPS/IPA/ACO Assuming Compliance Responsibilities
▪ Entity with greatest resources can ensure compliance ▪ Opportunity to standardize compliance approach across network to establish "community standard" ▪ Organization in best position to learn from challenges and mistakes across network ▪ Direct recipient of funds may have heightened legal duty ▪ Deep pocket may face liability in any event	▪ Lead entity may not be best positioned to monitor activities of participants ▪ External oversight may create resentment and resistance at individual provider level ▪ "One size fits all" approach to compliance may not be appropriate ▪ Assumption of responsibility may create liability for lead entity that would not otherwise exist

Self-Disclosure in Multi-Provider VBP Arrangements

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Entity receiving VBP payments from government or health plan may not be party directly responsible for relevant conduct.

- *Who should submit self-disclosure?* Could be billing entity, responsible entity or both.
- *Who should control content of self-disclosure?* Both entities may feel legal duty to self-disclose or want to control submission. Cooperation between entities is essential; single submission is generally preferable. Conflicting characterizations of incident will heighten scrutiny and prolong inquiry.
- *Who should repay funds resulting from self-disclosure?* May depend on agency receiving self-disclosure. Indemnification possible if billing entity must issue refund but other entity is responsible.

Questions?

Robert Belfort
Manatt, Phelps & Phillips, LLP
7 Times Square
New York, NY 10036
(212) 830-7270
rbelfort@manatt.com