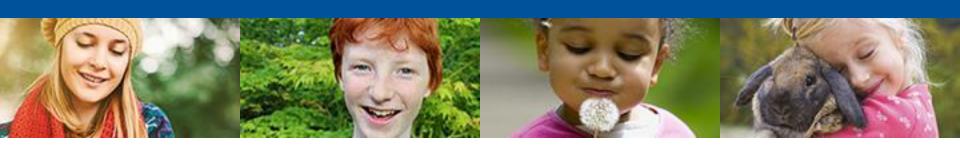


SHEA 2024

Prepared and Presented By: Kathleen (Kate) Gase, MBA, MPH, FACHE, FAPIC



Regulatory & Emergency Preparedness

DISCLOSURES

None

STATED OBJECTIVES

- State the role and functions of public health entities at local, state, and national levels
- Review core emergency preparedness concepts, including emergency response planning, incident command functions, and facility response to emergent events
- Assist in policy and response plan development and evaluation for infection-related events, such as bioterrorism or pandemic respiratory pathogens
- Recite an overview of the system of state, federal, and accrediting organization oversight and the requirements for healthcare facilities preparing for a visit from CMS, TJC, and State DPH

BUT REALLY ...

- I hope to at least, mostly...
 - Arm you with the essentials and build confidence;
 - Get you thinking and asking the right questions; and
 - Help you identify the right people to ask for help.



THE RULE MAKERS AND THE INFLUENCERS

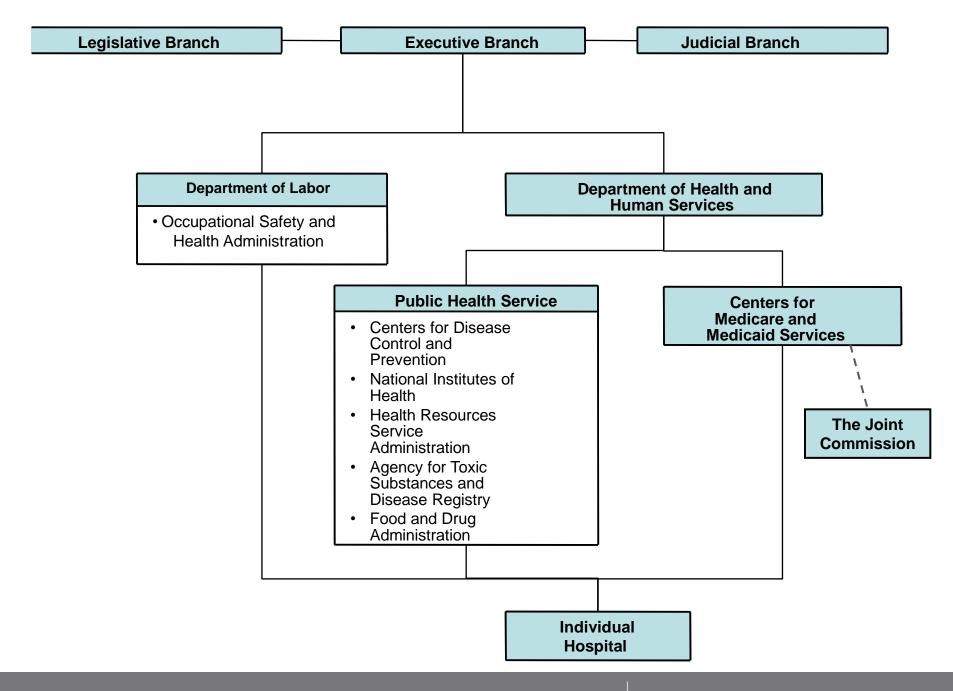
Federal Agencies That Govern and Influence Hospital Epi and Infection Prevention Programs













OSHA

Occupational Safety and Health Administration







OSHA – RULES & REGULATIONS

- Set and enforce standards
 - Levy fines
- Provide training, outreach, education, assistance
- General safety and health standards
 - One size fits all
- General duty clause
 - Employers must provide every worker a safe and healthy workplace
 - Specific standards or regulations
 - 'Perceived' hazard
 - Recognized guidelines or standards of care
 - Enforcement

