

No. 23-35014

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MONTANA MEDICAL ASSOCIATION, et al.,
Plaintiffs-Appellee,

MONTANA NURSES ASSOCIATION,
Intervenor-Plaintiff-Appellee,

v.

AUSTIN KNUDSEN, Montana Attorney General, et al.,
Defendants-Appellants,

Appeal from the United States District Court for the
District of Montana

No. D.C. No. 9:21-cv-00108-DWM (Hon. Don W. Molloy)

APPELLANTS' FURTHER EXCERPTS OF RECORD
VOLUME 1 OF 1

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Final Accreditation Report

**Providence Health and Services - Montana
500 West Broadway
Missoula, MT 59802**

**Organization Identification Number: 9306
Unannounced Full Event: 6/21/2022 - 7/20/2022**

**Program Surveyed
Hospital**

Final Report: Posted 7/21/2022
PL 236

The Joint Commission

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The Joint Commission Executive Summary

Program	Survey Dates	Event Outcome	Follow-up Activity	Follow-up Time Frame or Submission Due Date
Hospital	06/21/2022 - 06/24/2022, 07/19/2022 - 07/20/2022	Requirements for Improvement	Clarification (Optional)	Submit within 10 Business Days from the final posted report date
			Evidence of Standards Compliance (ESC)	Submit within 60 Calendar Days from the final posted report date

The Joint Commission What's Next - Follow-up Activity

Program: Hospital

Standard	EP	SAFER™ Placement	CoP	Tag	Included in the Evidence of Standard Compliance (within 60 calendar days)
EC.02.02.01	12	Low / Limited	§482.41 (a)	A-0701	✓
	5	Moderate / Limited	§482.41 (a)	A-0701	✓
EC.02.03.01	12	Moderate / Limited	§482.51 (b)	A-0951	✓
EC.02.03.05	28	Low / Widespread	§482.41 (b)(1)(i)	A-0710	✓
EC.02.05.01	15	Moderate / Pattern	§482.41 (d)(2)	A-0724	✓
	16	Low / Limited	§482.41 (d)(4)	A-0726	✓
	23	Moderate / Limited	§482.41 (d)(2)	A-0724	✓
	24	Low / Limited	§482.41 (d)(2)	A-0724	✓
	9	Low / Limited	§482.41 (a)	A-0701	✓
EC.02.05.02	3	Moderate / Pattern	§482.41 (d)(2)	A-0724	✓
EC.02.05.03	1	Moderate / Limited			✓
EC.02.05.05	5	Low / Limited	§482.41 (d)(2)	A-0724	✓
	6	Low / Limited	§482.41 (d)(2)	A-0724	✓
EC.02.05.09	11	Low / Limited	§482.41 (d)(2)	A-0724	✓

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Standard	EP	SAFER™ Placement	CoP	Tag	Included in the Evidence of Standard Compliance (within 60 calendar days)
	12	Moderate / Limited			✓
	2	Moderate / Limited	§482.41 (d)(2)	A-0724	✓
EC.02.06.01	1	Moderate / Pattern	§482.41	A-0700	✓
			§482.25 (b)(1)	A-0501	✓
			§482.41 (a)	A-0701	✓
IC.01.02.01	1	Low / Limited			✓
IC.02.01.01	2	Moderate / Limited	§482.42 (a)(3)	A-0750	✓
IC.02.02.01	2	Moderate / Limited	§482.42 (a)(2)	A-0749	✓
LS.02.01.10	1	Low / Limited	§482.41 (b)(1)(i)	A-0710	✓
	14	Low / Limited	§482.41 (b)(1)(i)	A-0710	✓
LS.02.01.35	14	Low / Limited	§482.41 (b)(1)(i)	A-0710	✓
	4	Low / Limited	§482.41 (b)(1)(i)	A-0710	✓
NPSG.06.01.01	3	Moderate / Limited			✓
NPSG.15.01.01	1	Moderate / Limited	§482.13 (c)(2)	A-0144	✓
PC.01.02.03	3	Moderate / Limited			✓
	5	Moderate / Pattern	§482.24 (c)(4)(i)(B)	A-0461	✓

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Standard	EP	SAFER™ Placement	CoP	Tag	Included in the Evidence of Standard Compliance (within 60 calendar days)
PC.01.02.07	8	Moderate / Limited			✓
PC.01.03.01	22	Low / Limited			✓
PC.02.01.11	2	High / Pattern			✓
PC.02.02.03	11	Low / Limited			✓
PC.03.01.03	1	High / Pattern	§482.52 (b)	A-1002	✓
RC.02.01.01	2	Low / Pattern			✓
RI.01.03.01	1	Low / Limited	§482.24 (c)(4)(v)	A-0466	✓

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SAFER™ Matrix
Program: Hospital

Likelihood to harm a Patient / Visitor / Staff

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ITHS			
	Limited	Pattern	Widespread
High		PC.02.01.11 EP 2 PC.03.01.03 EP 1	
Moderate	EC.02.02.01 EP 5 EC.02.03.01 EP 12 EC.02.05.01 EP 23 EC.02.05.03 EP 1 EC.02.05.09 EP 2 EC.02.05.09 EP 12 IC.02.01.01 EP 2 IC.02.02.01 EP 2 NPSG.06.01.01 EP 3 NPSG.15.01.01 EP 1 PC.01.02.03 EP 3 PC.01.02.07 EP 8	EC.02.05.01 EP 15 EC.02.05.02 EP 3 EC.02.06.01 EP 1 PC.01.02.03 EP 5	
Low	EC.02.02.01 EP 12 EC.02.05.01 EP 9 EC.02.05.01 EP 16 EC.02.05.01 EP 24 EC.02.05.05 EP 5 EC.02.05.05 EP 6 EC.02.05.09 EP 11 IC.01.02.01 EP 1 LS.02.01.10 EP 1 LS.02.01.10 EP 14 LS.02.01.35 EP 4 LS.02.01.35 EP 14 PC.01.03.01 EP 22 PC.02.02.03 EP 11 RI.01.03.01 EP 1	RC.02.01.01 EP 2	EC.02.03.05 EP 28
	Limited	Pattern	Widespread
Scope			

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The Centers for Medicaid and Medicare Services (CMS) Summary

Program: Hospital

CoP(s)	Tag	CoP Score	Corresponds to:
§482.13	A-0115	Standard	HAP
§482.13(c)(2)	A-0144	Standard	HAP/NPSG.15.01.01/EP1
§482.24	A-0431	Standard	HAP
§482.24(c)(4)(i)(B)	A-0461	Standard	HAP/PC.01.02.03/EP5
§482.24(c)(4)(v)	A-0466	Standard	HAP/RI.01.03.01/EP1
§482.25	A-0489	Standard	HAP
§482.25(b)(1)	A-0501	Standard	HAP/EC.02.06.01/EP1
§482.41	A-0700	Standard	HAP/EC.02.06.01/EP1
§482.41(a)	A-0701	Standard	HAP/EC.02.02.01/EP5 HAP/EC.02.02.01/EP12 HAP/EC.02.05.01/EP9 HAP/EC.02.06.01/EP1
§482.41(b)(1)(i)	A-0710	Standard	HAP/EC.02.03.05/EP28 HAP/LS.02.01.10/EP1 HAP/LS.02.01.10/EP14 HAP/LS.02.01.35/EP4 HAP/LS.02.01.35/EP14
§482.41(d)(2)	A-0724	Standard	HAP/EC.02.05.01/EP15 HAP/EC.02.05.01/EP23 HAP/EC.02.05.01/EP24 HAP/EC.02.05.05/EP5 HAP/EC.02.05.05/EP6 HAP/EC.02.05.09/EP2 HAP/EC.02.05.09/EP11 HAP/EC.02.05.02/EP3
§482.41(d)(4)	A-0726	Standard	HAP/EC.02.05.01/EP16
§482.42	A-0747	Standard	HAP
§482.42(a)(2)	A-0749	Standard	HAP/IC.02.02.01/EP2
§482.42(a)(3)	A-0750	Standard	HAP/IC.02.01.01/EP2

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CoP(s)	Tag	CoP Score	Corresponds to:
§482.51	A-0940	Standard	HAP
§482.51(b)	A-0951	Standard	HAP/EC.02.03.01/EP12
§482.52	A-1000	Standard	HAP
§482.52(b)	A-1002	Standard	HAP/PC.03.01.03/EP1

