Evolution of Healthcare Regulation

NM APIC
April 5, 2024

Steven Hirsch, MPA, FACHE

History of Oversight of Hospital Care

1910-1913 Ernest Codman, MD proposes “end result” system of hospital standardization (American College of Surgeons)

1917-1926 American College of Surgeons publishes “Minimum Standard for Hospitals” 1 page document—next slide

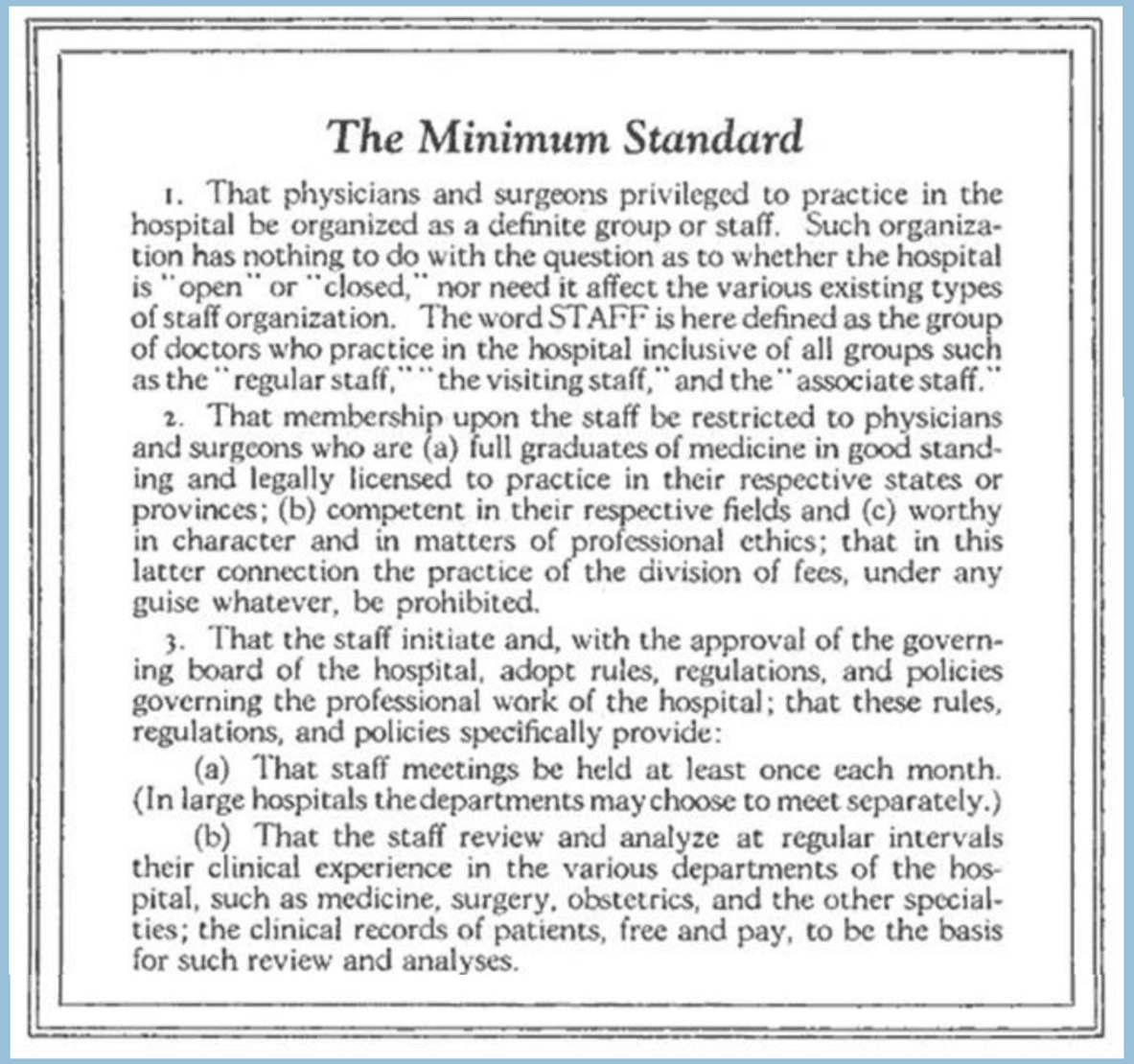
1950-1952 Joint Commission for Accreditation of Hospitals created