OSHA – INSPECTIONS

- Initiation driven by complaints
- Citations and penalties
 - Posted publicly
 - Vary according to seriousness of violation
 - Highest for willful or repeated violations of a standard
- Appeals
 - Facility and employees have right to appeal
 - Do not be afraid to contest citations

OSHA – STANDARDS & DIRECTIVES

- Bloodborne Pathogens Standard (29 CFR 1910.1030)
 - Needlestick Safety and Prevention Act, P.L. 106-430
 - Written exposure control plan
 - Standard precautions, workplace and engineering controls, cleaning/decontamination, regulated medical waste
 - Safety devices
 - Hepatitis B vaccination program
 - Post-exposure evaluation and follow-up
 - Recordkeeping system
- Personal Protective Equipment (29 CFR 1910.132)
- Eye and Face Protection Standard (29 CFR 1910.133)
- Respiratory Protection Standard (29 CFR 1910.134)
- TB Compliance Directive (CPL 02-02-078)



CMS

Centers for Medicare and Medicaid Services

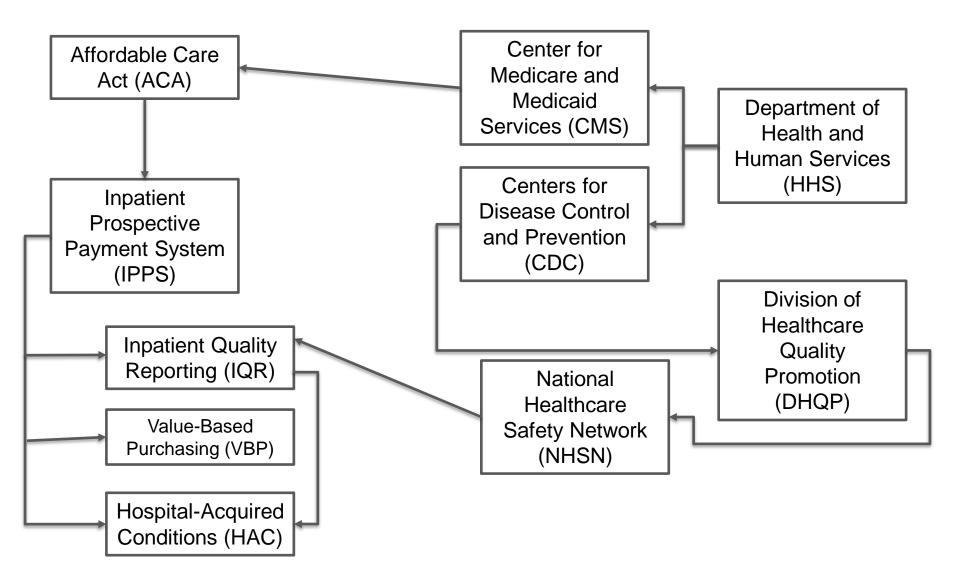








CMS – PAY FOR REPORTING/PERFORMANCE "INCENTIVE"



CMS – ACCREDITATION

- A hospital accredited by a CMS-approved accreditation program ('deeming' authority) may substitute that for a survey by the State Survey Agency
 - State health department surveyors act as agents of CMS
 - Validation survey
 - 5% of hospitals after accreditation; full, comprehensive survey
 - Full survey
 - Hospital does not participate in accreditation
 - Complaints
 - Partial or full survey
 - Licensure
 - Initial step for licensure and/certification

CMS – CONDITIONS OF PARTICIPATION

- Surveyors assess hospital's compliance with the Conditions of Participation (CoP) for all services, areas and locations covered by the hospital's provider agreement under its CMS Certification Number (CCN)
- CoP: Minimum health and safety standards that healthcare organizations must meet to be CMS certified and receive reimbursement

