

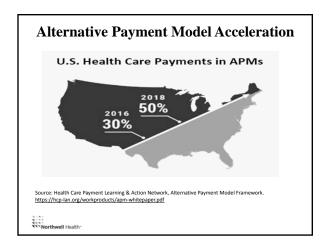
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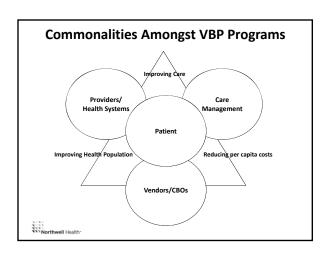
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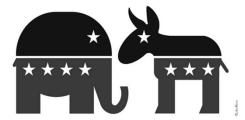
VBP Background







The U.S. Election's Impact on VBP



Key VBP Fraud and Abuse Laws

- •False Claims Act
- Anti-Kickback Statute
- Stark
- Civil Monetary Penalties
- Gainsharing law
- Beneficiary inducement



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FCA Cases Impacting VBP

- False reports or certifications (e.g., quality, annual compliance and data certifications)
- Incorrect information submitted during the performance year must be corrected before the recertification
- · Violations of Stark law, AKS, and CMPL
- Failure to return identified overpayments within 60 days
- Subpar "Quality of Care" cases





Sampling of Other Risks in VBPs



- $\bullet \, Data \, \, integrity P4R$
- Funds flow
- Data Use Agreements and privacy
- Antitrust
- Tax exempt
- Fee splitting/Corp. practice of medicine
- Intermediary network entities laws
- Insurance/managed care laws
- New value based contracting models

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VBP Compliance Nuances

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Delivery System Reform Incentive Payment (DSRIP) Program

- Authorized through Medicaid Section 1115 waivers
- New York's Program
- Allows the state to reinvest \$8 billion in federal savings generated by Medicaid Redesign Team (MRT) reforms
- Specific goal to achieve 25% reduction in avoidable hospital use over 5 years
- Projects focus on system transformation, clinical improvement, and population health improvement
- Prescribed compliance program requirements under NY law



Bundled Payments for Care Improvement

- · Comprised of 4 broadly defined models of care that link payments for the multiple services beneficiaries receive during an episode of care
- Places financial and performance accountability on the organization
- Designated compliance official or individual who is not legal counsel
- Mechanisms for identifying and addressing compliance problems
- Method for anonymous reporting to the compliance official
- Regular compliance training
- Requirement to report probable violations of law
- Requires annual certification

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Accountable Care Organizations (ACOs)

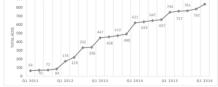


- Why is it called an ACO?
- What is an ACO?
- Commercial ACO vs. Medicare ACO Model?
- What is the Medicare Shared Savings Program?
- Are ACO requirements different from similar government programs?

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ACOs Growth

Figure 1 – ACOs Over Time



Source: HealthAffairs Blog http://healthAffairs.org/blog/2016/04/21/accountable-care-organizations-in-2016-private-and-public-sector-growth-and-dispersion/.

MSSP (42 CFR 425.300) v. OIG Compliance Guidance

$\label{eq:MSSP} \textbf{-} \, \underline{\text{at least}} \, \, \text{the following:}$

- Designated compliance official who is not legal counsel
- Mechanism for identifying and
- addressing compliance problems
 Mechanism for reporting suspected problems related to ACO
- Compliance training for affected persons
- Reporting of probable violations of law
- Periodic updates to reflect changes in law and regulations

OIG Compliance Guidance

- Written policies and procedures - Designated employee vested with the
- responsibility for the day-to-day operation of the compliance program
- Training and education Communication lines
- Auditing
- Consistency in disciplinary mechanisms
- Responding to compliance matters, including corrective action plans and reporting to government agencies



MSSP ACO Compliance Program

- No one size fits all
- Compliance coordination with ACO providers/suppliers
- Integration within a current compliance plan allowed
- Conduct a Compliance Gap Analysis/Assessment Early!
- ACO maintains ultimate responsibility with ACO agreement





Prohibition on Certain Required Referrals and Cost Shifting

- \bullet Concerns over overutilization of services for Medicare or other federal health programs with respect to care of individuals who are \underline{not} assigned to the ACO
- \bullet Prohibition of an ACO from conditioning participation in the ACO on referrals of non-ACO business
- \bullet Increased scrutiny of claims data to detect patterns of cost shifting, including patterns of shifting drug costs
- Prohibition on limiting or restricting referrals of beneficiaries to ACO participants/providers/suppliers within the same ACO, except in limited circumstances
- Beneficiary retains freedom of choice

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Avoidance of At-Risk Patients