1964-1965 Social Security amendments passed creating “deemed status” for Joint Commission accredited hospitals

1970-1972 Requirement for HHS to validate JCAH findings

1979 CAP laboratory accreditation recognized by accrediting organizations

American College of Surgeons



The Minimum Standard

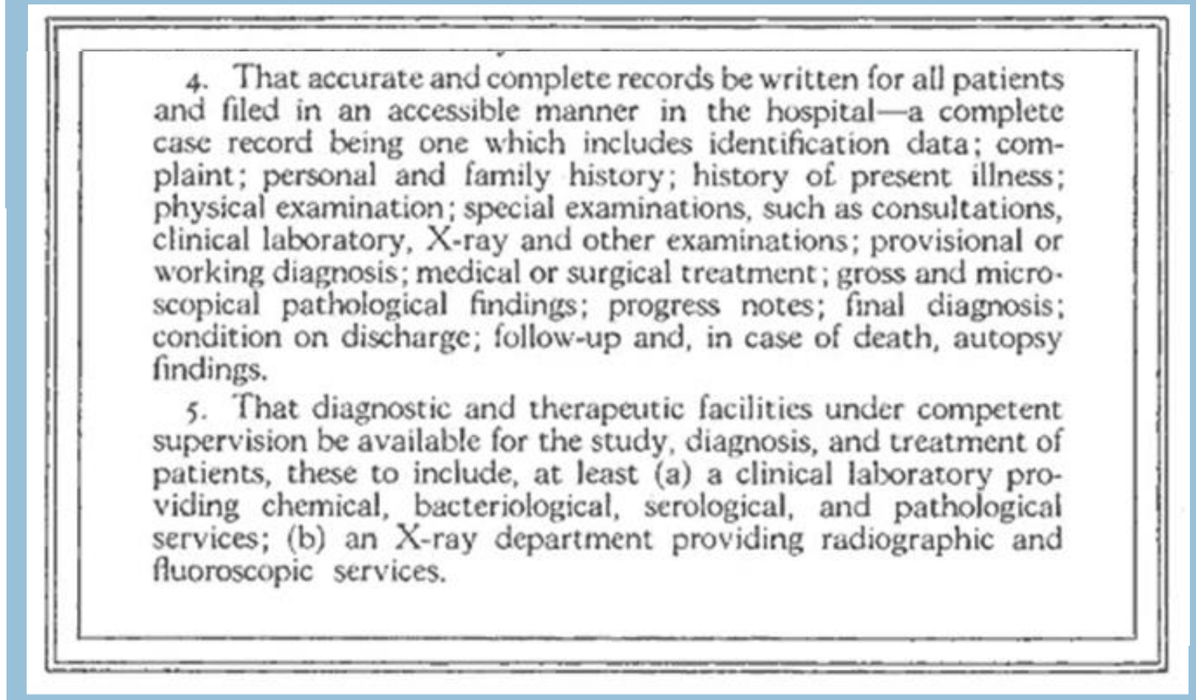
1. That physicians and surgeons privileged to practice in the hospital be organized as a definite group or staff. Such organization has nothing to do with the question as to whether the hospital is "open" or "closed," nor need it affect the various existing types of staff organization. The word STAFF is here defined as the group of doctors who practice in the hospital inclusive of all groups such as the "regular staff," "the visiting staff," and the "associate staff."

2. That membership upon the staff be restricted to physicians and surgeons who are (a) full graduates of medicine in good standing and legally licensed to practice in their respective states or provinces; (b) competent in their respective fields and (c) worthy in character and in matters of professional ethics; that in this latter connection the practice of the division of fees, under any guise whatever, be prohibited.

3. That the staff initiate and, with the approval of the governing board of the hospital, adopt rules, regulations, and policies governing the professional work of the hospital; that these rules, regulations, and policies specifically provide:

(a) That staff meetings be held at least once each month. (In large hospitals the departments may choose to meet separately.)