CMS – CONDITIONS OF PARTICIPATION

- Compliance enforced as condition for payment
- A citation can risk a healthcare facility's CMS standing
 - Standard vs. Immediate Jeopardy
- Interpretive guidelines for surveyors (worksheets)
 - May include examples of practices that are encouraged to be adopted but not required
- CoP often based on guidelines, recommendations, or expert opinions
 - To name a few: CDC, AORN, AAMI

CMS - COP 482.42

- Infection prevention and control and antibiotic stewardship programs
 - The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship.
- Four (Six) Standards
 - Infection prevention and control program organization and policies
 - Antibiotic stewardship program organization and policies
 - Leadership responsibilities
 - Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems
 - COVID-19 reporting
 - Reporting of acute respiratory illness

CMS - COP 482.42 (A)

- Infection prevention and control (IPC) program organization and policies
 - (1) Qualified individual(s) appointed by the governing body, based on the recommendations of medical and nursing leadership, to be responsible for IPC program
 - (2) IPC program employs methods for preventing and controlling the transmission of infection within the hospital and between the hospital and other institutions (policies and procedures)
 - (3) IPC program includes surveillance, preventions, and control of HAIs, including maintaining the environment to avoid sources and transmission of infection, and address issues identified by public health authorities
 - (4) IPC program reflects the scope and complexity of services provided

CMS - COP 482.42 (B)

- Antibiotic stewardship program (ASP) organization and policies
 - (1) Qualified individual(s) appointed by the governing body, based on the recommendations of medical and nursing leadership, to be responsible for ASP
 - (2) ASP demonstrates coordination among all components responsible to antibiotic use and resistance (ex. IPC, QAPI, med staff, nursing, pharmacy); ASP documents evidence-based use of antibiotics; ASP documents improvements in proper antibiotic use
 - (3) ASP adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use
 - (4) ASP program reflects the scope and complexity of services provided

CMS - COP 482.42 (C)

- Leadership responsibilities
 - (1) Governing body must ensure:
 - Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities;
 - All HAIs and other infectious diseases identified by the IPC program as well as antibiotic use issues identified by the ASP are addressed in collaboration with hospital QAPI leadership

CMS - COP 482.42 (C) CONTINUED

- Leadership responsibilities
 - (2) Infection preventionist is responsible for:
 - Development and implementation of hospital-wide infection surveillance, preventions, and control policies and procedures that adhere to nationally recognized guidelines;
 - All documentation of the ICP program and its surveillance, preventions, and control activities;
 - Communication/collaboration with the QAPI program;
 - Competency-based training and education of hospital personnel, medical staff, and contracted services on the practical applications of IPC guidelines, policies, and procedures;
 - Prevention and control of HAIs, including auditing adherence to policies and procedures by hospital personnel;
 - Communication and collaboration with the ASP

CMS - COP 482.42 (C) CONTINUED

- Leadership responsibilities
 - (3) Leader of the ASP is responsible for:
 - Development and implementation of hospital-wide ASP, based on nationally recognized guidelines, to monitor and improve the use of antibiotics;
 - All documentation of the ASP activities;
 - Communication/collaboration with the medical staff, nursing, and pharmacy, as well as with the ICP and QAPI programs;
 - Competency-based training and education of hospital personnel, medical staff, and contracted services on the practical applications of antibiotic stewardship guidelines, policies, and procedures

CMS - COP 482.42 (D)

- Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems
 - (1) Programs are established in a manner that considers each member hospital's unique circumstances and any significant differences in patient population and services offered;
 - (2) Programs establish and implement policies and procedures to ensure the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;
 - (3) Programs have mechanisms in place to ensure that issues localized to a particular hospital are duly considered and addressed;
 - (4) Qualified individuals with expertise in IPC and antibiotic stewardship designated at the hospital as responsible for communicating with the unified programs, implementing and maintaining policies and procedures governing the programs, and for providing education and training to hospital staff

CMS - COP 482.42 (E & F)

- (E) COVID-19 Reporting
- (F) Reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory illness





THE JOINT COMMISSION

Check on your neighbor to ensure they are awake!









