The Intersection of Quality and Regulatory Requirements in the Conditions of Participation and Beyond

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Objectives

1. How the backbone of Medicare hospital regulation, the Conditions of Participation, create internal friction when clinical / quality aspects and the governance /structure collide and how to identify and manage the intersection.

2. Managing the tension between systematized quality improvement and efficiency with the single hospital-focused COPs.

3. Lessons learned from an integrated health system’s transition to centralized efficiency while ensuring compliance with local COP requirements.

4. How to identify and manage developing tensions between historic regulation, more progressive regulation and a very transient healthcare landscape.
Agenda

Part 1: A Brief History of Hospital Standards
Part 2: Healthcare is Changing ... Quickly
Part 3: The Conditions of Participation are Changing ... Slowly
Part 4: New Rapidly Changing Regulation to the Rescue ... Or not exactly
Part 5: Group Exercise
1918

American College of Surgeons (ACS) developed the first “Minimum Standard” for the organization and operation of hospitals.

Brief History of Hospital Standards

These structural characteristic were considered essential patient safeguards and included:

1. Organized Medical Staff
2. Development of Policies and rules approved by governing body that governed the professional work at hospital
3. Rules required monthly medical staff meetings and periodic reviews of patients care in each department
4. Complete medical records, including coordination of discharge, follow up, and autopsy findings
5. Having a lab and an X-ray department
Brief History of Hospital Standards

The Joint Commission on Accreditation of Hospitals (JCAH) was created in 1951 to accredit hospitals that met a minimum set of standards that built on the ACS standards.
No National Standard

State processes for hospital licensure and inspection varied
Lawmakers didn’t want to create a federal process

Limitations:
• Legislative process
• Difference across the states
• Measuring quality was relatively unknown

Federal Hospital Standards are Created

Embedded within Medicare legislation, Section 1861 of the Social Security Act (SSA), was the following:
• Hospitals must meet a set of conditions to ensure the safety and health of Medicare beneficiaries
• Authority to create the conditions was granted to the Secretary of the Department of Health, Education, and Welfare (HEW), now the Department of Health and Human Services
• Accreditation by JCAH meant a participating hospital was automatically deemed to meet the conditions.
**COPs published October 18, 1966**

1. Maintenance of clinical records  
2. Medical staff bylaws  
3. 24-hour nursing service  
4. Utilization Review Planning  
5. Institutional Planning  
6. Capital budgeting  
7. State licensure

**1966 COPs (cont.)**

- Standards were indicators of the structural and organizational capacity to deliver care
- Emphasis on structure over process to measures organizational and clinical capacity
- States couldn’t make standards higher than JCAH
JCAH 1966

- Suffered national backlash for accrediting hospitals that had patient care problems
- Tension between the JCAH and federal government began to develop
- Created a set of aspirational standards that far exceeded the minimum standards of the past
- Emphasis on structure and process features of hospital organization and administration to deliver quality care

1972

- Congress amended SSA to give HEW / Health Care Financing Administration (HCFA, today CMS) the following additional authority:
  - Promulgate standards higher than JCAH
  - Conduct inspections on accredited hospitals
  - Investigate allegations of deficiencies
  - Decertify hospitals
- Tension between the Joint Commission and Government increased.
1979-80: Revisions Begin

Carter Administration GAO review of HEW surveys vs. JCAH surveys
- Found JCAH surveys identified more violations, and got faster compliance, than state surveyors
- HEW surveys were less reliable than JCAH surveys
- Recommended JCAH perform all certification surveys, with federal validation
1979-80: Revisions Begin

Draft revisions for COPs published in 1980
• Reduced prescribed standards and focused on necessary functions to be performed
Reagan Administration withdrew these proposals in January 1981

1986

“There have been significant changes in the organizational structure of hospitals and dramatic technological advancements since 1966. In addition there is need to provide for sufficient flexibility in the requirements to allow their application to both the smallest rural facility and the most complex urban facility” Federal Register Vol.51 No.116 Tuesday June 17, 1986
1986 COP Revisions

Emphasis on performance
• Infection control
• Surgical and anesthesia services

Quality Assurance added as a separate Condition

1986 Revisions (cont.)

Fewer prescriptive requirements for:
• Credentials
• Committees
• Departments

Followed Reagan administration deregulation focus
Part 2: Healthcare is Changing ... Quickly

Where is Healthcare Going?