The Joint Commission Requirements for Improvement

Program: Hospital

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.02.01	5	Moderate Limited	The hospital minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the SPD decontamination area the eyewash station was in a bathroom behind closed door. Observed by the facility staff..	§482.41(a)	Standard
EC.02.02.01	12	Low Limited	The hospital labels hazardous materials and waste. Labels identify the contents and hazard warnings. * Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements. (See also IC.02.01.01, EP 6)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Container of whiteboard cleaner in the lab was not labeled with health hazard warnings. Observed by the lab manager.	§482.41(a)	Standard
EC.02.03.01	12	Moderate Limited	When flammable germicides or antiseptics are used during surgeries utilizing electrosurgery, cautery, or lasers, the following are required: - Nonflammable packaging - Unit-dose applicators - Preoperative "time-out" prior to the initiation of any surgical procedure to verify the following: - Application site is dry prior to draping and use of surgical equipment - Pooling of solution has not occurred or has been corrected - Solution-soaked materials have been removed from the operating room prior to draping and use of surgical devices (For full text, refer to NFPA 99-2012: 15.13)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During observation of the prep and time-out process for a patient who was to undergo a vascular surgery, the circulating RN, who prepped the patient with an alcohol based skin prep, called out the drying time needed to wait prior to draping the patient. The surgeon had completed the draping prior to that time interval. The prep was completed at 11:47 and 23 seconds, and the RN called out that draping should wait until 11:50 and 53 seconds. The draping, including an occlusive plastic sheet, was completed by 11:50 and 56 seconds. This was confirmed by the OR director assisting in the tracer.	§482.51(b)	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.03.05	28	Low Widespread	Documentation of maintenance, testing, and inspection activities for Standard EC.02.03.05, EPs 1–20, 25 (including fire alarm and fire protection systems) includes the following: - Name of the activity - Date of the activity - Inventory of devices, equipment, or other items - Required frequency of the activity - Name and contact information, including affiliation, of the person who performed the activity - NFPA standard(s) referenced for the activity - Results of the activity Note: For additional guidance on documenting activities, see NFPA 25-2011: 4.3; 4.4; NFPA 72-2010: 14.2.1; 14.2.2; 14.2.3; 14.2.4.	1) Observed in Document Review at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Annual fire extinguisher maintenance did not include inventory of each extinguisher. This was observed by the facilities director.	§482.41(b)(1)(i)	Standard
EC.02.05.01	9	Low Limited	The hospital labels utility system controls to facilitate partial or complete emergency shutdowns. Note 1: Examples of utility system controls that should be labeled are utility source valves, utility system main switches and valves, and individual circuits in an electrical distribution panel. Note 2: For example, the fire alarm system's circuit is clearly labeled as Fire Alarm Circuit; the disconnect method (that is, the circuit breaker) is marked in red; and access is restricted to authorized personnel. Information regarding the dedicated branch circuit for the fire alarm panel is located in the control unit. For additional guidance, see NFPA 101-2012: 18/19.3.4.1; 9.6.1.3; NFPA 72-2010: 10.5.5.2.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In lab breaker 1CRGB had 3 breakers listed as spare that were in the "ON" position. Observed by the facility manager.	§482.41(a)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.01	15	Moderate Pattern	<p>In critical care areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, temperature, and humidity. For new and existing health care facilities, or altered, renovated, or modernized portions of existing systems or individual components (constructed or plans approved on or after July 5, 2016), heating, cooling, and ventilation are in accordance with NFPA 99-2012, which includes 2008 ASHRAE 170, or state design requirements if more stringent.</p> <p>Note 1: For hospitals that use Joint Commission accreditation for deemed status purposes: Existing facilities may elect to implement a Centers for Medicare & Medicaid Services (CMS) categorical waiver to reduce their relative humidity to 20% in operating rooms and other anesthetizing locations. Should the facility elect the waiver, it must be included in its Basic Building Information (BBI), and the facility's equipment and supplies must be compatible with the humidity reduction. For further information on waiver and equivalency requests, see https://www.jointcommission.org/resources/patient-safety-topics/the-physical-environment/life-safety-code-information-and-resources/.</p> <p>Note 2: For hospitals that use Joint Commission accreditation for deemed status purposes: Existing facilities may comply with the 2012 NFPA 99 ventilation requirements or the ventilation requirements in the edition of the NFPA code previously adopted by CMS at the time of installation (for example, 1999 NFPA 99).</p>	1) Observed in Medication Management Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . The anteroom to the medication compounding buffer room had not passed the specifications for positive air pressure relationship to the corridor/pharmacy. The most recent report from February 2022 showed that while the space was confirmed as classified ISO 7, the air pressure to the pharmacy was only 0.0124 instead of 0.02 mmH2O. The facilities department had been working to correct this issue, including contracting with an outside vendor, but had not been able to correct it at the time of the survey.	§482.41(d)(2)	Standard
				2) Observed in Document Review at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Corrective actions were not documented in the OR at times when the relative humidity was below 30%. This was observed by the facilities director.	§482.41(d)(2)	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				3) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the OR the CV Storage Area was measured as negative pressure with the door closed and the door was propped open with magnetic door hardware. This space must be maintained as positive air pressure differential to the corridor. Observed by the facility manager.	§482.41(d)(2)	Standard
EC.02.05.01	16	Low Limited	In non–critical care areas, the ventilation system provides required pressure relationships, temperature, and humidity. Note: Examples of non–critical care areas are general care nursing units; clean and soiled utility rooms in acute care areas; laboratories, pharmacies, diagnostic and treatment areas, food preparation areas, and other support departments.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Patient room FMC 1, an isolation patient room, was observed with a positive pressure and negative pressure switching device. FGI 2010 air flow table notes that airborne isolation patient rooms cannot be both negative and/or positive and cannot be switched. The Director of Facilities confirmed the observation.	§482.41(d)(4)	Standard
EC.02.05.01	23	Moderate Limited	Power strips in a patient care vicinity are only used for components of movable electrical equipment used for patient care that have been assembled by qualified personnel. These power strips meet UL 1363A or UL 60601-1. Power strips used outside of a patient care vicinity, but within the patient care room, meet UL 1363. In non–patient care rooms, power strips meet other UL standards. (For full text, refer to NFPA 99-2012: 10.2.3.6; 10.2.4; NFPA 70-2011: 400-8; 590.3(D); Tentative Interim Amendment [TIA] 12-5)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In operating room #4, the operating room table power cord was plugged into a Relocatable Power Tap(RPT) which was part of an assembly on an IV pole to supply power to two pieces of medical equipment attached to that pole. The OR director confirmed this finding.	§482.41(d)(2)	Standard
				2) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the OR a Bear Hugger device was plugged into an RPT that was not part of an equipment assembly. Observed by the facility manager.	§482.41(d)(2)	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.01	24	Low Limited	Extension cords are not used as a substitute for fixed wiring in a building. Extension cords used temporarily are removed immediately upon completion of the intended purpose. (For full text, refer to NFPA 99-2012: 10.2.3.6; 10.2.4; NFPA 70-2011: 400-8; 590.3(D); Tentative Interim Amendment [TIA] 12-5)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the Main Operating Room area, Cath Lab 1 was observed with a an electrical box that provided 4 receptacles and were observed supplied power from the single ceiling outlet. No cord strain relief devices were visible during the survey process and the devices were not UL1363 or UL60601 the devices were being utilized to supply permanent power for patient equipment components. The Facilities Manager and the Facility Representatives confirmed the observation.	§482.41(d)(2)	Standard
EC.02.05.02	3	Moderate Pattern	The individual or team responsible for the water management program manages the following: - Documenting results of all monitoring activities - Corrective actions and procedures to follow if a test result outside of acceptable limits is obtained, including when a probable or confirmed waterborne pathogen(s) indicates action is necessary - Documenting corrective actions taken when control limits are not maintained Note: See EC.04.01.01, EP 1 for the process of monitoring, reporting, and investigating utility system issues.	1) Observed in Document Review at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Legionella was tested periodically; however monitoring protocols were not conducted and no documentation that corrective actions taken when control limits are not maintained. Observed by the facility manager.	§482.41(d)(2)	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.03	1	Moderate Limited	For facilities that were constructed, or had a change in occupancy type, or have undergone an electrical system upgrade since 1983, the hospital has a Type 1 or Type 3 essential electrical system in accordance with NFPA 99, 2012 edition. This essential electrical system must be divided into three branches, including the life safety branch, critical branch, and equipment branch. Both the life safety branch and the critical branch are kept independent of all other wiring and equipment, and they transfer within 10 seconds of electrical interruption. Each branch has at least one automatic transfer switch. For additional guidance, see NFPA 99-2012: 6.4.2.2.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During the survey process the essential electrical system was observed not designed and installed to code requirements for health care facilities. The essential electrical system was not divided into three branches, including the life safety branch, critical branch, and equipment branch. Each branch did not have at least one automatic transfer switch. The life safety and critical branches were not kept independent of all other wiring and equipment and had shared main emergency distribution panels and normal distribution panels. An emergency electrical generator system was replaced during 2010 and was upgraded, new main electrical equipment with upgraded equipment and controls and does NOT have at least one automatic transfer switch and was observed not divided into 3 branches of electrical power. The Generator power source was not separate and independent from the normal power source. The electrical sources (normal utility and emergency generator) were observed with a switch gear configuration. No electrical branch division/s are present on the system and It did not have any devices that are defined by UL 1008-8 for transfer switch equipment. The design engineer was contacted during the survey process and could not provide any additional documentation to support the electrical design modifications related to NFPA 99 2012 and did not provide any other documents The Director of Engineering confirmed the observation. NFPA 110 2010; NFPA 99 - 2012		