TJC - SURVEY

- Unannounced survey
 - Approximately every 3 years
 - Survey team
 - Physician
 - Nurse
 - Life safety code specialist
 - Patient tracers
 - Infection prevention tracer
 - Observed breaches of policy/procedure
 - Gaps in staff knowledge
- Recommendation for accreditation made based on the facility's compliance with the Elements of Performance (EP)

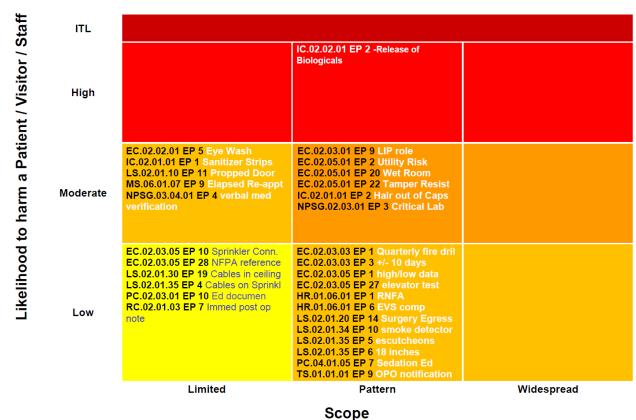
- High volume, high risk, problem-prone infection prevention issues are high priority for TJC
 - High risk
 - Hand hygiene
 - Sterilization, high level disinfection
 - Ambulatory areas
 - Procedure areas
 - Injection practices
 - Construction/renovation
- Periodically assess the infection prevention program using the standards
 - Meets the intent of each standard
 - Complies with the elements of performance
 - Compliance is documented

- Keep documentation up to date and available
 - Authority Statement
 - Infection Prevention Committee minutes
 - Discussion, conclusions, actions and results of actions
 - Infection prevention policies/procedures
 - HAI data and reports; projects and reports
 - Demonstrate improvement in quality of care and outcomes
 - Flow of information and reports
 - Annual reports to Medical Board, Board of Trustees
- Issues identified on past surveys
- Focus/pitfalls of recent surveys at other hospitals

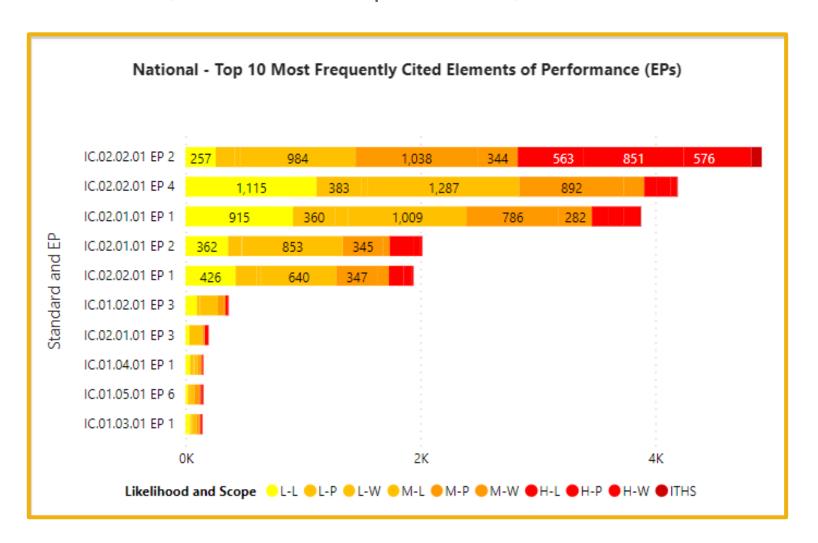
Review your SAFER Matric from previous visit

The Joint Commission SAFER™ Matrix

Program: Hospital



Be aware of, and ensure compliance with, the most-cited standards



TJC - NATIONAL PATIENT SAFETY GOAL

- Prevent Infection
 - NPSG.07.01.01: Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning.