- Payment Models
- Populations health
- Move to hospital systems
- Consumer focus
- Transition out of acute care
- Price transparency
- Expansion of licensure
- Regulatory complexity
- Healthcare insurance coverage
Where is healthcare going?

Most hospitals are part of systems
  • Economies of scale
  • Reimbursement changes
Quality-focused Payment Models

Some Challenges for Stand-alone Community Hospitals

Lack of purchasing power and scale
Increased cost for:
  • Compliance
  • Bond financing
  • Retaining physicians
Negotiating with third-party payers and sharing risk
Value-Based Payment Model

CMS’ Quality Initiatives began in 2001

CMS’ Focus

• Better Care for Individuals
• Better Health for Populations
• Lower Cost

There are multiple models

Example: Hospital Value-Based Purchasing Program

Stated Focus: improve care quality and patient experience

Hospitals are paid based on quality of care

Measures include:

• Mortality, Complications, and Healthcare-associated infections
• Patient safety and Patient experience
• Process
• Efficiency and cost reduction
Part 3:  
The Conditions of Participation are Changing ... Slowly

Tension created between COP and where healthcare is going

- The COPs were created under the premise that structure equated quality
- Structure does not measure quality
- Individual hospital structure(s) are costly to build and maintain
- Pooling resources can enhance quality and is generally less costly.
- Regulations, including the COPs, are slowly shifting
### Governing Body COP

1966

§ 405.1021

“The hospital has an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital carry out the functions herein pertaining to the governing body”

2019

§ 482.12

“There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body”

### Evolution of the Governing Body COP - Interpretative Guidelines

“If the hospital is part of a healthcare system that includes several separately certified hospitals, each with its own Medicare provider agreement and CMS Certification Number, the governing body of the healthcare system has the option to act as the governing body of each separately certified hospital, unless doing so would conflict with State law.”
Evolution of the Governing Body COP (cont.)

A hospital system also has the option to form several governing bodies, each of which is responsible for several separately certified hospitals.

Issues to consider:
Medicare payment requirements at §§412.22(e) - (h) applicable to certain types of hospitals, i.e., non-grandfathered Hospitals-within-Hospitals and Hospital Satellites

- In such cases where the hospital system owns both the tenant and the host hospital, using a single governing body for both hospitals would jeopardize the payment status of a hospital that is being paid by Medicare under a payment system excluded from the Hospital Inpatient Prospective Payment System (IPPS).

Medical Staff

1966

§ 405.1023
“The hospital has a medical staff organized under bylaws approved by the governing body made responsible to the governing body of the hospital for the quality of all medical care provider patients in the hospital and for the ethical and professional practices of its members.”

2019

§ 482.22
“The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.”
Evolution of the Medical Staff COP

Hospitals that are part of a system can have an integrated medical staff if each hospital shows:

• Medical staff members at each hospital vote to integrate
• The integrated medical staff bylaws, rules, and requirements describe processes for governance, credentialing, etc.
  ○ And include a process for members to be advised of their rights to vote to opt out of the integrated medical staff
• The integrated medical staff accounts for each hospital’s unique circumstances and patient populations
• Members’ concerns are given due consideration regardless of location

(42 CFR 482.22)

Infection Control

1966

Did not exist

1986

§ 482.42

“The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.”
Infection Control Condition of Participation

1986
Infection control officer must keep a log of infection and communicable disease incidents
Requires a “hospital wide quality assurance program”

Current
Requires a QAPI program and training programs to address problems

Quality assessment and performance improvement (QAPI) program Condition of Participation

Did not exist until 2003

§ 482.21 Condition of participation: Quality assessment and performance improvement program.
“The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital’s governing body must ensure that the program reflects the complexity of the hospital’s organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.”
Quality Assurance (cont.)