- CMS will monitor the assignment of beneficiaries from the prior year to the current year.
- May result in oversight through a corrective action plan or termination



"Your blood sugar is high, but your salt, pepper, ketchup, mustard

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Patient Notification

- ACO participants to post signs in their facilities indicating participation in the Shared Savings Program
- $\bullet ACO$ participants make available standardized written information developed by CMS to beneficiaries whom they serve
- Required in setting in which beneficiaries are receiving primary care services
- Not required to notify beneficiaries in the event that it terminates participation in the MSSP



Beneficiary Inducements

- In general, the ACO prohibited from providing gifts, cash, or other remuneration as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO
- Flexibility to offer beneficiary inducements for healthy behavior
- Must be a reasonable connection between the item or services and the medical care of the beneficiary
- Covers free or below FMV items or services (not cash or cost sharing waivers)
 Blood pressure cuff for a patient with a history of high blood pressure so that the patient can provide ongoing self-monitoring
- The items or services are in-kind and either are preventative care items or services to advance one or more of the prescribed clinical goals

Marketing Materials

- Include those materials and activities used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program
- ACOs may use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all marketing requirements
- ACO must use template language where available
- Materials must be provided in "plain" language
- Materials may not be used in a discriminatory manner or for discriminatory purpose, and must not be inaccurate or misleading
- · Applies to social media and websites





Documentation Check List

- · Documentation of waiver compliance
- Organizational charts
- Background checks
- Compliance training
- · Minutes and agendas of committee/leadership meetings
- Provider/supplier lists
- including removals • Updated policies and
- procedures
 TIN/NPI lists
- Conflict of interest reviews and disclosure statements





Documentation Check List (cont.)

- Shared savings/loss distribution methodologies and changes
 Approved marketing materials/CMS submissions
 ACO website updates
 Copies of all provider/supplier agreements
 Root cause analysis to address identified compliance issues (CMS likes data!)
 Corrective action plans including disciplinary documentation
 Beneficiary forms and signs (e.g., data opt-out, beneficiary notification requirement)
 Evidence of a culture of compliance (e.g., posters, compliance week, email alerts)



Waiver Protections

- ACO Waivers
- Pre-participation v. Participation Waiver – Stark and AKS
- Patient Incentive Waiver
- Self executing but prescriptive requirements to execute
- DSRIP
- Certificate of Public Advantage (COPA)
- Application process
- Limitations
- Will not cover all arrangements (e.g., commercial business)
- Will not cover activities that are not necessary to carry out the program





Leveraging your current Compliance Program to meet VBP requirements

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What are the Compliance Program Requirements?

- $\bullet \ Compliance \ Officer \\$
- •Elements prescribed v. best practice
- Self reporting
- Federal v. state regulations



Organizational Structure

- What kind of organization is involved in VBP programs?
- Existing organization with Compliance Program
- New entity under a parent organization
- Consortium
- Who is the governing body?
- Regulatory requirements (e.g., ACO governance)
- Audit/Compliance Committees?
- Who is involved in the VBP program?
- Employed v. community physicians
- Internal and external resources

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Compliance Official

- May use existing resources
- Regulatory requirements?
- ACO requirements
- Legal counsel and compliance officer must be different people
- Must report directly to ACO's governing body
- DSRIP
- Compliance Officer must be an employee of the PPS Lead and report directly to the PPS's chief executive or other senior administrator and periodically report directly to the governing body
- May not be legal counsel
- BPCI
- May not be legal counsel

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Policies & Procedures



- Code of Ethical Conduct
- Utilizing current policies
- Distributing/Publishing

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Reporting Mechanisms



- Existing reporting mechanisms
- Helpline
- Web-based
- Partnering with providers/suppliers' existing compliance programs
- Issues impacting one portion of an organization may also impact the participation in the VBPs

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Compliance Training

- Incorporate into current compliance training
- Computer-based training
- Access
- Access
- •Live training
- Labor intensive
- ROI
- Self learning
- Attestations
- $\bullet \, Governing \ body$







HIPAA, Data Sharing and Data Use Agreements

- Covered Entity or Business Associate?
- BAA
- State laws regarding protections for special categories of health information (e.g., mental health, substance abuse, $HIV)\,$
- Sharing of data amongst partners?
- Data Use Agreement
- Who can request data?
- What are the purposes for the data?
- Minimum necessary
- Data destruction



Engaging participants in the VBP Compliance Program

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Who is your Audience?

- Board of Directors
- Employees
- •Internal and external participants
- •Community-Based Organizations



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Leveraging Partners



- Who are your partners?
- Health systems
- Physician practice groups
- IPAs
- What resources do these partners have to support your compliance program?
- How can you engage these partners to spread the word?
- Participation Agreements

Thank You			
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