

Alternative Payment Models

Responding to Evolving Markets
with Integrated Compliance Solutions

HCCA
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Regional Conference
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Overview

- ➔ How APMs are Disrupting Current Markets
- ➔ Integrated Compliance Programs
- ➔ New Organizational Structures and Relationships
- ➔ Key Regulatory Challenges and Solutions,
- ➔ Government Enforcement and Emerging Legal Theories

APM Disruption in Current Markets

Alternative Payment Models

One of the most significant changes in healthcare has been the shift from "volume-based reimbursement" to payment models that are supplemented or replaced by "quality and value-based measures"



The diagram consists of two grey rounded rectangular boxes. The left box contains the text "Fee for Volume" and the right box contains "Fee for Value". A large, light grey arrow points from the left box to the right box, indicating a transition or shift from the former model to the latter.

Alternative Payment Models



Instead of providers being paid solely by the number of visits and tests they order their payments are increasingly based, at least in part, on the quality and the relative value of care they deliver.

Shared Savings Models

While value-based payment contracts are still being tested and are continuously evolving, the shared savings model has emerged as one of the most successful and widely used models.

Shared savings arrangements differ, but in general they incentivize providers to reduce spending for a defined patient population by offering them a percentage of any net savings they realize.

Commercial Payer Trends

During Anthem's first-quarter earnings call, its CEO told analysts:

- ➔ **Value-based contracts** tally up to about **58% its total medical spend** across all lines of business,
- ➔ **Over 75% is represented by shared savings agreements and population-based payment models**

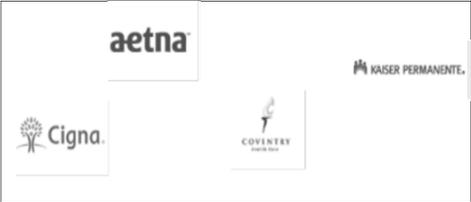
Commercial Payers

The CEO also highlighted the fact that Anthem:

- ➔ Entered into **159 ACO agreements**
- ➔ Has **64,000 providers** engaged in ACOs,
- ➔ Covers over **5.5 million commercial members**

Commercial Payer Trends

Other insurers have reported similar trends during their quarterly investment calls **noting that they are on track or ahead of schedule** in moving payments to alternative models:



Employers Move to Value Based Care

Citing the National Business Group on Health, Forbes reported that **nearly 40% of employers** are incorporating some type of value-based care in their workers' health plans.

- ➔ 21% of employers plan to promote ACOs in 2018
- ➔ The number could double by 2020 as another 26% are considering offering them.

Employers Accelerate Move to Value-Based Care
Forbes, August 2017

Integrated Compliance Solutions

Integrated Compliance Solutions

Today's emerging markets require a multi-disciplinary approach that integrates regulatory, financial, clinical and operational analysis into a **well-balanced, global perspective**.

Big Data

Moreover, advanced technology platforms are needed to implement **result-oriented, metric-driven** compliance programs.

- ➔ “Big Data” is used to incorporate **actionable business intelligence** into short and long term strategic plans.

Triple Aim

Shared Savings Models are similar in that they all focus on the **triple aim** of:

- ➔ Better care for individuals
- ➔ Better health for populations,
- ➔ Lower cost through **operational improvements** and optimizing care by applying the **right resource in the right setting**

Program Metrics

Shared Savings Programs often have **similar metrics** that focus on **key measures** such as:

- ➔ **Quality:** blends PQRS, readmission, and patient experience measures
- ➔ **Cost Reduction:** includes clinical practice improvement activities such as care coordination, beneficiary/community engagement, and patient safety,
- ➔ **Advancing Care Information:** Based on Meaningful Use. Tracks EHR utilization and compliance with HIPAA

Integrated Compliance Solutions

These new markets require **innovative compliance** programs that **mirror clinical integration** while simultaneously ensuring compliance with new quality, financial, marketing, and technical requirements.

- Technology**
 - Sharing data
 - Permitted uses
 - Security
- Quality**
 - Accurate Reporting
 - Coordinating care v Patient Steering
- Operating**
 - Cost reduction
 - Right level of care
- Financial**
 - Shared Savings
 - Kickbacks
 - Conflict of Interest

Integrated Compliance Solutions

By tracking the triple aim, integrated compliance programs can result in streamlined operations, cost reduction, and increased quality of care.