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.05	5	Low Limited	The hospital inspects, tests, and maintains the following: Infection control utility system components on the inventory. The completion date and the results of the activities are documented. Note 1: Required activities and associated frequencies for maintaining, inspecting, and testing of utility systems components completed in accordance with manufacturers' recommendations must have a 100% completion rate. Note 2: Scheduled maintenance activities for infection control utility systems components in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate.	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During the tracer tour of the kitchen, the dishwasher temperature log reflected greater than 20 events in the month of June that were greater than the temperature range on the logsheet. There was no corrective action documented. This was also observed by the Department Director.	§482.41(d)(2)	Standard
EC.02.05.05	6	Low Limited	The hospital inspects, tests, and maintains the following: Non-high-risk utility system components on the inventory. The completion date and the results of the activities are documented. Note: Scheduled maintenance activities for non-high-risk utility systems components in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital AEM program.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 1st floor within the 1.5T MRI equipment room area, an electrical junction box that had exposed wiring was observed. The wiring was observed to be 120/208V. The Safety Officer and the facility representatives verified and corrected the observation during survey.	§482.41(d)(2)	Standard
EC.02.05.09	2	Moderate Limited	All master, area, and local alarm systems used for medical gas and vacuum systems comply with the category 1–3 warning system requirements. (For full text, refer to NFPA 99-2012: 5.1.9; 5.2.9; 5.3.6.2.2)	1) Observed in Document Review at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Medical gas master alarm panel did not contain all required components as noted in the annual system inspection. Observed by the facility manager.	§482.41(d)(2)	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.09	11	Low Limited	The hospital makes main supply valves and area shutoff valves for piped medical gas and vacuum systems accessible and clearly identifies what the valves control. Piping is labeled by stencil or adhesive markers identifying the gas or vacuum system, including the name of system or chemical symbol, color code (see NFPA 99-2012: Table 5.1.11), and operating pressure if other than standard. Labels are at intervals of 20 feet or less and are in every room, at both sides of wall penetrations, and on every story traversed by riser. Piping is not painted. Shutoff valves are identified with the name or chemical symbol of the gas or vacuum system, room or area served, and caution to not use the valve except in emergency. (For full text, refer to NFPA 99-2012: 5.1.4; 5.1.11.1; 5.1.11.2; 5.1.14.3; 5.2.11; 5.3.13.3; 5.3.11)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 1st floor in the 3T MRI equipment room Medical gas piping was not labeled by stencil or adhesive markers identifying the gas or vacuum system, including the name of system or chemical symbol, color code. The Director of Engineering confirmed the observation.	§482.41(d)(2)	Standard
				2) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 4th floor above the dropped ceiling system for the south Ortho medical gas piping was not labeled by stencil or adhesive markers identifying the gas or vacuum system, including the name of system or chemical symbol, color code. The Director of Engineering confirmed the observation.	§482.41(d)(2)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
EC.02.05.09	12	Moderate Limited	The hospital implements a policy on all cylinders within the hospital that includes the following: - Labeling, handling, and transporting (for example, in carts, attached to equipment, on racks) in accordance with NFPA 99-2012: 11.5.3.1 and 11.6.2 - Physically segregating full and empty cylinders from each other in order to assist staff in selecting the proper cylinder - Adaptors or conversion fittings are prohibited - Oxygen cylinders, containers, and associated equipment are protected from contamination, damage, and contact with oil and grease - Cylinders are kept away from heat and flammable materials and do not exceed a temperature of 130°F - Nitrous oxide and carbon dioxide cylinders do not reach temperatures lower than manufacturer recommendations or -20°F - Valve protection caps (if supplied) are secured in place when cylinder is not in use - Labeling empty cylinders - Prohibiting transfilling in any compartment with patient care (For full text, refer to NFPA 99-2012: 11.6.1; 11.6.2; 11.6.5; 11.7.3)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During a tour of the outpatient imaging department, two CO2 gas cylinders were observed standing upright on the floor next to the rack used for storage of these. This was not in accordance with applicable standards and regulations which required medical gas cylinders to be secured.		
EC.02.06.01	1	Moderate Pattern	Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the Emergency Department, bubbled and peeling ceiling paint in the ambulance bay and ED patient care hallway were noted, as well as two stained ceiling tiles in the ED patient care hallway. The ED leader was present at the time of the observation.	§482.41	Standard
				2) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the Clinical Decision Unit, a stained ceiling tile was observed in the Medication Room. This was also observed by the Department leader.	§482.41	Standard

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				3) Observed in Medication Management Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . A pop-out style sprinkler head in the ceiling of the medication compounding buffer room, where laminar flow hoods were in use, had a significant gap between the sprinkler head and the ceiling (more that 1/4 inch) which resulted in exposed ceiling surface with paint edges pulling back slightly on the perimeter of the painted area. This created the risk the surfaces could harbor microorganisms and result in contamination of the medication compounding process. This was confirmed by the pharmacy director. Facilities immediately corrected the issue prior to the end of the survey.	§482.25(b)(1)	Standard
				4) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer tour of the kitchen, penetrations in the ceiling in the dishwasher room and the main kitchen were observed. The Department Director was present and also observed.	§482.41(a)	Standard
				5) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities on the 5 North Nursing Unit, ceiling penetrations were observed in the equipment and supply storage area. The Unit Director was present at the time of the observation.	§482.41(a)	Standard
				6) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . 2 sharps containers in the lab were being used as pencil holders in violation with bloodborne pathogen regulations. Observed by the laboratory manager.	§482.41(a)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
IC.01.02.01	1	Low Limited	The hospital provides access to information needed to support the infection prevention and control program. (See also IM.02.02.03, EP 2)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During the tracer tour of the kitchen, bottom shelves on the food preparation/serving supplies were less than 18 inches from the floor and noted to not have solid cover. This was observed by the Department Director.		
IC.02.01.01	2	Moderate Limited	The hospital uses standard precautions, * including the use of personal protective equipment, to reduce the risk of infection. Note: Standard precautions are infection prevention and control measures to protect against possible exposure to infectious agents. These precautions are general and applicable to all patients. Footnote *: For further information regarding standard precautions, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/hicpac/recommendations/core-practices.html (Infection Control in Healthcare Settings). (See also EC.02.02.01, EP 3)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During observation of the room cleaning process in the cardiac catheterization lab, a staff member was observed transitioning from cleaning the room to handling clean supplies for the next case without performing hand hygiene after removed soiled gloves and donning clean gloves. It was noted by the surveyor that the only hand sanitizer dispenser was located outside of the room in the control booth, and not in the procedure room where it would be more aligned with their workflow.	§482.42(a)(3)	Standard
IC.02.02.01	2	Moderate Limited	The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/#r3 (Sterilization and Disinfection in Healthcare Settings). (See also EC.02.04.03, EP 4)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . The process for precleaning instruments and keeping them moist in the cardiac catheterization lab did not include a means to accurately measure the water mixed with an enzymatic agent. This was not in accordance with the manufacturer's instructions for use, which stated the required ratio of water to detergent was 1/8 to 1/2 ounces of enzymatic per 1 gallon of water.	§482.42(a)(2)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				2) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . The process for testing new bottles of Cidex test strips for reprocessing TEE probes did not adhere to the manufacturer's recommendations. The technician who performed this task reported that the negative controls consisted of dipping the test strips in water only, while the manufacturer required a precise dilution of water and Cidex for the negative controls.	§482.42(a)(2)	Standard
				3) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . Ultrasound transvaginal probes were wiped with regular towels rather than low lint cloths during reprocessing of the probes after use. This was not in accordance with the manufacturer's instructions for use, which required use of low lint cloths for this step in the reprocessing cycle.	§482.42(a)(2)	Standard
				4) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . The process for performing precleaning of transvaginal probes in the outpatient imaging center did not include a step to preclean the biopsy channel of the probe. This was not in accordance with the manufacturer's instructions for use, which required the channel to be cleaned with a soft bristle brush wrapped in a cleaning wipe prior to performing high level disinfection.	§482.42(a)(2)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
LS.02.01.10	1	Low Limited	Buildings meet requirements for construction type and height. In Types I and II construction, alternative protection measures are permitted to be substituted for sprinkler protection in specific areas where state or local regulations prohibit sprinklers. All new buildings contain approved automatic sprinkler systems. Existing buildings contain approved automatic sprinkler systems as required by the construction type. (For full text, refer to NFPA 101-2012: 18/19.1.6; 18.3.5.1; 19.3.5.3; 18/19.3.5.4; 18/19.3.5.5; 18.3.5.6)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 1st floor 3T equipment room an HVAC air duct that was greater than 4 feet in width was observed without fire sprinkler protection below the HVAC duct. The Director of Facilities and the Safety Officer confirmed the observation. The surveyor discussed the Life Safety deficiency with the organization, and it was determined that the following ILSMs will be implemented until the deficiency has been resolved and according to the organization's ILSM policy: Conduct education promoting awareness of deficiencies(EP-13)	§482.41(b)(1)(i)	Standard
LS.02.01.10	14	Low Limited	The space around pipes, conduits, bus ducts, cables, wires, air ducts, or pneumatic tubes penetrating the walls or floors are protected with an approved fire-rated material. Note: Polyurethane expanding foam is not an accepted fire-rated material for this purpose. (For full text, refer to NFPA 101-2012: 8.3.5)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 2-hour fire rated wall between the Broadway Location and FMC identified by the facility representatives was observed not properly sealed with a "scab" type covering over the opening in the wall. The Facilities Manager and the Facility Representatives confirmed the observation. The surveyor discussed the Life Safety deficiency with the organization, and it was determined that the following ILSMs will be implemented until the deficiency has been resolved and according to the organization's ILSM policy: Conduct education promoting awareness of deficiencies(EP-13)	§482.41(b)(1)(i)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
LS.02.01.35	4	Low Limited	Piping for approved automatic sprinkler systems is not used to support any other item. (For full text, refer to NFPA 25-2011: 5.2.2.2)	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . On the 6th floor the fire sprinkler support in the mechanical space for AHUs (air handler units) was observed during survey supporting duct work for the HVAC system and the fire protection water sprinkler line. The Director of Engineering confirmed the observation. The surveyor discussed the Life Safety deficiency with the organization, and it was determined that the following ILSMs will be implemented until the deficiency has been resolved and according to the organization's ILSM policy: Conduct education promoting awareness of deficiencies(EP-13)	§482.41(b)(1)(i)	Standard
LS.02.01.35	14	Low Limited	The hospital meets all other Life Safety Code automatic extinguishing requirements related to NFPA 101-2012: 18/19.3.5.	1) Observed in Building Tour at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the OR outside the directors office, sprinkler heads were missing in areas that were originally designed as skylights that were later converted to a lighting system. Observed by the facility manager. This finding was observed during survey activity, but corrected onsite prior to the surveyor's departure. The corrective action taken needs to be included in the organization's Evidence of Standards Compliance submission	§482.41(b)(1)(i)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
NPSG.06.01.01	3	Moderate Limited	<p>Establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following:</p> <ul style="list-style-type: none"> - Clinically appropriate settings for alarm signals - When alarm signals can be disabled - When alarm parameters can be changed - Who in the organization has the authority to set alarm parameters - Who in the organization has the authority to change alarm parameters - Who in the organization has the authority to set alarm parameters to “off” - Monitoring and responding to alarm signals - Checking individual alarm signals for accurate settings, proper operation, and detectability <p>(For more information, refer to Standard EC.02.04.03)</p>	<p>1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the ICU setting, 3 of 8 cardiac monitors had HR parameters that varied from the HCO established default parameters. The HCO policy (Clinical Alarms Management) indicated that parameters can only be changed with approval from BioMed and Hospital Alarm Management Committee. The ICU director was present at the time of observation but was unable to present policy/documentation that allowed clinical staff to independently adjust alarm parameters.</p>		