(b) That the staff review and analyze at regular intervals their clinical experience in the various departments of the hospital, such as medicine, surgery, obstetrics, and the other specialties; the clinical records of patients, free and pay, to be the basis for such review and analyses.



4. That accurate and complete records be written for all patients and filed in an accessible manner in the hospital—a complete case record being one which includes identification data; complaint; personal and family history; history of present illness; physical examination; special examinations, such as consultations, clinical laboratory, X-ray and other examinations; provisional or working diagnosis; medical or surgical treatment; gross and microscopical pathological findings; progress notes; final diagnosis; condition on discharge; follow-up and, in case of death, autopsy findings.

5. That diagnostic and therapeutic facilities under competent supervision be available for the study, diagnosis, and treatment of patients, these to include, at least (a) a clinical laboratory providing chemical, bacteriological, serological, and pathological services; (b) an X-ray department providing radiographic and fluoroscopic services.

The 1924 Minimum Standard Document

Regulators

1965-Centers for Medicare and Medicaid Services

- Governmental agency
- Overarching authority based on law
- Established by congressional action
  - Conditions of Participation (CoPs)
  - State Operations Manual -Interpretive Guidelines
    - Appendix A-Acute Care Hospitals/Psychiatric Hospitals
    - Appendix W-Critical Access Hospitals
- Published by “Office of Clinical Standards/Survey and Certification”

State and Local Authority

- Governmental agencies
- Most stringent requirements apply
- Can levy fines and penalties

Accreditation organizations (TJC, ACHC, DNV, CIHQ)

- Acute care hospitals
- Critical access hospitals
- Behavioral health facilities
- Clinical laboratories
- Ambulatory Care
- Home Health

Deemed Status

In order for a healthcare organization to participate in and receive payment from the Medicare or Medicaid programs, it must be certified as complying with the Conditions of Participation (CoP), or standards, set forth in federal regulations.

Achieve approval of Medicare Certification through accreditation by AO with deeming authority

- Policies and procedures must be evidence based and must be reviewed and approved by Administration, governing body and medical staff (as applicable)
- Policies and procedures must be monitored for compliance.
- Failures identified by monitoring must be evaluated.
  - Corrective actions must be taken and documented, and monitored for effectiveness and sustainability.

Survey Process

Conducted by a Team

Surveyed against standards (CMS or State or Accreditation Organization)