New Organizational Structures & Business Relationships

Network Development

To accomplish these goals, health systems are building networks of primary care physicians, specialists, and post-acute providers that:

- ➔ Deliver **high quality** of care
- ➔ **Control costs** through avoiding unnecessary procedures
- ➔ **Actively manage and coordinate care** through effective communication within the network
- ➔ Can **document key metrics** needed for value-based programs,
- ➔ Have availability to treat patients and **do not discriminate** based on payer source, patient acuity, or otherwise cherry pick

Clinically Integrated Networks

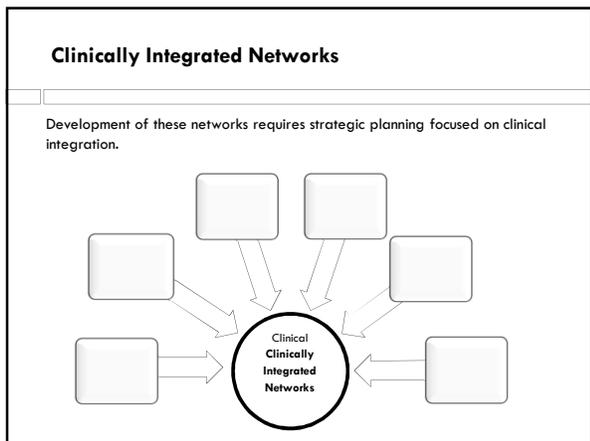
Establishing Clinically Integrated Networks to participate in value based programs is a very effective solution.

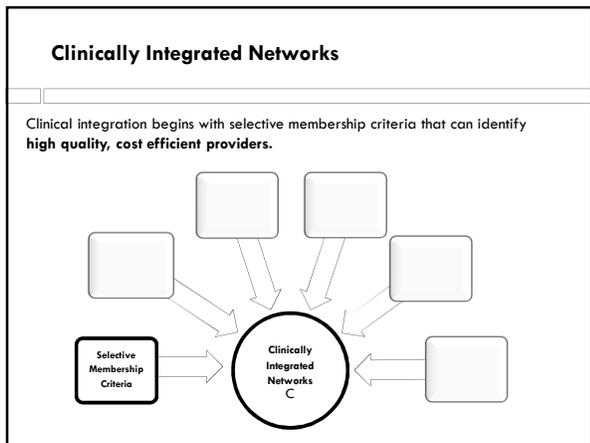
It allows health care systems and providers to **align incentives** through shared savings and gain sharing.

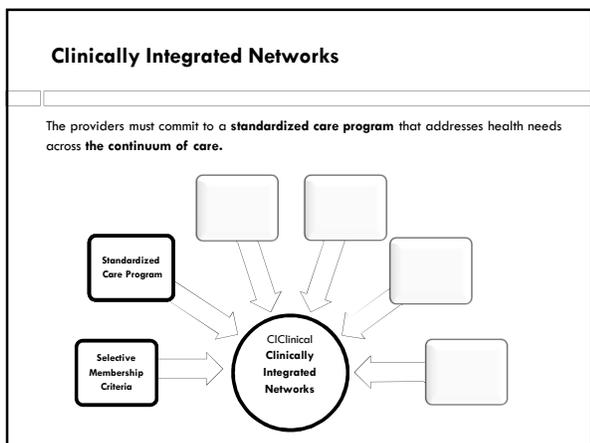
Clinically Integrated Networks

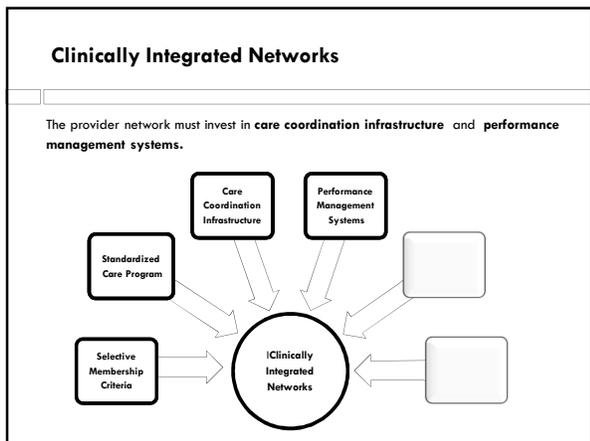
Moreover, it allows individual providers and groups to:

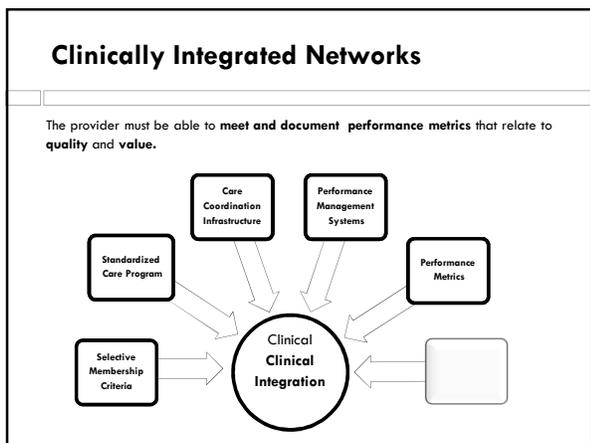
- ➔ Leverage the **expertise & resources** of health systems
- ➔ Improve **data analytics**
- ➔ Understand tactics used to **achieve metrics**
- ➔ Increase access to resources that are used to **manage complex cases,**
- ➔ Minimize administrative burdens related to **documenting and reporting metrics**

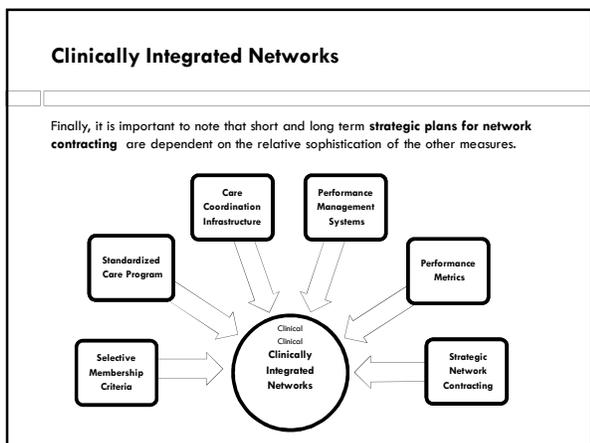












Clinically Integrated Networks

Successful clinically integrated networks take time to develop and require a significant investment of resources.

- ➔ CINs want to ensure that they **do not take on too much risk** until organizational and operational resources are in place.
- ➔ In light of the fact that value-based payment models are relatively new and still evolving, compliance officers must be mindful of the **key regulatory challenges and risk exposure** that exists.

Key Regulatory Challenges & Solutions

Fraud and Abuse Concerns

The Medicare Shared Savings Program focuses on **coordinating care between** and among providers, including those who are **potential referral sources** for one another.

HHS has noted that existing fraud and abuse laws could impede some of the innovative integrated-care models envisioned by precluding:

- ➔ Bona-fide investment and start-up arrangements
- ➔ Sharing savings distributions and gain sharing incentives
- ➔ Coordinated care arrangements, including free care management
- ➔ Provision of IT systems & services,
- ➔ Beneficiary support services and testing supplies

Fraud and Abuse Waivers

Accordingly, HHS/OIG waived certain provisions of Stark, the Anti-kickback statute, and the Beneficiary Inducement CMP through 5 waivers:

- ➔ Pre-Participation
- ➔ Participation
- ➔ Shared Savings Distributions
- ➔ Stark,
- ➔ Patient Incentives

Self-Implementing

The waivers are self- implementing. **No special procedures** are required by parties to be covered by a waiver, including the submission of a separate application for a waiver.

ACO Investments and Start-up Costs

As previously discussed, the development of CINs to participate in MSSP is an effective strategy that can:

- ➔ **Align incentives** between health care systems, physicians, and post-acute care providers
- ➔ Allow physicians to **leverage health system** resources and expertise

ACO Investments and Start-up Costs

As stated in the final rule, the intent of the pre-participation and participation waivers is to establish pathways to protect:

- Bona fide **ACO investment, start-up, operating, and other arrangements** to implement MSSP requirements.

ACO Investments and Start-up Costs

The Pre-Participation and Participation waivers are very helpful for the development of strategic relationships in that they apply to arrangements within the ACO **as well as ACO-related arrangements with outside providers**

Including hospitals, specialists, and post-acute care providers that might not be part of the ACO but do have a role in coordinating and managing care for its patients.

ACO Investments and Start-up Costs

Many ACOs have been developed **with the assistance of parent organizations** that desire to protect their own interests.

- However, HHS/OIG has stressed that the **parent company's own interests must not interfere with the ACO's ultimate authority** and obligation to comply with the requirements of MSSP.
- Nor must those interests interfere with **the fiduciary duty** of the ACO's governing body.