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
NPSG.15.01.01	1	Moderate Limited	<p>For psychiatric hospitals and psychiatric units in general hospitals: The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide; the hospital takes necessary action to minimize the risk(s) (for example, removal of anchor points, door hinges, and hooks that can be used for hanging).</p> <p>For nonpsychiatric units in general hospitals: The organization implements procedures to mitigate the risk of suicide for patients at high risk for suicide, such as one-to-one monitoring, removing objects that pose a risk for self-harm if they can be removed without adversely affecting the patient's medical care, assessing objects brought into a room by visitors, and using safe transportation procedures when moving patients to other parts of the hospital. Note: Nonpsychiatric units in general hospitals do not need to be ligature resistant. Nevertheless, these facilities should routinely assess clinical areas to identify objects that could be used for self-harm and remove those objects, when possible, from the area around a patient who has been identified as high risk for suicide. This information can be used for training staff who monitor high-risk patients (for example, developing checklists to help staff remember which equipment should be removed when possible).</p>	1) Observed in Building Tour at Providence Health & Services- Montana (902 North Orange Street, Missoula, MT) site . At the NBMI unit there were 3 phones observed in the hallway and open group area where the cord was approximately 24 inches in length. Observed by unit manager and facilities director.	§482.13(c)(2)	Standard
				2) Observed in Building Tour at Providence Health & Services- Montana (902 North Orange Street, Missoula, MT) site . At the MBMI Open Unit the Group Room with suspended ceiling had doors that were self-closing but not self-locking. There was a blind corner in this room where patient were not readily observable. Observed by unit manager and facilities director.	§482.13(c)(2)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				3) Observed in Building Tour at Providence Health & Services- Montana (902 North Orange Street, Missoula, MT) site . In the MBMI Open Unit patient bedroom beds had restraint hook points that created ligature risk. Observed by unit manager and facilities director.	§482.13(c)(2)	Standard
				4) Observed in Building Tour at Providence Health & Services- Montana (902 North Orange Street, Missoula, MT) site . At the Providence Center a nurses station on the 4th floor had door closers on the 2 entrance door that were located on the hallway side of the door creating ligature hazards. Observed by unit manager and facilities director.	§482.13(c)(2)	Standard
PC.01.02.03	3	Moderate Limited	Each patient is reassessed as necessary based on their plan for care or changes in their condition. Note: Reassessments may also be based on the patient's diagnosis; desire for care, treatment, and services; response to previous care, treatment, and services; discharge planning needs; and/or their setting requirements. (See also PC.06.01.01, EP 1)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During an individual tracer in the ICU setting, it was observed that a patient was receiving a Precedex infusion. The drip was to be titrated to achieve a RASS score of 0 to (-)2. The dose was decreased at 0300 and 0400 on 6/21/22 with no documented RASS score. The unit leader was present at time of observation.		

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
PC.01.02.03	5	Moderate Pattern	For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services. Note 1: For hospitals that use Joint Commission accreditation for deemed status purposes: Medical histories and physical examinations are performed as required in this element of performance, except any specific outpatient surgical or procedural services for which an assessment is performed instead. Note 2: For law and regulation guidance pertaining to the medical history and physical examination, refer to 42 CFR 482.22(c)(5)(iii) and 482.51(b)(1)(iii). Refer to "Appendix A: Medicare Requirements for Hospitals" (AXA) for full text. (See also MS.03.01.01, EP 19; RC.02.01.03, EP 3)	1) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During an individual tracer in the ICU setting, the patient record contained a completed H&P dated 6/15/22; the patient was admitted for surgery on 6/16/22. There was no update to the H&P prior to surgery found in the medical record. The ICU director concurred.	§482.24(c)(4)(i)(B)	Standard
				2) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . The history and physical update for a patient who had undergone a procedure in the cardiac catheterization lab had not been signed by the provider doing the procedure, and the surveyor was unable to validate that the update had actually been documented by the provider. A staff member explained that the history and physical, and the statement regarding the update were auto-populated by the electronic health record and were then supposed to be signed by the provider prior to the procedure.	§482.24(c)(4)(i)(B)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
PC.01.02.07	8	Moderate Limited	The hospital educates the patient and family on discharge plans related to pain management including the following: - Pain management plan of care - Side effects of pain management treatment - Activities of daily living, including the home environment, that might exacerbate pain or reduce effectiveness of the pain management plan of care, as well as strategies to address these issues - Safe use, storage, and disposal of opioids when prescribed	1) Observed in Record Review at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . A patient who had been discharged with a new opioid prescription following a procedure with sedation had not received discharge instructions that addressed safe storage and disposal of the medication. The discharge instructions addressed safe use of the medication only.		
PC.01.03.01	22	Low Limited	Based on the goals established in the patient's plan of care, staff evaluate the patient's progress.	1) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During an individual tracer on the 5 North Nursing Unit, there was no documentation on the patient's care plan for greater than 36 hours. The Nursing Leader was unable to locate.		
PC.02.01.11	2	High Pattern	Resuscitation equipment is available for use based on the needs of the population served. Note: For example, if the hospital has a pediatric population, pediatric resuscitation equipment should be available. (See also EC.02.04.03, EP 2)	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the Emergency Department, the Crash Cart/Defibrillator logsheet had 2/20 days in June and 2/31 days in May in which the safety checks had not been completed. The ED leader was present and concurred with observation.		
				2) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the Clinical Decision Unit, it was observed that there was missing documentation on the crash cart log for 1/20 days in June 2022. This was also observed by the Unit leader.		

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				3) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities on the 5 North Nursing Unit, it was observed that the defibrillator on the unit crash cart was not plugged into a power source. The power cable was missing from the Defibrillator unit and crash cart. This was observed and corrected by the Unit Leader.		
PC.02.02.03	11	Low Limited	The hospital stores food and nutrition products, including those brought in by patients or their families, using proper sanitation, temperature, light, moisture, ventilation, and security.	1) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During tracer activities in the kitchen, 8 of 22 days had refrigerator temperatures documented out of range with no corrective actions documented. The Department Director was present at the time of the observation.		
PC.03.01.03	1	High Pattern	Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The hospital conducts a presedation or preanesthesia patient assessment. (See also RC.02.01.01, EP 2)	1) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In 4 of 4 patient records reviewed, for patients who had undergone procedures with sedation in the cardiac catheterization lab, interventional radiology, or the emergency department, did not contain documentation of an airway assessment using the Mallampati score, which was required by the hospital's policy for procedural sedation. In addition, one of the records did not contain documentation of the ASA level.	§482.52(b)	Standard

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
				2) Observed in Tracer Activities at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . In the review of the medical record of a surgical patient, the Pre-anesthesia Evaluation Note was not completed prior to the start of the surgical procedure as required by the organization's policy "Medical Record Documentation" last reviewed 4/2020. The pre-anesthesia assessment note was completed at 12:42pm on 6/20/22 and the documented time of anesthesia induction and intubation was at 12:22 pm. This documentation discrepancy was confirmed by the RN staff assisting in the record review.	§482.52(b)	Standard
RC.02.01.01	2	Low Pattern	<p>The medical record contains the following clinical information:</p> <ul style="list-style-type: none"> - The reason(s) for admission for care, treatment, and services - The patient's initial diagnosis, diagnostic impression(s), or condition(s) - Any findings of assessments and reassessments - Any allergies to food - Any allergies to medications - Any conclusions or impressions drawn from the patient's medical history and physical examination - Any diagnoses or conditions established during the patient's course of care, treatment, and services (including complications and hospital-acquired infections). For psychiatric hospitals using Joint Commission accreditation for deemed status purposes: The diagnosis includes intercurrent diseases (diseases that occur during the course of another disease; for example, a patient with AIDS may develop an intercurrent bout of pneumonia) and the psychiatric diagnoses. - Any consultation reports - Any observations relevant to care, treatment, and services - The patient's response to care, treatment, and services - Any emergency care, treatment, and services provided to the patient before their arrival 	1) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . the policy and protocol used by the cardiac stress testing department for dobutamine stress tests was not retrievable at the individual patient level. A nurse who performed these tests reported that they referred to the printed policy and protocol for dosing, but that this was not linked in any fashion to the patient records.		