TJC - IPC STANDARDS

Reference Guide: Infection Control Standards Effective July 1, 2024, for Hospitals (HAP) & Critical Access Hospitals (CAH) Only			
Infection prevention and control program leader and responsibilities	IC.01.01.01, EPs 1,2,3, 4,6	IC.04.01.01, EPs 1,2	
Responsibilities of the governing body and hospital leaders	N/A	IC.04.01.01, EP 1 IC.05.01.01, EPs 1,2	
Resources for the infection prevention and control program	IC.01.02.01, EPs 1,2,3	IC.05.01.01, EP 1	
Infection risk identification and annual review	IC.01.03.01, EPs 1,2,3	IC.06.01.01, EPs 1,2	
Setting goals for/prioritizing infection prevention and control activities based on risk	IC.01.04.01, EP 1	IC.06.01.01, EP 1	
Infection prevention and control plan	IC.01.05.01, EP 2	N/A	
Requirements for infection control policies and procedures	N/A	IC.04.01.01, EPs 3,4	
Use of evidence-based national guidelines when developing infection prevention and control activities	IC.01.05.01, EP 1	IC.04.01.01, EP 3	
Requirements for policies and procedures addressing the reprocessing reusable devices, including the use of manufacturers' instructions	N/A	IC.04.01.01, EP 4	
Access to and use of public health and safety data	N/A	IC.05.01.01 EP 1 IC.06.01.01 EP 1	
Surveillance of infections or infection control processes	IC.01.05.01, EP 2 IC.02.01.01, EP 1	IC.06.01.01, EP 3	
Outbreak management	IC.01.05.01, EP 5 IC.02.01.01, EP 5	IC.06.01.01, EP 4	
The infection prevention and control program is hospitalwide	IC.01.05.01, EP 6	IC.04.01.01 EP 5	
Influx of potentially infectious patients	IC.01.06.01, EPs 2,3,4	See EM requirements	

TJC - IPC STANDARDS

Implementation of infection prevention and control activities, including cleaning,	IC.02.01.01, EPs 1,2,3,	IC.06.01.01, EP 3
disinfection, and sterilization	10, 11	
	IC.02.02.01, EPs	
	1,2,4,5	
Storage and disposal of infectious waste	IC.02.01.01, EP 6	See EC.02.02.01
	IC.02.02.01, EP 3	
Communication of information to staff, visitors, patients, families on	IC.02.01.01, EP 7	IC.06.01.01, EP 4
responsibilities in infection prevention and control, e.g., posters or pamphlets		
Communication of infection surveillance, prevention, and control information to	IC.02.01.01, EP 8	IC.05.01.01, EP 2
the appropriate staff within the hospital		IC.06.01.01, EP 4
		IC.07.01.01, EP 1
Reporting to local, state, and federal public health authorities	IC.02.01.01, EP 9	IC.04.01.01, EP 3
		IC.07.01.01, EP 1
Patient notification and follow-up after exposure to infection or incorrectly	IC.02.03.01, EP 4	IC.04.01.01, EP 4
reprocessed medical/surgical device		
Occupational health	IC.02.03.01, EPs 1, 2	IC.06.01.01, EP 5
Protocols to support preparedness for high-consequence infectious diseases or	N/A	IC.07.01.01, EPs 1,2
special pathogens		
Staff vaccination against influenza	IC.02.04.01 EPs 1-9	IC.04.01.01, EP 3
		IC.06.01.01, EP 5
Practices to prevent HAIs (MDRO, CLABSI, CAUTI, SSI)	IC.02.05.01, EPs 1, 2, 3	IC.04.01.01 EP 3
		IC.06.01.01 EP 3
Evaluation of the infection prevention and control plan	IC.03.01.01, EPs 1,7	N/A
Communication of evaluation results with the quality and safety leaders.	IC.03.01.01, EP 6	IC.05.01.01, EP 2
Total Number of EPs	51	14

TJC - IPC STANDARDS

Standard	Details
IC 04.01.01 5 EPs	The hospital wide infection prevention and control program for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases
IC 05.01.01 2 EPs	The hospital's governing body is accountable for the implementation, performance, and sustainability of the infection prevention and control program
IC 06.01.01 5 EPs	The hospital implements its infection prevention and control program through surveillance, prevention, and control activities
IC 07.01.01 2 EPs	The hospital implements processes to support preparedness for high-consequence infectious diseases or special pathogens

IC 04.01.01 – HOSPITAL WIDE IP PROGRAM

- EP 1
 - The hospital governing body, based on the recommendation of the medical staff and nursing leaders, appoints an infection preventionist(s) or infection control professional(s) qualified through education, training, experience, or certification in infection prevention to be responsible for the infection prevention and control program.