Prohibited Reserved Powers

While a parent organization may wish to retain certain authorities to protect its interests and ensure its subsidiary's success, **retention of ACO decision-making authority by a parent company is prohibited.**

- The ACO's governing body must retain the ultimate authority to execute the functions of an ACO.

Prohibited Reserved Powers

The ACO's Board of Managers must have ultimate authority to:

- Develop and **implement required processes** to promote evidence-based medicine and patient engagement, to report on quality and cost measures, and to coordinate care.
- **Appoint and remove** members of the governing body, leadership, and management,
- Determine how **shared savings** are used and distributed

The last two measures are often subject to reserved "**final approval powers**" that allow the parent company to override decisions made by the board.

§425.106(1) Shared Governance

Compliance Review

Accordingly, compliance officials should **review key organizational documents** to ensure that they do not contain or suggest any of the **prohibited reserved powers**, including the:

- Operating Agreement and Articles of Incorporation
- Policies of the parent organization that purport to apply to all subsidiaries or controlled entities,
- Management service agreements with the parent organization or any related entities

Using IPAs or Existing Entities

The ACO must have a governing body that has a **fiduciary responsibility to the ACO alone** and not to any other individual or entity.

If an existing entity, such as **an IPA representing many group practices** wants to apply as an ACO using its existing legal structure and governing body.

- ➔ **Each group practice** must agree to be an **ACO participant**,
- ➔ **Each Medicare enrolled provider** within each group practice must agree to be an ACO participant.

§425.106(2) Shared Governance

Using IPAs or Existing Entities

If **only some of the represented group practices** want to become ACO participants

- ➔ Then the IPA **cannot use its existing legal structure** and governing body for the ACO.

Compliance Concerns

Please note that the second **condition required** to implement the **Participation waiver** is that the ACO meets the requirements of §425.106 & 108 concerning its **governance, leadership, and management**.

- ➔ The fact that these requirements are explicitly cross-referenced in the final rule is a **clear indication of the importance HHS/OIG places upon them**.

Compliance Concerns

Moreover, in addition to the general certification that all information contained is truthful, the ACO application has certifications for each of these requirements.

4. Is your ACO formed by two or more ACO participants?
 YES NO

If your ACO is formed by a subset of the TINs that participate in an organization, such as an integrated health delivery system or independent physician association, CMS considers your ACO to be formed by two or more ACO participants. Accordingly, you must answer YES to this question.

5. If you answered YES to question 4, do you certify that your ACO is a legal entity separate from any of the ACO participants and comprised only of ACO participants? If you answered NO to question 4, select N/A.
 YES NO N/A

15. I certify that my ACO's operations are managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of my ACO's governing body, and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes.
 YES

Shared Savings/Gain Sharing

One of an ACO's primary concerns is that shared savings distributions and gain sharing incentives may violate Anti-Kickback prohibitions or Stark.

- However, ACOs can utilize Shared Savings Distribution and Stark Waivers.
- A key requirement is that the distributions and incentives must be **reasonably related** to the purposes of MSSP.

Reasonably Related

In the final rule, HHS/OIG provides two examples of arrangements that could be reasonably related, even if the arrangement resulted in a **greater likelihood** that the patient might be **referred to or within an ACO**.

- Arrangements with post acute providers, such as SNFs, to engage in **care coordination** or **implement evidence-based protocols**
- Compensation to a physician for achieving certain **quality metrics**

Not-Reasonably Related

HHS/OIG also gave examples of arrangements that were not reasonably related to MSSP:

- ➔ Expressly paying a specialist \$500 for every referral generated
- ➔ Expressly paying a nursing facility staff member \$100 for every patient transported to the ACO's hospital.

Compliance Question

HHS/OIG stated that express "per-referral" payments are prohibited. However, payments to a doctor for meeting certain quality metrics could be permitted, even though the arrangement could result in increased ACO referrals.

- ➔ In light of the cost savings that arise from care coordination, would a physician incentive program that tracked and was tied to "in-network" referrals be permitted?

I think this is a grey area with some risk.

Compliance Tip

Although the ACO waivers do not require written agreements, it is a best documentation practice.

- ➔ Also, it is one way to satisfy the writing requirement included in Stark exceptions if a waiver does not apply.

IT Integration

Clinical integration requires the ability for clinicians to send and receive data for **care coordination** and **data analytics related to quality metrics**.

- ➔ Physicians may not be able to afford **advanced data analytics software** and the **required interfaces**
- ➔ Health systems that provide these resources may violate Anti-Kickback Prohibitions or Stark.

