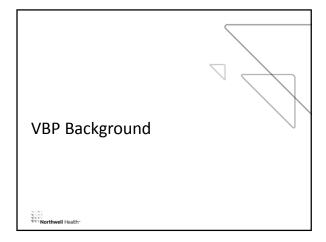
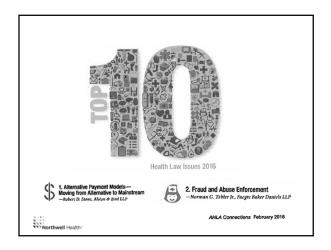
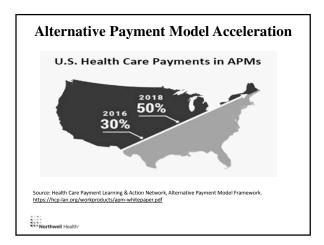


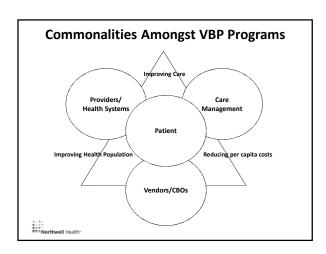
Disclaimer

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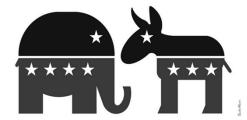








The U.S. Election's Impact on VBP



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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



- 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

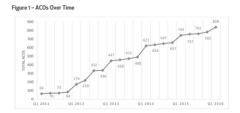
Accountable Care Organizations (ACOs)



- 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



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

MSSP – at least 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 <u>probable</u> violations of law
- Periodic updates to reflect changes in law and regulations

OIG Compliance Guidance

- Written policies and procedures
 Designated employee vested with the
- 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

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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
- 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

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 terparticipation in the MSSP



 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

Beneficiary Inducements

- Flexibility to offer beneficiary inducements for healthy behavior
- \bullet 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.
- compinance issues (CMS links 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)



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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

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
- Flexibility
- Live training
- Labor intensive
- ROI
- Self learning
- Attestations
- $\bullet \, Governing \,\, body$

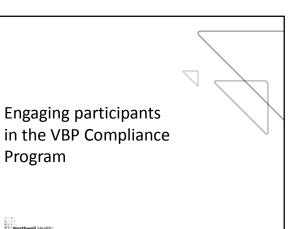






HIPAA, Data Sharing and Data Use Agreements

- 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



Who is your Audience?

- Board of Directors
- $\bullet Employees$

Program

- 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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Aaron Lund Director of Corporate Compliance & Privacy Officer alund@northwell.edu		
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