IC 04.01.01 – HOSPITAL WIDE IP PROGRAM

- EP 2
 - The infection preventionist is responsible for the following:
 - Development and implementation of hospital wide infection surveillance, prevention, and control policies and procedures that adhere to law and regulation and nationally recognized guidelines
 - Documentation of the infection prevention and control program and its surveillance, prevention, and control activities
 - Competency-based training and education of hospital staff on infection prevention and control policies and procedures and their application

IC 04.01.01 - HOSPITAL WIDE IP PROGRAM

- EP 2, continued
 - The infection preventionist is responsible for the following:
 - The prevention and control of health care—associated infections and other infectious diseases, including auditing staff adherence to infection prevention and control policies and procedures
 - Communication and collaboration with all components of the hospital involved in infection prevention and control activities, including but not limited to the antibiotic stewardship program, sterile processing department, and the water management program
 - Communication and collaboration with the hospital's quality assessment and performance improvement program to address infection prevention and control issues (See also EC.02.05.02, EP 2)

IC 04.01.01 – HOSPITAL WIDE IP PROGRAM

- EP 3
 - The hospital's infection prevention and control program has written policies and procedures to guide its activities and methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings. The policies and procedures are in accordance with the following hierarchy of references

TJC - HIERARCHY OF IP RESOURCES



IC 04.01.01 – HOSPITAL WIDE IP PROGRAM

EP 4

- The hospital's policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:
 - Cleaning, disinfection, and sterilization of reusable medical and surgical devices in accordance with the Spaulding classification system and manufacturers' instructions
 - The use of EPA-registered disinfectants for noncritical devices and equipment according to the directions on the product labeling, including, but not limited to, indication, specified use dilution, contact time, and method of application
 - The use of FDA-approved liquid chemical sterilants for the processing of critical devices and high-level disinfectants for the processing of semi critical devices in accordance with the FDA cleared label and device manufacturers' instructions

IC 04.01.01 - HOSPITAL WIDE IP PROGRAM

- EP 4, continued
 - The hospital's policies and procedures for cleaning, disinfection, and sterilization of reusable medical and surgical devices and equipment address the following:
 - Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical and biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection
 - Resolution of conflicts or discrepancies between a medical device manufacturer's instructions and manufacturers' instructions for automated high-level disinfection or sterilization equipment
 - Criteria and the process for the use of immediate-use steam sterilization
 - Actions to take in the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s) or after the reprocessed item(s) was used or stored for later use

IC 04.01.01 – HOSPITAL WIDE IP PROGRAM

- EP 5
 - The infection prevention and control program reflects the scope and complexity of the hospital services provided by addressing all locations, patient populations, and staff

IC 05.01.01 – GOVERNING BODY

- EP 1
 - The hospital's governing body is responsible for the implementation, performance, and sustainability of the infection prevention and control program and provides resources to support and track the implementation, success, and sustainability of the program's activities
- EP 2
 - The hospital's governing body ensures that the problems identified by the infection prevention and control program are addressed in collaboration with hospital quality assessment and performance improvement leaders and other leaders (for example, the medical director, nurse executive, and administrative leaders)

IC 06.01.01 – IMPLEMENTATION

- EP 1
 - To prioritize the program's activities, the hospital identifies risks for infection, contamination, and exposure that pose a risk to patients and staff based on the following:
 - Its geographic location, community, and population served
 - The care, treatment, and services it provides
 - The analysis of surveillance activities and other infection control data
 - Relevant infection control issues identified by the local, state, or federal public health authorities that could impact the hospital