IT Donation Exception

The Meaningful Use IT Donation Exception, which is applicable to all providers, is helpful but **has certain limitations**. Most problematic:

- ➔ Physician Practices must pay a portion of the expense (15%)
- ➔ The donation **must integrate with the Electronic Health Record** & thus, cannot be used for free standing payment software.

Pre-participation & Participation Waivers

In contrast, the ACO waivers allow the CIN to **pay for the entire donation**.

Moreover, the ACO waivers are broad and **do not require integration with the EHR**. They could include:

- ➔ Interfaces for electronic health **information exchanges**
- ➔ Data reporting systems, including **payer claims data**,
- ➔ **Data analytics**, including staff and systems

Care Coordination

Value based models focus on applying the **right resource in the right setting**. Providers deliver the most value when they work at the **top of their license**.

- ➔ While care coordination often requires extra staffing, assisting with this activity or supplying staffing gives rise to potential **Anti-Kickback and Stark violations**.

Care Coordination

Pre-participation & Participation waivers allow for the provision of staffing to support:

- ➔ Complex Care Treatment
- ➔ Care Coordination
- ➔ Disease Management
- ➔ Post-Discharge Follow-Up
- ➔ Transition of Care
- ➔ Preventative Care Services

Patient Incentives

Because beneficiary compliance with care management is critical to success, HHS/OIG concluded that **ACOs should have more flexibility** than what may be allowed under current law.

Accordingly, HHS/OIG adopted a patient incentives waiver to **foster patient engagement in improving quality and lowering costs**.

Patient Incentives

ACO waivers protect items or services provided for free or at below FMV if there is a **reasonable connection with medical care**.

- ➔ They must also be **in-kind**, and either relate to **preventive care** or **advance a clinical goal**.

Patient Incentives

Examples of permissive patient incentives cited in the final rule include:

- ➔ A post-surgical patient receiving free home visits to coordinate in-home care during the recovery period
- ➔ A hypertensive patient using home telehealth monitoring of blood pressure
- ➔ Smoking cessation treatments,
- ➔ Transportation to a medical appointment or pharmacy

Application to Non-Medicare Patients

In an effort to promote broad improvement in care coordination and quality, the waivers are not limited to beneficiaries assigned to an ACO and may protect incentives to other patients.

Publication Requirements

The pre-participation and participation waivers require that a **description of the arrangement** for which protection is sought must be publicly disclosed.

The description must be published within **60 days of the date of the arrangement** and include:

- All parties to the transaction
- The type of item, service, or good provided,
- The date the of the **arrangement**.
(many websites list the **date the board approved**, which is a **different measure**)

Compliance Concerns

If an ACO failed to have its governing body make a determination that an arrangement is **reasonably related to the MSSP** and/or failed to meet the **60 day** publication requirement ...

- Then it would **not have waiver protection** until it meets those regulatory requirements.

In the final rule, HHS/OIG **emphasized** that the waiver protects an arrangement only when **all criteria** have been met; **there is no retroactive protection**.

DEPARTMENT OF HEALTH & HUMAN SERVICES
 Medicare & Medicaid Services
 7500 Maryland Drive, Mail Stop W3-06-05
 Maryland 21244-1850



Medicare and Medicaid Innovation (CMMI)

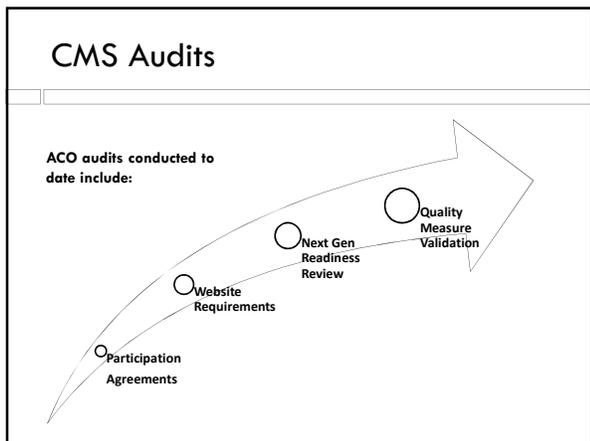
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IR will focus on several key areas including governance, compliance plans, and beneficiary notification. In addition, due to the importance of the "O's" Participant and Preferred Provider lists, the IRR will include a re-agreements with Participants and Preferred Providers to verify that they are timely, and compliant with the PA. At the conclusion of the IRR, the IGACO will feedback and guidance to help ensure NGACO.

