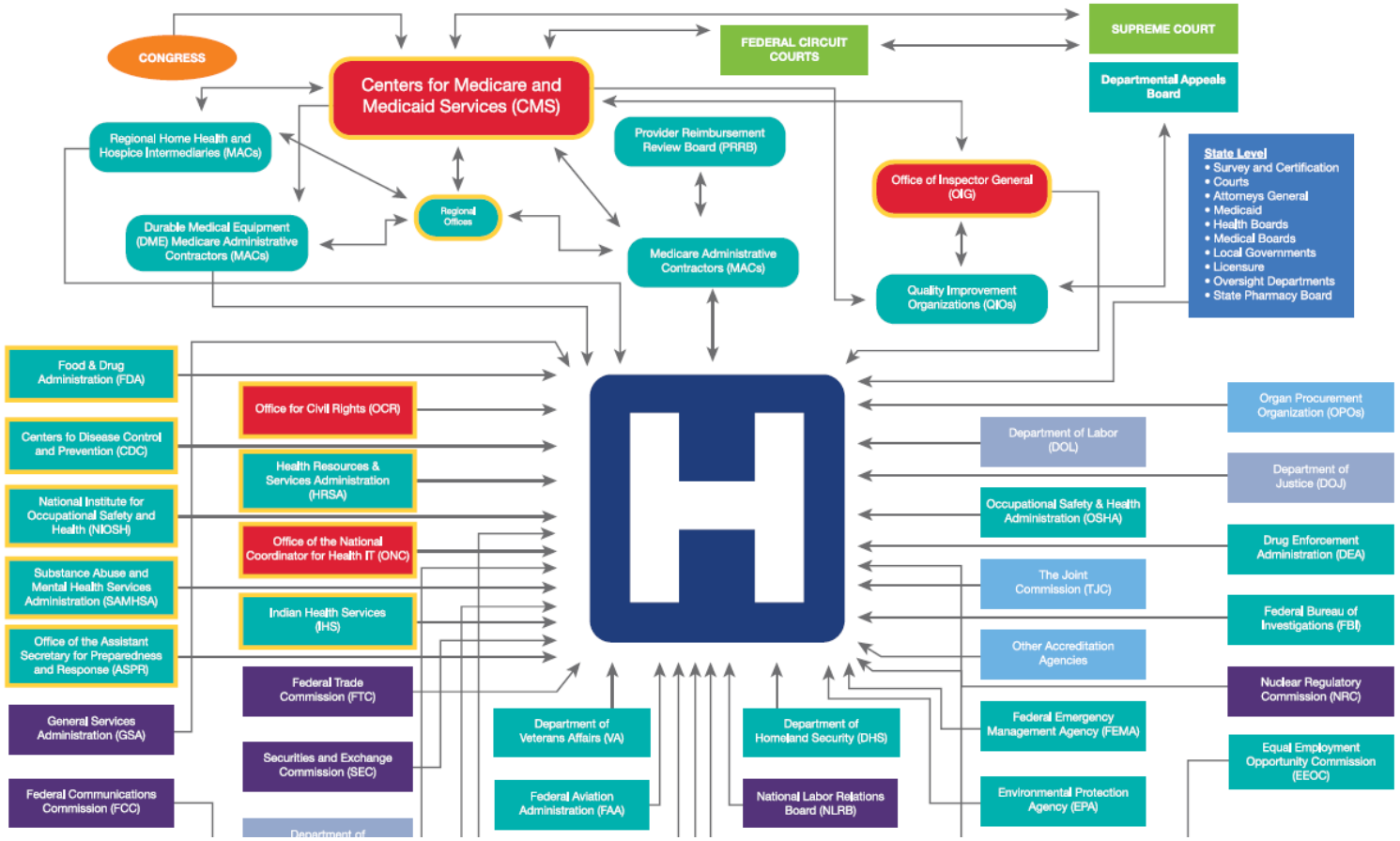
Minnesota Hospital Association

Regulatory Bodies and Oversight

John Sellner PharmD

Objectives

- Develop a foundation of knowledge in regulatory bodies; their purpose and oversight
- Describe the difference between accrediting bodies and regulatory bodies
- Evaluate important regulatory bodies pertinent to DCT board
- Explain the process of accreditation reviews and regulatory visits



Key:

- Accreditation and Licensure
- Federal Executive Agency
- Federal Executive Department
- Independedent Executive Agency
- Judicial Government
- Legislative Government
- State Level Oversight

- Agencies part of the Department of Health and Human Services
- Agencies reviewed for AHA report

Accrediting Bodies

Accrediting Organizations

Accreditation is a process of review that allows healthcare organizations to demonstrate their ability to meet regulatory requirements and standards established by a recognized accreditation organization.