IC 06.01.01 - IMPLEMENTATION

- EP 2
 - The hospital reviews identified risks at least annually or whenever significant changes in risk occur
- EP 3
 - The hospital implements activities for the surveillance, prevention, and control of health care—associated infections and other infectious diseases, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities that could impact the hospital. (See also NPSG.07.01.01, EP 1)

IC 06.01.01 - IMPLEMENTATION

- EP 4
 - The hospital implements its policies and procedures for infectious disease outbreaks, including the following:
 - Implementing infection prevention and control activities when an outbreak is first recognized by internal surveillance or public health authorities
 - Reporting an outbreak in accordance with state and local public health authorities' requirements
 - Implementing outbreak investigation
 - Communicating information necessary to prevent further transmission of the infection among patients, visitors, and staff, as appropriate

IC 06.01.01 - IMPLEMENTATION

- EP 5
 - The hospital implements policies and procedures to minimize the risk of communicable disease exposure and acquisition among its staff, in accordance with law and regulation. The policies and procedures address the following:
 - Screening and medical evaluations for infectious diseases
 - Immunizations
 - Staff education and training
 - Management of staff with potentially infectious exposures or communicable illnesses

IC 07.01.01 - PREPAREDNESS

- EP 1
 - The hospital develops and implements protocols for high-consequence infectious diseases or special pathogens. The protocols are readily available for use at the point of care and address the following:
 - Identify: Procedures for screening at the points of entry to the hospital for respiratory symptoms, fever, rash, and travel history to identify or initiate evaluation for high-consequence infectious diseases or special pathogens
 - Isolate: Procedures for transmission-based precautions
 - Inform: Procedures for informing public health authorities and key hospital staff

IC 07.01.01 - PREPAREDNESS

- EP 1, continued
 - The hospital develops and implements protocols for high-consequence infectious diseases or special pathogens. The protocols are readily available for use at the point of care and address the following:
 - Required personal protective equipment and proper donning and doffing techniques
 - Infection control procedures to support continued and safe provision of care while the patient is in isolation and to reduce exposure among staff, patients, and visitors using the hierarchy of controls
 - Procedures for waste management and cleaning and disinfecting patient care spaces, surfaces, and equipment (See also EC.02.05.01, EP 15)

IC 07.01.01 - PREPAREDNESS

- EP 2
 - The hospital develops and implements education and training and assesses competencies for the staff who will implement protocols for high-consequence infectious diseases or special pathogens



HICS

Hospital Incident Command Structure (System)





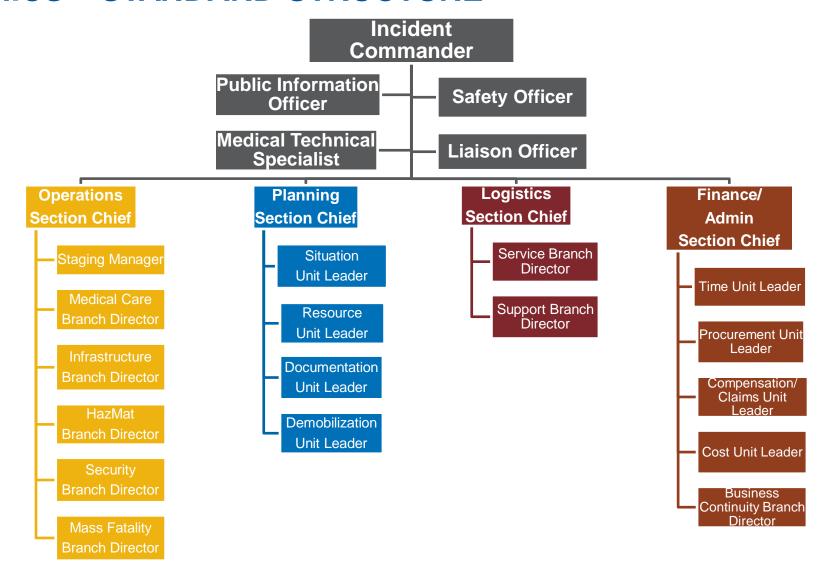
HEICS – HOSPITAL EMERGENCY INCIDENT COMMAND