September 20, 2018, the following was proposed in the Federal Register:

Hospital systems may have a unified QAPI program

- This must meet State and local requirements

The system governing body must ensure each hospital meets the requirements

- The unified QAPI takes into account each hospital’s circumstances and patient populations
- The unified QAPI establishes policies to ensure the needs of each hospital are considered
- The unified QAPI has mechanisms to ensure local issues are considered and addressed
A tension is being created.
Healthcare delivery and payment is being changed at a rate that far surpasses the rate of updating regulation.

Part 4:
New Rapidly Changing Regulation to the Rescue ...
Or not exactly
Example: Affordable Care Act - ACO SNF 3 day waiver

As of Jan. 1, 1967, Medicare covers long-term care after three days in a hospital

Three midnights is a big deal: OIG said uncovered SNF stays averaged $10,503 per beneficiary in 2012

Changes in the past 50 years?
• In 1965, average inpatient stay for a Medicare beneficiary was 14 days
• In 2017, it was 5 days

Example: Affordable Care Act ACO SNF 3-Day Waiver

Section 3022

“SHARED SAVINGS PROGRAM

“SEC. 1899. (a) ESTABLISHMENT.—
“(1) IN GENERAL.—Not later than January 1, 2012, the Secretary shall establish a shared savings program (in this section referred to as the ‘program’) that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under such program—
Example: Affordable Care Act - ACO SNF 3 day waiver

ACO Beneficiaries are eligible for the 3-day rule to be waived if the ACO:

• Meets eligibility criteria
• Submits a SNF Affiliate List
• Submits sample SNF Affiliate Agreements
• Completes the SNF Affiliate Agreement table for Medicare
• Submits an executed agreement for each proposed SNF affiliate
• Submits communication, beneficiary evaluation and admission, and care management plans

Example: Affordable Care Act - ACO SNF 3 day waiver

42 CFR §482.43 Condition of Participation: Discharge Planning

Hospital must identify patients who need discharge planning (especially for post-hospital care)

Requires hospitals to “develop ... a discharge plan” by counseling with the patient
### Example: Affordable Care Act - ACO SNF 3 day waiver

**Patient Choice**

The hospital must:
- Inform the patient of freedom to choose a post-hospital provider
- Provide list of post-hospital services in the geographic area
- Identify any post-hospital services in which the hospital has a financial interest

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### Example: Affordable Care Act - ACO SNF 3 day waiver

**But...**

From ACO 3-Day Rule Waiver:

“The SNF 3-Day Rule Waiver does not restrict a beneficiary’s choice of provider or supplier.”

“A beneficiary continues to have the option to seek care from any Medicare FFS provider or supplier, including from a SNF or other facility that is not an affiliate of an ACO that is participating in the Shared Savings Program. In such circumstances, normal Medicare requirements apply, including the requirement for a 3-day, inpatient hospitalization.”
How to condense the regulations and provide meaningful guidance to leadership

Set up guardrails to avoid going over the edge

• Identify risks
  o Regulatory limits
  o Operational limitations
  o Organizational goals

• Create policies to limit risk exposure

Part 5:
Group Exercise
ACA 30-day Readmission Group Exercise.
Identify the tensions

Public Law 111–148
111th Congress

An Act
Entitled The Patient Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 3025. HOSPITAL READMISSIONS REDUCTION PROGRAM.
(a) IN GENERAL.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww), as amended by sections 3001 and 3008, is amended by adding at the end the following new subsection:
“(q) HOSPITAL READMISSIONS REDUCTION PROGRAM.—

ACA 30-day Readmission Group Exercise.
Identify the tensions

§482.43  Condition of participation: Discharge planning.
“The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.”
ACA 30-day Readmission Group Exercise. Identify the tensions

§ 1395dd. Examination and treatment for emergency medical conditions and women in labor

(a) Medical screening requirement

In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual’s behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (e)(1) of this section) exists.

ACA 30-day Readmission Group Exercise. Identify the tensions

Any other pertinent regulations?
Questions?