May be subjective- accreditation organizations actively working on consistency

Appeal process

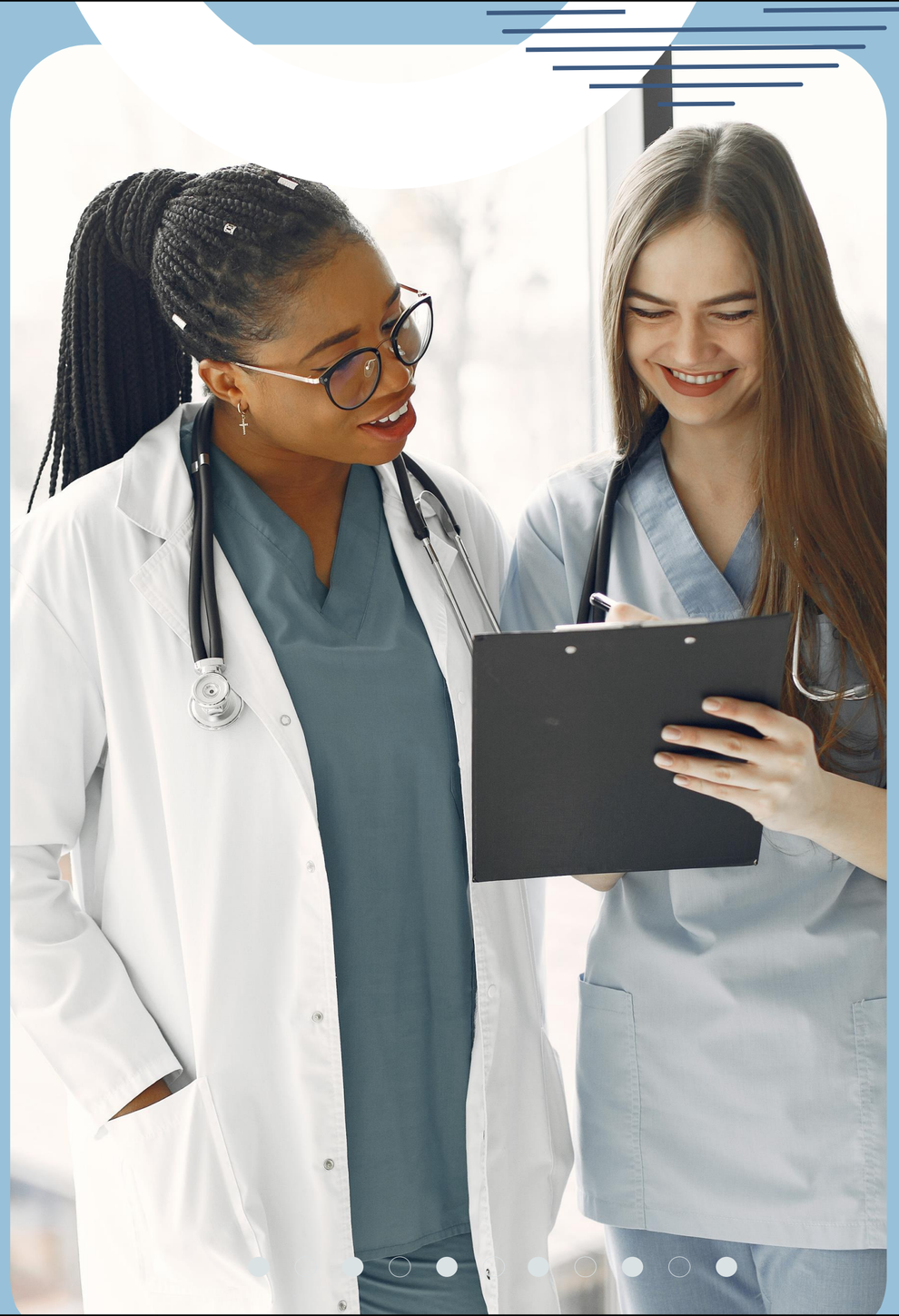
Failure can result in loss of accreditation/deemed status or Medicare Certification

Survey Findings

Deficiencies presented in survey report by Accreditation Organization

CMS and state Departments of Public Health present deficiencies on Form 2567

Generally a Plan of Correction must be submitted within 10 calendar days



Severity of Deficiency

Immediate Jeopardy/Immediate Threat to Health and Safety (TJC)

- Situation that is likely to result in harm to patients and/or staff
- Can result in suspension of the survey
- Organization must submit immediate Plan of Correction for mitigation

Condition Level-can be cited by Accreditation Organization, CMS or Department of Health Public

- Can represent a single observation of non-compliance (i.e. Hand Hygiene, improper air balance)
- Can be expected to cause harm

Standard Level-general observation of non-compliance

Plans of Correction

Accreditation organizations allow for clarification/contesting of findings (must be submitted within defined timeframe (10 days for TJC)

Full Plan of Correction must be developed within 10 calendar days for high level observations (Condition Level); lower-level deficiencies must be responded to within timeline defined by Accreditation Organization

Plans of Correction-Format

Must detail actions taken to achieve compliance

Must identify date of completion of corrective action

- CMS and Departments of Public Health require date of completion prior to submittal
- Accreditation Organizations may allow timeline for implementation that extends beyond POC submittal date

All POCs must include:

- Specific actions taken to resolve non-compliance
- Date of final actions to achieve sustainable compliance
- Title of staff member responsible for implementation of corrective action and sustained compliance
- Process for ongoing monitoring and frequency of monitoring
- Leadership involvement and oversight
  - To whom are monitoring reports submitted and how often
  - To what levels of Leadership are reports submitted
  - Include submittal of reports to governing body
  - Duration of reporting until sustained compliance is achieved (i.e. 6 months)
- Important to focus POC on location of actual observation resulting in citation of deficiency-APPLY CORRECTIVE ACTION FACILITY WIDE

