


Helpful Tips for Value Based Payment (VBP) Compliance Programs

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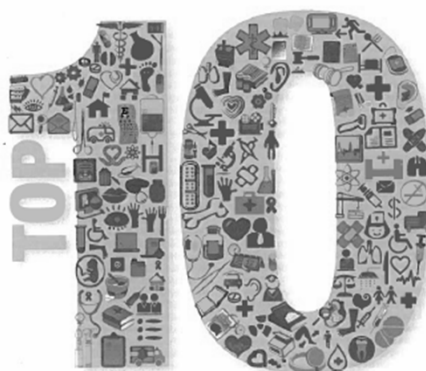
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VBP Background



Health Law Issues 2016



**1. Alternative Payment Models—
Moving from Alternative to Mainstream**
—Robert D. Stone, Alston & Bird LLP



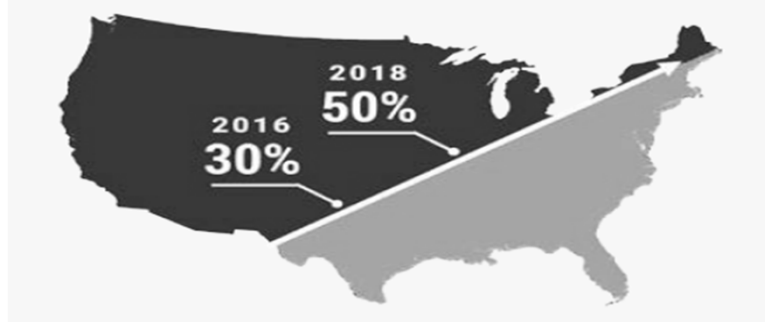
2. Fraud and Abuse Enforcement
—Norman G. Tabler Jr., Faegre Baker Daniels LLP



AHLA Connections February 2016

Alternative Payment Model Acceleration

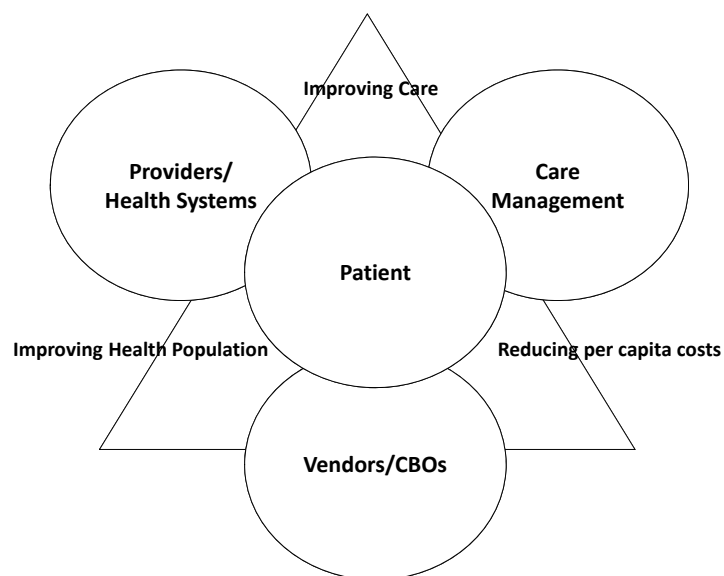
U.S. Health Care Payments in APMs



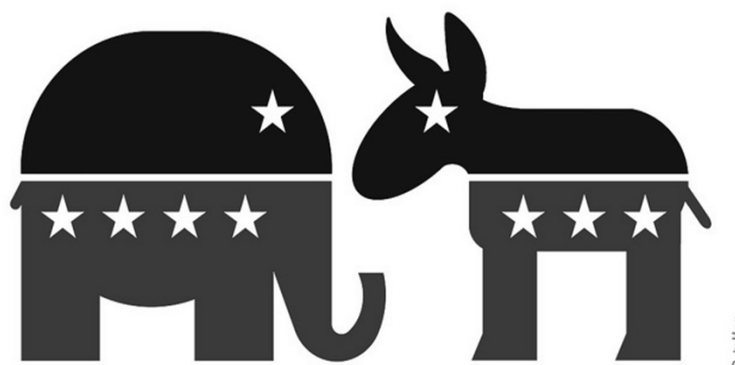
Source: Health Care Payment Learning & Action Network, Alternative Payment Model Framework.
<https://hcp-lan.org/workproducts/apm-whitepaper.pdf>



Commonalities Amongst VBP Programs



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



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



VBP Compliance Nuances



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
- BPCI Awardee Agreement Compliance Program Requirements - Section 111.1.2
 - 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?



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

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 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

- Concerns over overutilization of services for Medicare or other federal health programs with respect to care of individuals who are not assigned to the ACO
- 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 and grated cheese levels are fine."



Patient Notification

- ACO participants to post signs in their facilities indicating participation in the Shared Savings Program
- 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



What are the Compliance Program Requirements?

- 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



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



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



Compliance Training

- Incorporate into current compliance training
- Computer-based training
 - Access
 - Flexibility
- Live training
 - Labor intensive
 - ROI
- Self learning
 - Attestations
- 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



Who is your Audience?

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



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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