Current Trends

Government Audits

40



Quality Measure Validation Audits

Every year CMS conducts a webinar to review lessons learned from its Quality Measure Validation Audits.

Web Interface Measure Reporting: Lessons Learned from the Performance Year 2015 Quality Measures Validation Audit

Rabia Khan, MPH, CMS
Sherry Grund, RN, Telligen

August 15, 2016
1:30pm – 2:30pm ET

Factors that Create High Error Rates

CMS has noted that the **more complicated a measure**, the more likely an error & has cautioned ACOs to **pay particular attention** to measures that contain or include:

- ◆ Complex denominators
- ◆ Follow-up components
- ◆ Coordination of care,
- ◆ Spatial relationships or time periods

Some common errors & issues raised in prior years include

CARE-2 (ACO#13): Screening for Future Fall Risk

Common issues or errors include:

- ➔ No documentation that the patient or caregiver was queried regarding their history of falls
- ➔ Usually, a comprehensive screening tool was used that did not include the query.

Doesn't mean it didn't happen Just was not Documented

DM-7 (ACO#41): Eye Exam

No documentation indicating that the patient received a dilated or retinal exam

The primary issue is **access to the optician record**. Primary care providers must ensure patients provide eye exam records or **direct their optician to send them to the office**.

Center for Medicare Medicaid Innovation Training

- Ensure key staff participate in CMMI webinars
- Facilitate discussion groups: apply guidance to existing practices & policy enhancements
- Audit for common errors & problematic measures

Emerging Trends

FCA & Value Based Care

Identifying Fraud During Value-Based Transition

Maintaining **program integrity during the transition to value-based** payment models has been a **top priority for the OIG over the past 5 years**. The OIG has noted that:

- ➔ "Many value-based payment mechanisms rely on complex data, electronic health information, and sophisticated quality and performance measures."
- ➔ When payments are linked to quality, outcomes, or performance, the **Department must ensure the reliability of underlying data.**

OIG: Top Management & Performance Challenges
Transitioning to Value-Based Payments

Inaccurate Quality Data

The OIG, DOJ and State Attorney Generals are developing criminal theories that focus on quality data and performance measures:

"Consequently, **inaccurate reporting of quality data** could result in the misrepresentation of the status of patients and residents, **the submission of false claims, and potential enforcement action.**"

*Corporate Responsibility and Health Care Quality:
A Resource for Health Care Boards of Directors
Joint Publication by HHS & OIG*

Quality-Related Fraud Settlements

New **Corporate Integrity Agreements** are currently being tailored for quality-related fraud settlements. Compliance with the new CIAs can be **costly**:

- ➔ Peer Review Consultants
- ➔ Quality Monitors
- ➔ Focused review of Medical Credentialing,
- ➔ Focused review of Medical Necessity



Emerging Legal Theories

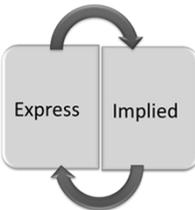
Emerging legal theories involve a combination of related factors that focus on **quality of care**....



Implied False Certification

Implied false certification is a relatively new legal theory.

- ➔ Legal requirement **does not have to be expressly** labeled a condition of payment
- ➔ An affirmative representation that the condition has been met is not required, but **can be implied**
- ➔ The focus is on the materiality of the **legal requirement**



Supreme Court Adopts Implied Certification

June 16, 2016, the Supreme Court upheld the Fourth Circuit decision and ruled that **FCA liability** can be premised on a theory of **implied false certification** provided that:

- The claim does not merely request payment, but also **makes specific representations** about the goods or services provided,
- There is either a failure to **disclose non-compliance** or **"misleading half truths"** related to material statutory, regulatory, or contractual requirements.

UHS v. U.S. ex rel. Escobar

Integrated Compliance Programs

In each of the cases reviewed, an integrated compliance program that focused on the unique risks created by the new payment models could have prevented the issues from arising.



Implied False Claims Application to ACO

Compliance officials should confirm the accuracy of the various ACO Program Certifications

- Information included in the application is accurate, complete, and truthful
- Compliance Program meets regulatory requirements
- Quality measures are accurately reported and have supporting documentation.
- Processes are in place to promote evidence-based medicine, patient engagement, and coordination of care
- Board of managers has the power to hire and fire key executives
- All CIN members participate in the Medicare ACO Program