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Standard	EP	SAFER™ Placement	EP Text	Observation	CoP	CoP Score
			<ul style="list-style-type: none"> - Any progress notes - All orders - Any medications ordered or prescribed - Any medications administered, including the strength, dose, route, date and time of administration <p>Note 1: When rapid titration of a medication is necessary, the hospital defines in policy the urgent/emergent situations in which block charting would be an acceptable form of documentation.</p> <p>Note 2: For the definition and a further explanation of block charting, refer to the Glossary.</p> <ul style="list-style-type: none"> - Any access site for medication, administration devices used, and rate of administration - Any adverse drug reactions - Treatment goals, plan of care, and revisions to the plan of care - Results of diagnostic and therapeutic tests and procedures - Any medications dispensed or prescribed on discharge - Discharge diagnosis - Discharge plan and discharge planning evaluation <p>(See also PC.01.02.01, EP 1; PC.01.02.03, EP 6; PC.01.03.01, EP 23; PC.03.01.03, EPs 1, 8; PC.06.01.01, EP 1)</p>			
RI.01.03.01	1	Low Limited	<p>The hospital follows a written policy on informed consent that describes the following:</p> <ul style="list-style-type: none"> - The specific care, treatment, and services that require informed consent - Circumstances that would allow for exceptions to obtaining informed consent - The process used to obtain informed consent - How informed consent is documented in the patient record <p>Note: Documentation may be recorded in a form, in progress notes, or elsewhere in the record.</p> <ul style="list-style-type: none"> - When a surrogate decision-maker may give informed consent (See also RI.01.02.01, EP 2) 	<p>1) Observed in Individual Tracer at Providence Health and Services - Montana (500 West Broadway, Missoula, MT) site . During an individual tracer in the ICU setting, a consent for a surgical procedure had no time associated with the signature for 2/2 consents. The HCO policy (Informed Consent for Medical Procedures Policy) requires the physician to include time with signature and date. The ICU director was present at the time of the observation.</p>	§482.24(c)(4)(v)	Standard

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Appendix

Conditions of Participation Text

Program: Hospital

CoP	Tag	CoP Standard text
§482.13 Condition of Participation: Patient's Rights	A-0115	§482.13 Condition of Participation: Patient's Rights A hospital must protect and promote each patient's rights.
§482.13(c)(2) Standard: Privacy and Safety	A-0144	(2) The patient has the right to receive care in a safe setting.
§482.25 Condition of Participation: Pharmaceutical Services	A-0489	§482.25 Condition of Participation: Pharmaceutical Services The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.
§482.25(b)(1) Standard: Delivery of Services	A-0501	(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.
§482.41 Condition of Participation: Physical Environment	A-0700	§482.41 Condition of Participation: Physical Environment The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.
§482.41(a) Standard: Buildings	A-0701	§482.41(a) Standard: Buildings The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.
§482.41(b)(1)(i) Standard: Life Safety from Fire	A-0710	(i) The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.
§482.41(d)(2) Standard: Facilities	A-0724	(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.
§482.41(d)(4) Standard: Facilities	A-0726	(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

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CoP	Tag	CoP Standard text
§482.51 Condition of Participation: Surgical Services	A-0940	<p>§482.51 Condition of Participation: Surgical Services</p> <p>If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.</p>
§482.51(b) Standard: Delivery of Service	A-0951	<p>§482.51(b) Standard: Delivery of Service</p> <p>Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.</p>
§482.52 Condition of Participation: Anesthesia Services	A-1000	<p>§482.52 Condition of Participation: Anesthesia Services</p> <p>If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.</p>
§482.52(b) Standard: Delivery of Services	A-1002	<p>§482.52(b) Standard: Delivery of Services</p> <p>Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and postanesthesia responsibilities. The policies must ensure that the following are provided for each patient:</p>
§482.42 Condition of Participation: Infection Control	A-0747	<p>§482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.</p> <p>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. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.</p>
§482.42(a)(2) Standard: Infection prevention and control program organization and policies.	A-0749	<p>(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;</p>
§482.42(a)(3) Standard: Infection prevention and control program organization and policies.	A-0750	<p>(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, 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; and</p>
§482.24 Condition of Participation: Medical Record Services	A-0431	<p>§482.24 Condition of Participation: Medical Record Services</p> <p>The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.</p>

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CoP	Tag	CoP Standard text
§482.24(c)(4)(i)(B) Standard: Content of Record	A-0461	(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(4)(i)(C) of this section. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.
§482.24(c)(4)(v) Standard: Content of Record	A-0466	[All records must document the following, as appropriate:] (v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

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Appendix

Standard and EP Text

Program: Hospital

Standard	EP	Standard Text	EP & Addendum Text
EC.02.02.01	5	The hospital manages risks related to hazardous materials and waste.	The hospital minimizes risks associated with selecting, handling, storing, transporting, using, and disposing of hazardous chemicals.
EC.02.02.01	12	The hospital manages risks related to hazardous materials and waste.	The hospital labels hazardous materials and waste. Labels identify the contents and hazard warnings. * Footnote *: The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and Hazard Communications Standards and the National Fire Protection Association (NFPA) provide details on labeling requirements. (See also IC.02.01.01, EP 6)
EC.02.03.01	12	The hospital manages fire risks.	When flammable germicides or antiseptics are used during surgeries utilizing electrosurgery, cautery, or lasers, the following are required: <ul style="list-style-type: none"> - Nonflammable packaging - Unit-dose applicators - Preoperative "time-out" prior to the initiation of any surgical procedure to verify the following: <ul style="list-style-type: none"> - Application site is dry prior to draping and use of surgical equipment - Pooling of solution has not occurred or has been corrected - Solution-soaked materials have been removed from the operating room prior to draping and use of surgical devices (For full text, refer to NFPA 99-2012: 15.13)
EC.02.03.05	28	The hospital maintains fire safety equipment and fire safety building features. Note: This standard does not require hospitals to have the types of fire safety equipment and building features described below. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.	Documentation of maintenance, testing, and inspection activities for Standard EC.02.03.05, EPs 1–20, 25 (including fire alarm and fire protection systems) includes the following: <ul style="list-style-type: none"> - Name of the activity - Date of the activity - Inventory of devices, equipment, or other items - Required frequency of the activity - Name and contact information, including affiliation, of the person who performed the activity - NFPA standard(s) referenced for the activity - Results of the activity Note: For additional guidance on documenting activities, see NFPA 25-2011: 4.3; 4.4; NFPA 72-2010: 14.2.1; 14.2.2; 14.2.3; 14.2.4.
EC.02.05.01	9	The hospital manages risks associated with its utility systems.	The hospital labels utility system controls to facilitate partial or complete

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Standard	EP	Standard Text	EP & Addendum Text
			<p>emergency shutdowns.</p> <p>Note 1: Examples of utility system controls that should be labeled are utility source valves, utility system main switches and valves, and individual circuits in an electrical distribution panel.</p> <p>Note 2: For example, the fire alarm system's circuit is clearly labeled as Fire Alarm Circuit; the disconnect method (that is, the circuit breaker) is marked in red; and access is restricted to authorized personnel.</p> <p>Information regarding the dedicated branch circuit for the fire alarm panel is located in the control unit. For additional guidance, see NFPA 101-2012: 18/19.3.4.1; 9.6.1.3; NFPA 72-2010: 10.5.5.2.</p>
EC.02.05.01	15	The hospital manages risks associated with its utility systems.	<p>In critical care areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, temperature, and humidity. For new and existing health care facilities, or altered, renovated, or modernized portions of existing systems or individual components (constructed or plans approved on or after July 5, 2016), heating, cooling, and ventilation are in accordance with NFPA 99-2012, which includes 2008 ASHRAE 170, or state design requirements if more stringent.</p> <p>Note 1: For hospitals that use Joint Commission accreditation for deemed status purposes: Existing facilities may elect to implement a Centers for Medicare & Medicaid Services (CMS) categorical waiver to reduce their relative humidity to 20% in operating rooms and other anesthetizing locations. Should the facility elect the waiver, it must be included in its Basic Building Information (BBI), and the facility's equipment and supplies must be compatible with the humidity reduction. For further information on waiver and equivalency requests, see https://www.jointcommission.org/resources/patient-safety-topics/the-physical-environment/life-safety-code-information-and-resources/.</p> <p>Note 2: For hospitals that use Joint Commission accreditation for deemed status purposes: Existing facilities may comply with the 2012 NFPA 99 ventilation requirements or the ventilation requirements in the edition of the NFPA code previously adopted by CMS at the time of installation (for example, 1999 NFPA 99).</p>
EC.02.05.01	16	The hospital manages risks associated with its utility systems.	<p>In non-critical care areas, the ventilation system provides required pressure relationships, temperature, and humidity.</p> <p>Note: Examples of non-critical care areas are general care nursing units; clean and soiled utility rooms in acute care areas; laboratories, pharmacies, diagnostic and treatment areas, food preparation areas, and other support departments.</p>
EC.02.05.01	23	The hospital manages risks associated with its utility systems.	Power strips in a patient care vicinity are only used for components of