Accreditation reflects an agency's dedication and commitment to meeting standards that demonstrate a higher level of performance and patient care.

Accrediting Body

- Formed to assess standards of quality and safety in healthcare organizations prior to regulatory visits to allow organizations to address shortcomings
- Provide voluntary accreditation as evidence of an organization's commitment to quality and safety standards relative to pre-established performance standards
- Send trained external peer-reviewers to evaluate a healthcare organization's performance via surveys

Regulatory Body

- Formed to set standards and enforce regulations that ensure a minimum standard of quality and safety in hospitals
- Perform regular inspections of healthcare facilities to determine if the organization is meeting standards
- Additional responsibilities include managing complaints and poorly performing physicians/healthcare professionals

TJC

- An independent, non-profit organization
  - Accredits & certifies 19,000 programs and programs in the US
    - Recognized nationwide as a symbol of quality -organization meets certain performance standards
- Accreditation provided for numerous programs:

TJC

- Organizations are accredited for 3 years after a 4–6-month preparation period
- Except laboratory accreditation-only 2 years
- Cost of accreditation varies by the number of sites accredited and the number of visits performed

The Joint Commission

Care, Treatment, and Services (CTS)

The "Care, Treatment, and Services" (CTS) chapter reflects the flow of care, treatment, and are provided in behavioral health care organizations. Care, treatment, and services are provided through the successful coordination and completion of a series of core processes that include the following:

- Entry to care, treatment, or services
- Screening and assessment
- Planning of care, treatment, or services
- Delivery of care, treatment, or services
- Special behavioral procedures
- Continuity of care, treatment, or services

These core processes also address the following activities:

- Providing care, treatment, and services based on principles of recovery and resilience.
- Providing individuals with access to the appropriate programs and services with appropriate staff.
- Providing care, treatment, and services based on an individualized plan.
- Teaching individuals served what they need to know about their care, treatment, and services.
- Coordinating care, treatment, and services, if needed, when the individual is referred, transferred, or discharged.

Examples:

CTS 02.01.01: The organization has a screening procedure for the early detection of risk of imminent harm to self or others.

CTS 02.01.06: For organizations providing residential care: The organization screens all individuals served to determine the individual's need for a medical history and physical examination. (This standard does not apply to organizations that provide physical examinations to all individuals served as a matter of policy or to comply with law and regulation.)

CTS 02.02.03: A complete and accurate assessment drives the identification and delivery of the care, treatment, and services needed by the individual served.

CTS.02.02.05: The organization identifies individuals served who may have experienced trauma, abuse, neglect, or exploitation.

TJC surveys

- TJC performs unannounced on-site surveys via the following methods:
  - Tracer method: surveyors follow a patient through various hospital departments to assess real time compliance with accreditation standards
  - Interviews/observations: Surveyors interview staff, leadership and patients and directly observe care practices
  - Policy & document review: Surveyors examine hospital policies, procedures and performance improvement initiatives
  - Environment of care review: Surveyors inspect facilities, equipment, infection control practices and emergency preparedness.
- Surveyors provide preliminary feedback at the end of the survey
  - Official report sent out within 10 days detailing any requirement of improvement
- Accreditation decision is made if compliance standards are met

DNV

- Accredits over 1000 healthcare organizations in the US
- 2nd largest accrediting organization for the following hospitals:
  - Acute care
  - Critical access
  - Psychiatric
  - Behavioral

Our requirements cover key aspects of organizational governance and clinical care, including:

- Quality management system and governance;
- Pro-active Risk management;
- Higher risk services such as anesthesia, obstetrics and ER;
- Medication management;
- Patient rights;
- Physical environment.