- Based on the Orange County Hospital Emergency Incident Command System, which was initiated as a part of the California Fire Service during the 1970s FIRESCOPE – Fire Resources of California Organized for Potential Emergencies
- Historian Indicates
 Historian Indicates

HICS

- Purpose
 - Facilitate communication
 - Allow efficient decision making
- Span of control
 - Number of persons a leader can effectively manage in each environment
 - Ideally 3–7 people
- Unity of command
 - Each individual reports to, and takes instructions from, only one supervisor
- Information flow
 - Passed upward at each level
 - Too little or too much can paralyze the system/response

HICS - STANDARD STRUCTURE



- Incident Commander
 - Responsible for overall incident
 - Assures that emergency care is provided to patients
 - Assures that hospital staff are protected and remain capable of critical functions
 - Assures that the needed emergency functions of hospitals are preserved
 - Organizes and directs the Incident Command Center
 - Strategic direction for hospital incident management and support activities, including emergency response and recovery
 - Authorizes total facility evacuation if warranted

- Safety and Liaison Officer(s)
 - Assure safety of patients, staff, visitors, responders
 - Liaison between hospital and community responders
 - Monitor and correct hazardous conditions
 - Authority to halt any operation that poses immediate threat to life and health
- Public Information Officer
 - Manages release of patient tracking and other sensitive information
 - Liaisons with media
 - Serves as the conduit for information to internal and external stakeholders, including staff, visitors and families, and the news media, as approved by the Incident Commander

- Medical Technical Specialist
 - Brings expertise to the command team related to issues evolving during the event
 - Biological / Infectious Disease, Chemical, Radiological, Administration, Legal, Risk, Ethics, Pediatrics, etc.

- Operations (Doers)
 - Responsible for activities to respond to incident
- Planning (Thinkers)
 - Gather and process data needed to plan response
- Logistics (Getters)
 - Obtain equipment needed to respond
 - Meet needs of responders (meals, occupational health, etc.)
- Finance (Payers)
 - Record expenses for future reimbursement

HICS – ACTIVATION

- Criteria for Opening the Command Post
 - National Event (9/11)
 - Media Alerts of a developing crisis (Civil unrest)
 - Notification of a regional or statewide highest-level alert (Terror alert)
 - Influx of patients that will tax a hospital (Mass casualty)
 - Significant business interruption (IT outage)
 - A planned event requiring major coordination within a hospital (Presidential debate)
 - Standardized, coordinated response needed (COVID-19, drug shortages)
- Progression by a Tiered approach
 - Virtual, Partial, Full

HICS - LIFE CYCLE

- Alert and notification
- Situation assessment and monitoring
- Emergency Operations Plan implementation
- Establishing the HICS
- Building the HICS structure
- Incident action planning
- Communications and coordination
- Staff health and safety
- Operational considerations
- Legal and ethical considerations
- Demobilization
- System recovery
- Response evaluation and organizational learning





SUMMARY

Regulatory & Emergency Preparedness









REGULATORY & EMERGENCY PREPAREDNESS

- It's complicated
- You cannot (should not) do it alone!
 - Multidisciplinary team approach
 - Pull in content experts
 - Provide content expertise
- Use existing structures
- Talk to your colleagues at other hospitals/similar facilities
- Good luck!!

CONTACT & REFERENCES

- E-mail: kathleen.gase@bjc.org
- OSHA: www.osha.gov/laws-regs
- CDC: <u>www.cdc.gov</u>
 - Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings

https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html

- CMS: www.cms.gov
 - Conditions of Participation

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-C/section-482.42

- The Joint Commission: www.jointcommission.org
 - National Patient Safety Goals

https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2024/hap-npsg-simple-2024-v2.pdf

Standards Reference Guide

https://www.jointcommission.org/-/media/tjc/documents/standards/prepublications/2024/reference-guide-hap-cah-ic.pdf