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Standard	EP	Standard Text	EP & Addendum Text
			movable electrical equipment used for patient care that have been assembled by qualified personnel. These power strips meet UL 1363A or UL 60601-1. Power strips used outside of a patient care vicinity, but within the patient care room, meet UL 1363. In non-patient care rooms, power strips meet other UL standards. (For full text, refer to NFPA 99-2012: 10.2.3.6; 10.2.4; NFPA 70-2011: 400-8; 590.3(D); Tentative Interim Amendment [TIA] 12-5)
EC.02.05.01	24	The hospital manages risks associated with its utility systems.	Extension cords are not used as a substitute for fixed wiring in a building. Extension cords used temporarily are removed immediately upon completion of the intended purpose. (For full text, refer to NFPA 99-2012: 10.2.3.6; 10.2.4; NFPA 70-2011: 400-8; 590.3(D); Tentative Interim Amendment [TIA] 12-5)
EC.02.05.02	3	The hospital has a water management program that addresses Legionella and other waterborne pathogens. Note: The water management program is in accordance with law and regulation.	The individual or team responsible for the water management program manages the following: - Documenting results of all monitoring activities - Corrective actions and procedures to follow if a test result outside of acceptable limits is obtained, including when a probable or confirmed waterborne pathogen(s) indicates action is necessary - Documenting corrective actions taken when control limits are not maintained Note: See EC.04.01.01, EP 1 for the process of monitoring, reporting, and investigating utility system issues.
EC.02.05.03	1	The hospital has a reliable emergency electrical power source.	For facilities that were constructed, or had a change in occupancy type, or have undergone an electrical system upgrade since 1983, the hospital has a Type 1 or Type 3 essential electrical system in accordance with NFPA 99, 2012 edition. This essential electrical system must be divided into three branches, including the life safety branch, critical branch, and equipment branch. Both the life safety branch and the critical branch are kept independent of all other wiring and equipment, and they transfer within 10 seconds of electrical interruption. Each branch has at least one automatic transfer switch. For additional guidance, see NFPA 99-2012: 6.4.2.2.
EC.02.05.05	5	The hospital inspects, tests, and maintains utility systems. Note: At times, maintenance is performed by an external service. In these cases, hospitals are not required to possess maintenance documentation but must have access to such documentation during survey and as needed.	The hospital inspects, tests, and maintains the following: Infection control utility system components on the inventory. The completion date and the results of the activities are documented. Note 1: Required activities and associated frequencies for maintaining, inspecting, and testing of utility systems components completed in accordance with manufacturers' recommendations must have a 100% completion rate. Note 2: Scheduled maintenance activities for infection control utility systems components in an alternative equipment maintenance (AEM)

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Standard	EP	Standard Text	EP & Addendum Text
			program inventory must have a 100% completion rate.
EC.02.05.05	6	The hospital inspects, tests, and maintains utility systems. Note: At times, maintenance is performed by an external service. In these cases, hospitals are not required to possess maintenance documentation but must have access to such documentation during survey and as needed.	The hospital inspects, tests, and maintains the following: Non-high-risk utility system components on the inventory. The completion date and the results of the activities are documented. Note: Scheduled maintenance activities for non-high-risk utility systems components in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital AEM program.
EC.02.05.09	2	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	All master, area, and local alarm systems used for medical gas and vacuum systems comply with the category 1–3 warning system requirements. (For full text, refer to NFPA 99-2012: 5.1.9; 5.2.9; 5.3.6.2.2)
EC.02.05.09	11	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	The hospital makes main supply valves and area shutoff valves for piped medical gas and vacuum systems accessible and clearly identifies what the valves control. Piping is labeled by stencil or adhesive markers identifying the gas or vacuum system, including the name of system or chemical symbol, color code (see NFPA 99-2012: Table 5.1.11), and operating pressure if other than standard. Labels are at intervals of 20 feet or less and are in every room, at both sides of wall penetrations, and on every story traversed by riser. Piping is not painted. Shutoff valves are identified with the name or chemical symbol of the gas or vacuum system, room or area served, and caution to not use the valve except in emergency. (For full text, refer to NFPA 99-2012: 5.1.4; 5.1.11.1; 5.1.11.2; 5.1.14.3; 5.2.11; 5.3.13.3; 5.3.11)
EC.02.05.09	12	The hospital inspects, tests, and maintains medical gas and vacuum systems. Note: This standard does not require hospitals to have the medical gas and vacuum systems discussed below. However, if a hospital has these types of systems, then the following inspection, testing, and maintenance requirements apply.	The hospital implements a policy on all cylinders within the hospital that includes the following: <ul style="list-style-type: none"> - Labeling, handling, and transporting (for example, in carts, attached to equipment, on racks) in accordance with NFPA 99-2012: 11.5.3.1 and 11.6.2 - Physically segregating full and empty cylinders from each other in order to assist staff in selecting the proper cylinder - Adaptors or conversion fittings are prohibited - Oxygen cylinders, containers, and associated equipment are protected from contamination, damage, and contact with oil and grease - Cylinders are kept away from heat and flammable materials and do not exceed a temperature of 130°F - Nitrous oxide and carbon dioxide cylinders do not reach temperatures lower than manufacturer recommendations or -20°F - Valve protection caps (if supplied) are secured in place when cylinder is

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Standard	EP	Standard Text	EP & Addendum Text
			not in use - Labeling empty cylinders - Prohibiting transfilling in any compartment with patient care (For full text, refer to NFPA 99-2012: 11.6.1; 11.6.2; 11.6.5; 11.7.3)
EC.02.06.01	1	The hospital establishes and maintains a safe, functional environment. Note: The environment is constructed, arranged, and maintained to foster patient safety, provide facilities for diagnosis and treatment, and provide for special services appropriate to the needs of the community.	Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.
IC.01.02.01	1	Hospital leaders allocate needed resources for the infection prevention and control program.	The hospital provides access to information needed to support the infection prevention and control program. (See also IM.02.02.03, EP 2)
IC.02.01.01	2	The hospital implements its infection prevention and control plan.	The hospital uses standard precautions, * including the use of personal protective equipment, to reduce the risk of infection. Note: Standard precautions are infection prevention and control measures to protect against possible exposure to infectious agents. These precautions are general and applicable to all patients. Footnote *: For further information regarding standard precautions, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/hicpac/recommendations/core-practices.html (Infection Control in Healthcare Settings). (See also EC.02.02.01, EP 3)
IC.02.02.01	2	The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.	The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/#r3 (Sterilization and Disinfection in Healthcare Settings). (See also EC.02.04.03, EP 4)
LS.02.01.10	1	Building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.	Buildings meet requirements for construction type and height. In Types I and II construction, alternative protection measures are permitted to be substituted for sprinkler protection in specific areas where state or local regulations prohibit sprinklers. All new buildings contain approved automatic sprinkler systems. Existing buildings contain approved automatic sprinkler systems as required by the construction type. (For full text, refer to NFPA 101-2012: 18/19.1.6; 18.3.5.1; 19.3.5.3; 18/19.3.5.4; 18/19.3.5.5; 18.3.5.6)
LS.02.01.10	14	Building and fire protection features are designed and maintained to	The space around pipes, conduits, bus ducts, cables, wires, air ducts, or

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Standard	EP	Standard Text	EP & Addendum Text
		minimize the effects of fire, smoke, and heat.	pneumatic tubes penetrating the walls or floors are protected with an approved fire-rated material. Note: Polyurethane expanding foam is not an accepted fire-rated material for this purpose. (For full text, refer to NFPA 101-2012: 8.3.5)
LS.02.01.35	4	The hospital provides and maintains systems for extinguishing fires.	Piping for approved automatic sprinkler systems is not used to support any other item. (For full text, refer to NFPA 25-2011: 5.2.2.2)
LS.02.01.35	14	The hospital provides and maintains systems for extinguishing fires.	The hospital meets all other Life Safety Code automatic extinguishing requirements related to NFPA 101-2012: 18/19.3.5.
NPSG.06.01.01	3	Improve the safety of clinical alarm systems.	Establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following: <ul style="list-style-type: none"> - Clinically appropriate settings for alarm signals - When alarm signals can be disabled - When alarm parameters can be changed - Who in the organization has the authority to set alarm parameters - Who in the organization has the authority to change alarm parameters - Who in the organization has the authority to set alarm parameters to "off" - Monitoring and responding to alarm signals - Checking individual alarm signals for accurate settings, proper operation, and detectability (For more information, refer to Standard EC.02.04.03)
NPSG.15.01.01	1	Reduce the risk for suicide. Note: EPs 2–7 apply to patients in psychiatric hospitals or patients being evaluated or treated for behavioral health conditions as their primary reason for care. In addition, EPs 3–7 apply to all patients who express suicidal ideation during the course of care.	For psychiatric hospitals and psychiatric units in general hospitals: The hospital conducts an environmental risk assessment that identifies features in the physical environment that could be used to attempt suicide; the hospital takes necessary action to minimize the risk(s) (for example, removal of anchor points, door hinges, and hooks that can be used for hanging). For nonpsychiatric units in general hospitals: The organization implements procedures to mitigate the risk of suicide for patients at high risk for suicide, such as one-to-one monitoring, removing objects that pose a risk for self-harm if they can be removed without adversely affecting the patient's medical care, assessing objects brought into a room by visitors, and using safe transportation procedures when moving patients to other parts of the hospital. Note: Nonpsychiatric units in general hospitals do not need to be ligature resistant. Nevertheless, these facilities should routinely assess clinical areas to identify objects that could be used for self-harm and remove those objects, when possible, from the area around a patient who has been identified as high risk for suicide. This information can be used for training staff who monitor high-risk patients (for example, developing checklists to help staff remember which equipment should be removed