DNV

- Uses a continuous improvement model called NIAHO (National Integrated Accreditation for Healthcare Organizations) instead of episodic inspections
  - Provides accreditation for 3 years based on annual care quality surveys
  - Collaborative surveys allow staff to understand what works for the organization, along with what can be done to make further improvements daily

DNV survey

- Surveys are conducted annually, unannounced. Surveyor team incorporates international experience with local knowledge (headquartered in Norway)
- Surveyors (all have healthcare background) assess the following aspects of organizational governance:
  - Quality management system and governance
  - Proactive risk management
  - Higher risk services such as anesthesia, obstetrics, ER
  - Medication management
  - Patient rights
  - Physical environment
- Information is collected via:
  - Staff and patient interviews
  - Medical record review
  - Organizational document review
  - Building and offsite visits
- Preliminary feedback provided at end of survey

CARF

- Independent, non-profit accreditor of HHS organizations
  - Accredits 6,000+ organizations
  - International accreditation provides a visible symbol that assures the public of an organization's commitment to continuous quality and safety advancement
- Organizations are accredited for 1 or 3 years after 9-12 months survey preparation and 6-9 months re-accreditation preparation

CARF cont.

- Cost of accreditation varied depending on number of programs reviewed, number of viewers, etc.
  - There is an additional $995 application fee
- Areas of accreditation:
  - Ageing services
  - Continuing Care Retirement Communities (CCRC)
  - Behavioral health
  - Opioid treatment programs (OTPs)
  - Child and youth services
  - Medical rehabilitation
  - Vision rehabilitation services
  - Employment and community services

CARF survey

- Surveys conducted unannounced every ~1-3 years during accreditation period. A follow up survey is conducted 6 months after the imitation of services
- Surveyors are initially selected by matching their administrational/program and field expertise with the organization's unique requirements
- Survey is conducted onsite by:
  - Observing healthcare services provided at locations set out at the beginning of the survey
  - Interviewing patients and other stakeholders (i.e. family members)
  - Reviewing documentation (i.e. medical records)
  - Consultation of organization personnel
- CARF reviews the survey findings and notifies the organization of the accreditation outcome in ~6-8 weeks. CARF also provides a written survey report and Quality Improvement Plan (QIP) at this time

Malcolm Baldrige

Highest level of nation recognition for performance excellence that a U.S. organization can receive. The award focuses on performance in 5 key areas: product and process, customer, workforce, leadership and governance, financial and market

Comparison element	TJC	CARF	DNV	
Website	https://www.jointcommission.org/what-we-offer/accreditation/accredited/accreditation-milestones/	https://carf.org/accreditation/programs/	https://www.dnv.com/news/dnv-accredits-1000th-healthcare-organization-in-the-us/	
About	Independent, non-profit-accredits and certifies 20,000+ organizations and programs in the US	Independent nonprofit accreditor of HHS	Independent, for-profit, private accreditation company that provided national and international accreditation services	
Number of accredited organizations	20,000+	6,000+	1000+ (in the US)	
Cost	Varies per number of sites and visits	Varies per number of sites, surveyors and visits + $995 site visit fee	Varies per number of sites and visits, less $$	
Accreditation prep period	4-6 months	9-12 mos for new survey, 6-9 mos for re-accreditation	Up to 1 year	
Accreditation period	3 years, lab:2 years	1-3 years, CARF-CFCC: 5 years	3 years	
Nationwide acceptance	Accreditation seen as symbol of quality throughout US	National and international proof of continuous quality improvement	Accepted nationwide, less prestige associated with accreditation compared to TJC and CARF	

Regulatory Bodies

OSHA – Occupational Safety and Health Administration

Purpose

- Setting and Enforcing Standards
- Providing training and aiding businesses
- Enforcing whistleblower protections

MN OSHA vs Federal OSHA

- **A workplace accident and injury reduction (AWAIR) program**
  - MN Statue 182.653
- **Employee right-to-know** and **Hazard Communication/GHS**
  - Minnesota Rules Chapter 5206
- **Employer-paid personal protective equipment**
  - Minnesota Statue 182.655, subd. 10a
- **Safety Committees**
  - MN Statue 181.676

MN OSHA vs Federal OSHA

- **Record keeping requirements**
- **Lockout devices in construction**
  - Minnesota Rules 5207.0600
- **Permissible Exposure Limits**
  - 29 CFR 1910.1000 – Air Contaminants
- **Powered industrial trucks**
  - 29 CFR 1910.178(m)(12))

Centers of Medicare & Medicaid Services (CMS)

Purpose

- Ensure effective and up-to-date healthcare coverage
- Quality oversight for beneficiaries
- Administering programs like Medicare, Medicaid, and the Children's Health Insurance Program

CMS – Quality Oversight

- Establishes Standards and Regulations
- Survey and Certification
- Quality Measurement and Reporting
- Value-Based Payment Programs
- Quality Improvement Organizations (QIOs)

CMS surveys

- CMS survey team performs unannounced onsite hospital surveys via the following process:
  - Entrance conference conducted with hospital admin staff sets out the purpose, scope and process of the survey
  - Initial on-site team meeting to review the scope of hospital services, identify hospital locations to be surveyed and review a list of patient records (patient sample that serves as a cross-section representative of patient population) to observe
  - A comprehensive patient review of care and services received by each patient on the patient list via the following methods:
    - Observations of patient care/services
    - Patient or family interviews
    - Staff interviews
    - Document (medical records, personnel files, P&P, credential files) review and photocopying

CMS surveys cont.