Infection Prevention and Control and Antibiotic Stewardship-Current Regulations

482.42(a)/§485.640(a) Standard: Infection prevention and control program organization and policies. The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

482.42(c)/§485.640(c) Standard: Leadership responsibilities

(1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership

482.42(c)/§485.640(c) Standard: Leadership responsibilities

(2) The infection preventionist(s)/infection control professional(s) is responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

482.42(c)/§485.640(c) Standard: Leadership responsibilities

(2) The infection preventionist(s)/infection control professional(s) is responsible for:

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

Survey Hot Buttons

In 2023 TJC called 26 Immediate Threats to Health & Safety-represents 27% of RFIs in Infection Prevention and Control. 49.1% of surveyed hospitals is 2023 were cited for HLD/Sterilization deficiencies (58% in Red on SAFER matrix-harm could occur at any time)

Sterile instruments-cited frequently as Immediate Jeopardy or Immediate Threat

- Lack of proper decontamination, disinfection or sterilization of surgical instruments: improper sterilization time or temperature
- Closed hinged instruments
- Wrong sterilization parameters applied
- Water spots
- Instrument tape
- Over-weight instrument cassettes
- Expired sterile products (manufacturer’s date or hospital applied expiration date)
- Improper application/storage of peel packs

Survey Hot Buttons

High level disinfection (endoscopes) and Intracavity probe disinfection

- Cleaning and processing
- Temperature too low for HLD solution-Immediate Jeopardy finding
- Staff competency
- Dating for reprocessing if not used
- Improper storage (touching other scopes in storage cabinet/not hanging to allow drainage)
- Soiled storage cabinets

Trends per TJC

- Lack of proper storage of medical instruments
- Lack of bi-directional tracking of instruments undergoing sterilization or HLD
- Single use lancet devices used on multiple patients-Immediate Jeopardy finding
- Improper cleaning prior to disinfection of probes contacting broken skin or entering body cavities
- Hand Hygiene-single missed opportunity is Conditional Level finding

Survey Hot Buttons

Temperature & Humidity-can be cited as Immediate Jeopardy or Condition Level

- Out of range temperature & humidity without documented corrective action
- Critical air pressures incorrect with no process in place for ongoing monitoring
  - Adjust and hold cases/reschedule cases
- Use of humidity range of 20%-60% without documented risk assessment
- Do Not Start A Case if parameters are not in range-only exception is documented life saving procedure

Improper cleaning and preventative maintenance of dialysis equipment and wall boxes

Failure to follow established policies and procedures

- Isolation guidelines
- Use of PPE by visitors

Survey Hot Buttons

Environmental Services

- Lack of maintenance of clean environment
- Stained ceiling tiles (considered mold)
- Proper/consistent dilution of cleaning chemicals
- Use of disinfectant wipes (open containers/wet dwell time)
- Water management program not developed or not properly/consistently implemented

Infection Preventionist

- Must establish and document competency
- Must be appointed by Governing Body based on recommendation of Nursing and Medical Staff

Accountability

Surveys are all about accountability

- High level findings/deficiencies are cited
  - Under subject matter
  - Quality Assurance/Performance Improvement
  - Leadership/Governing Body

Build a multidisciplinary team-IC is everyone’s responsibility

Establish reporting relationship with formal communication

Establish Leadership support to promote accountability

Leadership Support

- Ensure that the governing body is accountable for the success of infection prevention activities
- Allocate sufficient human and material resources
- Consistent and prompt action to remove or mitigate infection risks and stop transmission of infections
- Staffing and resources do not prevent nurses, environmental staff, et. al., from consistently adhering to infection prevention and control practices
- Assign one or more qualified individuals with training in infection prevention and control to manage the facility’s infection prevention program
- Empower and support the authority of those managing the infection prevention program to ensure the effectiveness of the program

Questions

Thanks!

Steven Hirsch, MPA, FACHE

714-965-2800

www.shassociates.com