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Standard	EP	Standard Text	EP & Addendum Text
			when possible).
PC.01.02.03	3	The hospital assesses and reassesses the patient and the patient's condition according to defined time frames.	Each patient is reassessed as necessary based on their plan for care or changes in their condition. Note: Reassessments may also be based on the patient's diagnosis; desire for care, treatment, and services; response to previous care, treatment, and services; discharge planning needs; and/or their setting requirements. (See also PC.06.01.01, EP 1)
PC.01.02.03	5	The hospital assesses and reassesses the patient and the patient's condition according to defined time frames.	For a medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's condition is completed within 24 hours after registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services. Note 1: For hospitals that use Joint Commission accreditation for deemed status purposes: Medical histories and physical examinations are performed as required in this element of performance, except any specific outpatient surgical or procedural services for which an assessment is performed instead. Note 2: For law and regulation guidance pertaining to the medical history and physical examination, refer to 42 CFR 482.22(c)(5)(iii) and 482.51(b)(1)(iii). Refer to "Appendix A: Medicare Requirements for Hospitals" (AXA) for full text. (See also MS.03.01.01, EP 19; RC.02.01.03, EP 3)
PC.01.02.07	8	The hospital assesses and manages the patient's pain and minimizes the risks associated with treatment.	The hospital educates the patient and family on discharge plans related to pain management including the following: - Pain management plan of care - Side effects of pain management treatment - Activities of daily living, including the home environment, that might exacerbate pain or reduce effectiveness of the pain management plan of care, as well as strategies to address these issues - Safe use, storage, and disposal of opioids when prescribed
PC.01.03.01	22	The hospital plans the patient's care.	Based on the goals established in the patient's plan of care, staff evaluate the patient's progress.
PC.02.01.11	2	Resuscitative services are available throughout the hospital.	Resuscitation equipment is available for use based on the needs of the population served. Note: For example, if the hospital has a pediatric population, pediatric resuscitation equipment should be available. (See also EC.02.04.03, EP 2)
PC.02.02.03	11	The hospital makes food and nutrition products available to its patients.	The hospital stores food and nutrition products, including those brought in by patients or their families, using proper sanitation, temperature, light, moisture, ventilation, and security.
PC.03.01.03	1	The hospital provides the patient with care before initiating operative or	Before operative or other high-risk procedures are initiated, or before

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Standard	EP	Standard Text	EP & Addendum Text
		other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.	moderate or deep sedation or anesthesia is administered: The hospital conducts a pre-sedation or preanesthesia patient assessment. (See also RC.02.01.01, EP 2)
RC.02.01.01	2	The medical record contains information that reflects the patient's care, treatment, and services.	<p>The medical record contains the following clinical information:</p> <ul style="list-style-type: none"> - The reason(s) for admission for care, treatment, and services - The patient's initial diagnosis, diagnostic impression(s), or condition(s) - Any findings of assessments and reassessments - Any allergies to food - Any allergies to medications - Any conclusions or impressions drawn from the patient's medical history and physical examination - Any diagnoses or conditions established during the patient's course of care, treatment, and services (including complications and hospital-acquired infections). For psychiatric hospitals using Joint Commission accreditation for deemed status purposes: The diagnosis includes intercurrent diseases (diseases that occur during the course of another disease; for example, a patient with AIDS may develop an intercurrent bout of pneumonia) and the psychiatric diagnoses. - Any consultation reports - Any observations relevant to care, treatment, and services - The patient's response to care, treatment, and services - Any emergency care, treatment, and services provided to the patient before their arrival - Any progress notes - All orders - Any medications ordered or prescribed - Any medications administered, including the strength, dose, route, date and time of administration <p>Note 1: When rapid titration of a medication is necessary, the hospital defines in policy the urgent/emergent situations in which block charting would be an acceptable form of documentation.</p> <p>Note 2: For the definition and a further explanation of block charting, refer to the Glossary.</p> <ul style="list-style-type: none"> - Any access site for medication, administration devices used, and rate of administration - Any adverse drug reactions - Treatment goals, plan of care, and revisions to the plan of care - Results of diagnostic and therapeutic tests and procedures - Any medications dispensed or prescribed on discharge - Discharge diagnosis - Discharge plan and discharge planning evaluation (See also PC.01.02.01, EP 1; PC.01.02.03, EP 6; PC.01.03.01, EP 23; PC.03.01.03,

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Standard	EP	Standard Text	EP & Addendum Text
			EPs 1, 8; PC.06.01.01, EP 1)
RI.01.03.01	1	The hospital honors the patient's right to give or withhold informed consent.	<p>The hospital follows a written policy on informed consent that describes the following:</p> <ul style="list-style-type: none">- The specific care, treatment, and services that require informed consent- Circumstances that would allow for exceptions to obtaining informed consent- The process used to obtain informed consent- How informed consent is documented in the patient record <p>Note: Documentation may be recorded in a form, in progress notes, or elsewhere in the record.</p> <ul style="list-style-type: none">- When a surrogate decision-maker may give informed consent (See also RI.01.02.01, EP 2)

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Appendix

Report Section Information

SAFER™ Matrix Description

All Requirements for Improvement (RFIs) are plotted on the SAFER matrix according to the likelihood the issue could cause harm to patient(s), staff, and/or visitor(s), and the scope at which the RFI is observed. Combined, these characteristics identify a risk level for each RFI, which in turn will determine the level of required post-survey follow up. As the risk level of an RFI increases, the placement of the standard and Element of Performance moves from the bottom left corner to the upper right. The definitions for the Likelihood to Harm a Patient/Staff/Visitor and Scope are as follows:

Likelihood to Harm a Patient/Staff/Visitor:

- Low: harm could happen, but would be rare
- Moderate: harm could happen occasionally
- High: harm could happen any time

Scope:

- Limited: unique occurrence that is not representative of routine/regular practice
- Pattern: multiple occurrences with potential to impact few/some patients, staff, visitors and/or settings
- Widespread: multiple occurrences with potential to impact most/all patients, staff, visitors and/or settings

The Evidence of Standards Compliance (ESC) or Plan of Correction (POC) forms with findings of a higher risk will require two additional fields within the ESC or POC. The organization will provide a more detailed description of Leadership Involvement and Preventive Analysis to assist in sustainment of the compliance plan. Additionally, these higher risk findings will be provided to surveyors for possible review or onsite validation during any subsequent onsite surveys, up until the next full triennial survey occurs. The below legend illustrates the follow-up activity associated with each level of risk.

SAFER™ Matrix Placement	Required Follow-Up Activity
HIGH/LIMITED HIGH/PATTERN HIGH/WIDESPREAD	<ul style="list-style-type: none"> Two additional areas surrounding Leadership Involvement and Preventive Analysis will be included in the ESC or POC Finding will be highlighted for potential review by surveyors on subsequent onsite surveys up to and including the next full survey or review
MODERATE/PATTERN MODERATE/WIDESPREAD	
MODERATE/LIMITED LOW/PATTERN LOW/WIDESPREAD	<ul style="list-style-type: none"> ESC or POC will not include Leadership Involvement and Preventive Analysis
LOW/LIMITED	

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Appendix

Report Section Information

CMS Summary Description

For organizations that utilize The Joint Commission for deeming purposes, observations noted within the Requirements for Improvement (RFI) section that are crosswalked to a CMS Condition of Participation (CoP)/Condition for Coverage (CfC) are highlighted in this section. The table included within this section incorporates, from a Centers for Medicare and Medicaid Services (CMS) perspective, the CoPs/CfCs that were noted as noncompliant during the survey, the Joint Commission standard and element of performance the CoP/CfC is associated with, the CMS score (either Standard or Condition Level), and if the standard and EP will be included in an upcoming Medicare Deficiency Survey (MEDDEF) if applicable.

Requirements for Improvement Description

Observations noted within the Requirements for Improvement (RFI) section require follow-up through the Evidence of Standards Compliance (ESC) process. The identified timeframes for submission for each observation are found in the Executive Summary section of the Final Report. If a follow-up survey is required, the unannounced visit will focus on the requirements for improvement although other areas, if observed, could still become findings. The time frame to perform the unannounced follow-up visit is dependent on the scope and severity of the issue identified within Requirements for Improvement.

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Appendix

Report Section Information

Clarification Instructions

Documents not available at the time of survey

Any required documents that are not available at the time of survey will no longer be eligible for the clarification process. These RFIs will become action items in the post-survey ESC process.

Clerical Errors

Clerical errors in the report will no longer be eligible for the clarification process. The Joint Commission will work with the organization to correct the clerical error, so that the report is accurate. The corrected RFIs will become action items in the post-survey process.

Audit Option

There will no longer be an audit option as part of the clarification process. With the implementation of the SAFER™ matrix, the "C" Element of Performance (EP) category is eliminated. The "C" EPs were the subject of Clarification Audits.

The clarification process provides an organization the opportunity to demonstrate compliance with standards that were scored "not compliant" at the time of the survey. The organization has 10 business days from the date the report is published on the extranet site to submit the clarification. *The Evidence of Standards Compliance (ESC) due dates will remain the same whether or not the organization submits a clarification and/or is successful in the clarification process.*

Clarifications may take either of the following forms:

- An organization believes it had adequate evidence available to the surveyor(s) and was in compliance **at the time of the survey**. (Please note that actions taken during or immediately after the survey will not be considered.) The organization must use the clarification form to support their contention.
- The organization has detailed evidence that was not immediately available **at the time of the survey**. The clarification must include an explanation as to why the surveyor(s) did not have access to the information or why it was not provided to the surveyor(s) at the time of the survey. However, any required documents that are not available at the time of survey are not eligible for the Clarification Process. These RFIs will become action items in the post-survey ESC process.
- Please do not submit supplemental documentation unless requested by The Joint Commission. If additional information is requested, the organization will be required to highlight the relevance to the standards in the documentation.

Montana Nurses Association



MNA Position Statement Regarding Vaccinations May 18, 2021

Purpose

Historically, the Montana Nurses Association (MNA) has strongly supported immunizations to protect the public from highly communicable and deadly diseases such as measles, mumps, diphtheria, pertussis, and influenza, moreover, has supported appropriate evidence based vaccination policies for registered nurses and health care workers. Under certain circumstances, MNA understands the need for mandatory vaccines (exemptions noted below), especially due to the several recent and significant measles outbreaks in the United States, as well as the global pandemic of COVID-19.