- An exit conference is set up at the end of the survey to inform the hospital staff of preliminary findings
- After the survey, CMS survey team develops a plan of correction to make sure the hospital is compliant with Federal requirements in the Medicare Conditions of Participation (CoP) as needed to continue to receive Medicare/Medicaid payment

CMS Surveys

Major Survey & Certification Functions			
	Major Function	**Focus**	**Frequency – CMS Policy**
1	Comprehensive ("Standard") Surveys	Survey all the major requirements for quality that are specified in regulation.	Nursing Homes – average every year Home Health Agencies and Hospices– every 3 years, every provider Hospitals – every 3 years, on average IFC/IID – average every year Others – 3-6 year averages, depending on provider type.
2	Complaint Investigations	Investigate complaints & providers' compliance with CMS requirements.	Frequency varies by provider type. In FY2016 approximately 56,522 nursing home and 3,420 hospital/CAH complaints were investigated.
3	Minimum Data Set (MDS) (Nursing Homes)	Monitor assessments that nursing homes are required to conduct for every nursing home resident and educating providers. Investigate problems in the MDS coding by NHs during surveys.	
4	Outcome & Assessment Information Set (OASIS)	CMS uses OASIS assessment data to inform oversight of home health agencies.	
5	Validation of State Surveys	CMS conducts validation surveys to verify the accuracy of State surveys. Two main types of validation surveys are done: (a) comparative surveys, in which a CMS team or contractor conducts an independent survey within 60 days of the State survey (to compare results) and (b) observational surveys, in which a CMS team or contractor accompanies the State team to observe the process of the State team. Sample size varies with provider type..	
6	Validation of Accrediting Organization (AO) Surveys	Two main types of validation surveys of AOs are done: (a) Representative Sample Validation surveys, in which the SA conducts a survey within 60 days of the AO survey and, less frequently (b) "mid-cycle" or Substantial Allegation complaint validation surveys that are not tied to the timing of an AO survey but are designed to assess the extent of accredited provider/supplier compliance, for particular purposes, usually in comparison to non-accredited providers/suppliers. Sample size varies according to the budget, and provider/supplier type. CMS must report annually to Congress on the performance of all CMS-approved national accreditation programs in assuring the compliance with Medicare health and safety standards of accredited, deemed providers/suppliers. In addition, complaint surveys are conducted in response to substantial allegations of non-compliance in accredited, deemed facilities.	
7	Accrediting Organization Approvals & Oversight	CMS reviews the applications of national accrediting organizations (AOs) for initial approval as well as renewal of Medicare-approved accreditation programs under which providers/suppliers may be "deemed" by CMS to meet required health and safety standards. The statute requires that the AO standards meet or exceed those of Medicare and that the AO requirements for accreditation, survey procedures, ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, monitoring procedures for provider entities found out of compliance with the conditions or requirements, and ability to provide CMS with necessary data for validation be comparable to those of Medicare. Representative Sample and Substantial Allegation Validation surveys represent an important aspect of CMS' on-going AO oversight once CMS-approval has been granted.	
8	Public Information	CMS and States provide high quality content on public websites regarding a variety of provider types. CMS' *Five-Star Quality Rating System* offers consumers easy-to-understand information about the quality of care in the nation's nursing homes, on the CMS *Nursing Home Compare* website. The website offers key information about quality measures, staffing and survey results. As a service to the public, the website improves the ability of consumers to make informed decisions and to ask pertinent questions of providers. As a tool for quality, the website provides incentives for nursing homes to improve their quality. CMS also publishes nursing home survey reports (Form 2567s) in a searchable database available to the public via the internet, as well as hospital complaint investigation surveys.	

OIG – Office of Inspector General

State OIG

- Prevent and detect fraud, waste and abuse on state level
  - Promote state economy efficiency and effectiveness
  - Conducting audits on any entities that receive state dollars
  - Ensure state agencies meet high ethical and financial standards

Federal OIG

- Prevent and detect fraud, waste and abuse on federal level
  - Promote federal economy efficiency and effectiveness
  - Conducting audits on any entities that receive federal dollars
  - Ensure federal agencies meet high ethical and financial standards

State Regulators

Minnesota Department of Health (MDH)

- The state agency responsible for protecting, maintaining, and improving the health of all people in Minnesota.
- Built upon a strong partnership between MDH, local public health agencies, Tribal governments, and other organizations.
- Monitor outbreaks, support statewide food programs, ensure tap water is safe to drink, inspect nursing homes, hospitals, and other facilities.

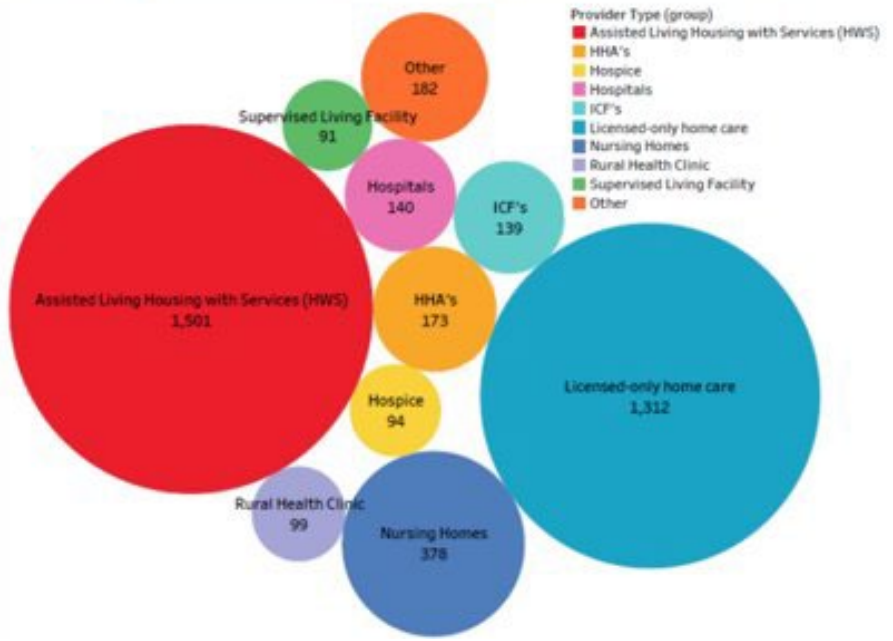
Minnesota Department of Health
Health Regulation Division

HRD by the Numbers

HRD works with other state agencies and local partners to ensure Minnesotans are well cared for. To this end, each year we:

- Monitor 4,200 health care facilities and providers for safety and quality
- Review qualifications and regulate more than 6,700 health professionals
- Enforce interagency agreement with DHS who conducts 130,000 criminal background checks for healthcare workers at facilities the Health Regulation Division (HRD) regulates
- Maintain a registry of more than 60,000 nursing assistants
- Inspect 560 funeral establishments and license 1,300 morticians
- Process more than 1 million and audit more than 8,000 federal nursing home resident health assessments to ensure accurate submission, completion and billing for services
- Register more than 3,400 spoken language health interpreters

Provider Types Monitored by the Health Regulation Division of MDH



Licensing/certification process

Who: State department of health

What: In-person survey

Where: Hospital/Long Term Care Facility

When: Once every 1-4 years

How: Surveyors review documentation, interview patients and staff, tour the facility, observe cares, etc.

MDH Surveys

- Types:
  - Full survey: Similar to CMS process, with exception of specific MN regulations.
  - Complaint: completed through the Office of Health Facility Complaints (OHFC)
    - Both LTC and hospitals can have OHFC visits.
    - LTC & Assisted Living facilities have different regulations than hospitals/CAHs.
- Other Health Regulation Division programs include:
  - CLIA (lab inspections), Engineering services (life safety code), Health Occupations licensing, case mix review, mortuary science (funeral licensure)

Office of Health Facility Complaints (OHFC)

Investigates reports and complaints of health care facilities violating state or federal regulations. OHFC investigates:

- Complaints relating to quality of life and quality of care at health care facilities/agencies including resident rights concerns
- Minnesota licensed facilities:
  - Hospitals
  - Nursing homes
  - Boarding care homes
  - Supervised living facilities
  - Assisted living and home health agencies
- Individuals or organizations exempted from licensure
- Allegations of child maltreatment in non-licensed personal care provider organizations
- Personal care assistance staff working in home care agencies

DHS vs MDH

Department Human Services

Focus: Human Services

- Health Care programs for low-income Minnesotans through Minnesota Health Care Programs (MHCP)
- Child Care Assistance
- Employment Services
- Food Support (i.e. SNAP)
- Mental Health Services
- Child Services

Department of Health

Focus: Public Health

- Disease Control
- Environmental Health
- Public Policy
- Regulation of Healthcare Providers
- Data and Reporting

Category	Minnesota Department of Health (MDH)	Minnesota Department of Human Services (DHS)
Primary Role	**Protects and promotes public health**	**Administers social services and healthcare programs**
Focus Areas	Disease prevention, environmental health, healthcare regulation	Public assistance programs, Medicaid, mental health services
Healthcare Oversight	Regulates hospitals, clinics, and healthcare facilities	Administers healthcare coverage for low-income individuals (e.g., Medicaid)
Public Health Initiatives	Manages vaccination programs, infectious disease control, and health education	Supports mental health services, substance abuse treatment, and disability services
Licensing & Regulation	Licenses healthcare providers and facilities	Licenses social service providers, child welfare agencies, and foster care
Emergency Preparedness	Responds to public health emergencies (pandemics, outbreaks, natural disasters)	Supports crisis response for vulnerable populations during emergencies
Nutrition & Food Safety	Oversees food safety regulations, nutrition programs, and water quality	Administers SNAP (food assistance) and nutrition support for low-income families
Maternal & Child Health	Provides prenatal care programs, infant health screenings, and WIC program oversight	Supports child protection services, foster care, and family assistance programs
Aging & Disability Services	Provides health-related guidance for aging populations	Administers long-term care, home and community-based services for elderly and disabled individuals
Behavioral & Mental Health	Addresses public health concerns related to substance abuse and mental health	Funds and manages state mental health programs and crisis intervention
Medicaid & Insurance	Works on public health insurance policies and healthcare system improvement	Administers Minnesota's Medicaid program (Medical Assistance) and MinnesotaCare
Community Health Programs	Supports local health departments, health equity initiatives	Provides direct support services to individuals and families in need
Funding & Grants	Provides funding for health research, local health programs, and disease prevention	Manages federal and state funds for social services programs

MDH and DHS Collaborations

- Shared Goals
- Collaboration on Healthcare Access
- Public Health & Social Services Integration
- Joint Emergency Response
- Data Sharing & Policy Coordination

Example: Maternal and Child Health Initiative

Additional Regulatory Bodies and Regulations

Billing Oversight

- National Government Services – CMS
- DHS – Medicaid Fraud Control Unit – Medicaid

General Regulations

- HIPAA (Health Insurance Portability and Accountability Act): standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge
- EMTALA (Emergency Medical Treatment & Labor Act): ensure public access to emergency services regardless of ability to pay

Questions?

References

- https://www.ngsservices.com/
- https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/#:~:text=Medicaid%20Fraud%20Control%20Units%20(MFCUs)%20investigate%20and%20prosecute%20Medicaid%20provider,of%20each%20MFCU's%20operational%20costs.
- https://www.aha.org/system/files/2018-01/info-regulatory-burden-federal-agencies.pdf
- https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf
- https://pmc.ncbi.nlm.nih.gov/articles/PMC3156520/
- https://www.iamra.com/What-is-a-Medical-Regulatory-Authority
- https://www.jointcommission.org/what-we-offer/accreditation/accredited/accreditation-milestones/
- https://www.dnv.com/news/dnv-accredits-1000th-healthcare-organization-in-the-us/
- https://carf.org/accreditation/programs/
- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf
- https://www.dnv.com/services/hospital-accreditation-7516/
- https://www.healthworkforceta.org/wp-content/uploads/2024/08/MDH_Health_Workforce_Survey_2024.pdf
- https://oig.hhs.gov/about-oig/#:~:text=Since%20its%201976%20establishment%2C%20the%20Office%20of,of%20Health%20&%20Human%20Services%20(HHS)%20programs
- https://www.oig.dhs.gov/about/faqs#:~:text=DHS%20Office%20of%20Inspector%20General%20(OIG)%20is,OIG%20is%20also%20independent%20of%20the%20Department