Statement of MNA Position

Effective protection of the public health necessitates that all individuals who are able to do so receive immunizations against vaccine-preventable diseases according to the best and most current evidence outlined by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP). Accordingly, all health care personnel (HCP), including registered nurses (RNs) and advance practice registered nurses (APRNs), should be vaccinated according to current recommendations for immunization of HCP by the CDC and Association for Professionals in Infection Control and Epidemiology (APIC).

Consistent with state and federal law, MNA strongly supports exemptions from immunization for medical contraindications or sincerely held religious beliefs. For example, the United States Equal Opportunity Employment Commission (EEOC) has issued guidance that “once an employer is on notice that an employee’s sincerely held religious belief, practice, or observance prevents the employee from receiving the vaccination, the employer must provide a reasonable accommodation for the religious belief, practice, or observance unless it would pose an undue hardship under Title VII of the Civil Rights Act.” For additional guidance from the EEOC, including on the relationship between federal disability protections and vaccine requirements in the workplace, visit <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

MNA understands that some RNs and APRNs may not be able to obtain vaccinations as a result of the above noted contraindications and the MNA supports employers making accommodations in these circumstances. Under the recently enacted Montana House Bill 702, individuals exempted from vaccination may be required to adopt measures or practices in the workplace to reduce the chance of disease transmission and expect employers to offer reasonable accommodations in such circumstances. The MNA encourages RNs and APRNs to work together with their employers to ensure that such accommodations are tailored to reduce disease transmission and encourages all nurses and HCP to stay up to date on and follow policies guided by current, evidence-based CDC and ACIP recommendations.

Approved by MNA Board of Directors May 18, 2021

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Montana Nurses Association



Appropriate personal protective equipment (PPE), along with evidence-based policies and practices, should be made available for all health care workers, whether they choose to vaccinate or not.

MNA strongly recommends that registered nurses be vaccinated against COVID-19. However, as the Covid-19 vaccine is currently under EUA (emergency use authorization) we recognize that without a well-established safety profile, the risk benefit analysis could be such that nurses choose not to be vaccinated. MNA recognizes and supports those nurses choosing to wait to be vaccinated until final FDA approval or more evidence based safety data about the Covid-19 vaccine effectiveness and/or medical contraindications is developed.

MNA does not believe nurses should be retaliated against by employers if they choose **NOT** to be vaccinated and supports employers accommodating all nurses and HCP who choose against vaccination at this time.

Still, the MNA recognizes that nurses have a professional responsibility and an ethical duty to protect patients at all levels—as individuals, families, groups, communities, and populations. We recognize the immense power of vaccines in the history and protection of public health, and encourage all nurses, HCPs, and community members to consider vaccination as an important step each one of us can take to protect ourselves, each other, and the patients we work so hard to care for. If any individual has concerns regarding getting vaccinated, please reach out to your local public health department and discuss your particular decision with your health care provider.

As novel diseases emerge, such as COVID-19, MNA supports ongoing scientific research and development of safe, easily accessible, and affordable vaccinations for these public health threats.

Vaccinations must be available to everyone!

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Approved by MNA Board of Directors May 18, 2021

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MNA 00150

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Montana Nurses Association



MNA Position Statement Regarding Vaccinations September 1, 2021

Purpose

Historically, the Montana Nurses Association (MNA) has strongly supported immunizations to protect the public from highly communicable and deadly diseases such as measles, mumps, diphtheria, pertussis, and influenza, moreover, has supported appropriate evidence based vaccination policies for registered nurses and health care workers. Under certain circumstances, MNA understands the need for mandatory vaccines (exemptions noted below), especially due to the several recent and significant measles outbreaks in the United States, as well as the global pandemic of COVID-19.

Statement of MNA Position

Effective protection of the public health necessitates that all individuals who are able to do so receive immunizations against vaccine-preventable diseases according to the best and most current evidence outlined by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP). Accordingly, all health care personnel (HCP), including registered nurses (RNs) and advance practice registered nurses (APRNs), should be vaccinated according to current recommendations for immunization of HCP by the CDC and Association for Professionals in Infection Control and Epidemiology (APIC).

Consistent with state and federal law, MNA strongly supports exemptions from immunization for medical contraindications or sincerely held religious beliefs. For example, the United States Equal Opportunity Employment Commission (EEOC) has issued guidance that “once an employer is on notice that an employee’s sincerely held religious belief, practice, or observance prevents the employee from receiving the vaccination, the employer must provide a reasonable accommodation for the religious belief, practice, or observance unless it would pose an undue hardship under Title VII of the Civil Rights Act.” For additional guidance from the EEOC, including on the relationship between federal disability protections and vaccine requirements in the workplace, visit <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

MNA understands that some RNs and APRNs may not be able to obtain vaccinations as a result of the above noted contraindications/exemptions and the MNA supports employers making accommodations in these circumstances. Under the recently enacted Montana House Bill 702, individuals exempted from vaccination may be required to adopt measures or practices in the workplace to reduce the chance of disease transmission and expect employers to offer reasonable accommodations in such circumstances.

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MNA encourages RNs and APRNs to work together with their employers to ensure that such accommodations are tailored to reduce disease transmission and encourages all nurses and HCP to stay up to date on and follow policies guided by current, evidence-based CDC and ACIP recommendations.

Appropriate personal protective equipment (PPE), along with evidence-based policies and practices, should be made available for all nurses and health care workers, whether they are able to vaccinate or not.

Vaccination requirements for employment as a professional nurse are not new to nurses. MNA strongly recommends that registered nurses be vaccinated against COVID-19, especially now with FDA approval (Pfizer-BioNTech full FDA approval 8/23/2021 for ages 16 and over--Moderna vaccine FDA application for full approval has been submitted and is awaiting approval). This vaccine, along with other FDA approved vaccines, will continue to be encouraged by MNA.

MNA does not believe nurses should be retaliated against by employers if they **cannot** be vaccinated and supports employers accommodating all nurses and HCP who, due to the exemptions noted, cannot be vaccinated.

MNA recognizes that nurses have a professional responsibility and an ethical duty to protect patients at all levels—as individuals, families, groups, communities, and populations. We recognize the immense power of vaccines in the history and protection of public health, and encourage all nurses, HCPs, and community members to consider vaccination as an important step each one of us can take to protect ourselves, each other, and the patients we work so hard to care for. If any individual has concerns regarding getting vaccinated, please reach out to your local public health department and discuss your particular decision with your health care provider.

As novel diseases emerge, such as COVID-19, MNA supports ongoing scientific research and development of safe, easily accessible, and affordable vaccinations for these public health threats.

Vaccinations must be available to everyone!

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MNA Resolution #3: VACCINATIONS

MNA Resolution #3
MNA and VACCINATIONS

- Whereas MNA has strongly supported immunizations to protect the public from highly communicable and deadly diseases, such as, but not limited to, measles, mumps, diphtheria, pertussis, influenza, and hepatitis B;
- Whereas MNA has supported appropriate evidence-based vaccination policies for registered nurses and health care workers;
- Whereas MNA supports that all health care personnel (HCP), including registered nurses (RNs) and advance practice registered nurses (APRNs), should be vaccinated according to current recommendations for immunization;
- Whereas under certain circumstances, MNA understands the need for mandatory vaccines as a job requirement with exemptions noted for medical and sincerely held religious beliefs;
- Whereas vaccine requirements as a professional nurse is not new to the profession, MNA supports the Centers for Disease Control (CDC) advocacy for and the Food and Drug Administration (FDA) approval of vaccines, especially due to the several recent and significant measles and pertussis outbreaks in the United States, as well as the global pandemic of COVID-19;
- Whereas effective protection of public health necessitates that all individuals, who are able to do so, receive immunizations against vaccine-preventable diseases according to the best and most current evidence and best practice; and
- Whereas MNA understands that some RNs and APRNs may not be able to obtain vaccinations as a result of the above noted contraindications/exemptions, however, over 85% of MNA professional nurse membership surveyed are fully vaccinated against COVID-19; now, therefore, be it
- Resolved*, that MNA supports HCP that are exempted from vaccination may be required to adopt measures or practices in the workplace to reduce the chance of disease transmission and MNA expects employers to offer reasonable accommodations in such circumstances;
- Resolved*, that MNA encourages RNs and APRNs to work together with their employers to ensure that such accommodations are tailored to reduce disease transmission and encourages all nurses and HCP to stay up to date on and follow policies guided by current, evidence-based CDC and Association for Professionals in Infection Control and Epidemiology (APIC) recommendations;
- Resolved*, that MNA requests that employers provide the appropriate personal protective equipment (PPE), along with evidence-based policies and practices, making these available for all nurses and HCP, whether they are able to vaccinate or not;
- Resolved*, that MNA does not believe nurses should be retaliated against by employers if they cannot be vaccinated and supports employers accommodating all nurses and HCP who, due to the exemptions noted, cannot be vaccinated;
- Resolved*, that MNA recognizes that nurses have a professional responsibility and an ethical duty to protect patients at all levels—as individuals, families, groups, communities, and populations; and
- Resolved*, that MNA recognize the immense power of vaccines in the history and protection of public health, and encourage all nurses, HCPs, and community members to consider vaccination as an important step each one of us can take to protect ourselves, each other, and the patients we work so hard to care for.

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Approved by MNA HOD 10/8/2021

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