Northwell Health Institute for Clinical Excellence and Quality/Patient Safety Mock Survey Report

Phelps Memorial Hospital
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Northwell Health®

Overview

The Institute for Clinical Excellence and Quality/Patient Safety coordinated and conducted a comprehensive review to assess regulatory compliance, survey readiness and to identify opportunities for improvement related to The Joint Commission Standards at Phelps Memorial Hospital. There were four repeat previous TJC findings related to individualized goals, titration, H&Ps, and labeling medications/solutions on and off the sterile field. The top priority focus areas identified during the mock survey were Infection Control, Environment of Care/Life Safety, Medication Management, Clinical Contract Management, National Patient Safety Goals (patient ID, labeling medications/solutions off the sterile field , suicide risk reduction), Provision of Care (i.e. assessment, reassessment, pain, H&P, falls, abuse/neglect, plan of care – individualized goals, orders including implementation, restraints, documentation of provider choices at discharge, patient nutrition refrigerator temperature logs, resuscitation equipment, pre and post anesthesia assessment) and processes and practices in Interventional Radiology. It should also be noted that some policies were outdated and there is a need to adopt Northwell Health policies especially related to Pain Management and Suicide Screening Assessment and Risk Mitigation. Closed records were reviewed. However, some records were not appropriate as per the request. Recommendation is to review the records prior to providing to the survey team to ensure records meet the request and standards.

TJC has enhanced its review processes and implemented safe physical distancing (i.e. limiting the number of individuals in group sessions, minimizing the number of staff that accompany a surveyor or reviewer during tracer activities), and enhanced technology. Therefore, it is recommended to ensure that the technology is functioning properly and is available. Staff was engaged during mock survey activities and there was overall evidence of teamwork and clinical and administrative support to assist in providing safe and quality patient care. Organization response to COVID was notable. It was apparent that the organization implemented safety measures to reduce the spread of COVID-19 while caring for the patients and keeping the staff safe.

Survey Team

Institute for Clinical Excellence & Quality/Patient Safety Northwell Health	**Patient Care Survey Activity**
Allison Carballo, RN, Senior Advisor	Emergency Department, ICU, Peds infusion, L&D, Mother/Baby, Closed Record Review
Denise McPartland, Advisor	Perioperative Services (3 Center, OR/Pain Center, ASU, Surgi Center-OR, PACU) Endo, Radiology, 2 Center, Closed Record Review, Grievance Management Process
Elizabeth Stefanucci, RN, Advisor	1 South, 2 South, Cancer Institute/Infusion Center/ ATS Ossining/ Mental Health Counseling, Closed Record Review
Susanne Schultz, RN, AVP	5S-Tele, 5N, 2N, ECT, Dialysis Patient Tracer, Closed Record Review
Anita Taylor-Germain, Senior Advisor	Wound Care Center, Hyperbaric, Pulmonary Lab/EEG, Sleep Center, Cardiopulmonary Rehab, Cardiovascular Lab, Clinical Contracts

EOC/Life Safety

Steve Marzo, CHSP, AVP, Safety Regulation, Corporate Facilities Services, Northwell Health

Infection Prevention
Donna Armellino, RN, DNP, CIC, VP, Infection Prevention, Northwell Health

Medical Staff
Allison Rossi, Manager, Medical Staff Services, Northwell Health

Human Resources *(Survey Date TBD)*
Jodi Krebs, Director, HR Compliance, Northwell Health
Margaret Johnson, Sr. HR Compliance Specialist, Northwell Health

Sterile Compounding
Melanie A. Galvin, PharmD, BCSCP, Senior Advisor, Pharmacy Service Line, Northwell Health

Emergency Management
Glenn Schaefering, Director, Corporate Emergency Management, Northwell Health

Section I:

Patient Care Tracer Report

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2021 Hospital Accreditation Standards				
Joint Commission Mock Tracer				
Phelps Memorial Hospital				
	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Information Management (IM)				
IM.02.01.03 Hospital maintains the security and integrity of health information.				
EP 5 The hospital protects against unauthorized access, use, and disclosure of health information.	✓			**Mother/Baby Unit:** Vital sign form with patients' names left facing up in a public corridor.
Leadership (LD)				
LD.04.01.05 The hospital effectively manages its programs, services, sites or departments				
EP 4 Staff are held accountable for their responsibilities.	✓			**Wound Center:** In medical record reviewed, the provider signed the consent form before the procedure. **ENDO:** The specimen collection card was pre-signed by the RN prior to the start of the procedure. **IR:** The post-anesthesia assessment was signed by the provider prior to the start of the procedure.
LD.04.01.07 The hospital has policies and procedures that guide and support patient care, treatment, and services				
EP 1 Leaders review, approve, and manage the implementation of policies and procedures that guide and support patient care, treatment, and services.	✓			**General:** Current Pain Pain Management Policy and Suicide Screening Assessment and Mitigation Policy are Phelps-specific and are not compliant with all requirements. Conversion to these Northwell Health policies is recommended. Also, policy Medication storage, handling, security, and disposition provided was outdated (last reviewed 10/15). **Note: General:** 2020 NPSG's posted. Ensure most up to date references are posted **Note: Wound Center:** The Mission and Vision that is posted in the waiting area is the not the most current.

	RFI	CNSLTVE	PF	
LD.04.03.09 Care, treatment, and services provided through contractual agreement are provided safely and effectively.				
EP 6 Leaders monitor contracted services by evaluating these services in relation to the hospital's expectations.	✓			**Clinical Contract Review:** Listing of clinical contracts was provided. Four Phelps specific contracts were reviewed for inclusion and management of performance metrics (Mother's Milk Bank, Renal Care, Language Line Solutions, Persante). All contracts that were reviewed the performance metrics specifically delineated in the contracts were not the same metrics listed on the clinical contract list that was provided. In addition, evaluations of contracts were not performed. It was noted that the organization is monitoring some metrics but not the metrics that were listed on the clinical contract list. Further review required.
Medication Management (MM)				
MM.03.01.01 The hospital safely stores medications.				
EP 2 The hospital stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions.		✓		**5N:** Although medication refrigerator temperature was within acceptable range and monitored by pharmacy, display not working properly on unit. A replacement unit will now be ordered.
EP 3 The hospital stores all medications and biologicals, including controlled (scheduled) medications, in a secured area to prevent diversion, and locked when necessary, in accordance with law and regulation. and/or EP 6 The hospital prevents unauthorized individuals from obtaining medications in accordance with its policy and law and regulations.	✓			**OR:** Bottles of propofol were seen in a red biohazard bin with no top. Also, syringes with medication were also seen in the red biohazard bin. Other bins are present in the OR but are not being properly utilized. **ASU:** Keys for medication refrigerator/cart were found on top of Pyxis. **ECT:** During initial unit tour, 4 partially used vials of succinylcholine were found unattended on desk. These were later discarded by the Anesthesiologist. **ICU:** When discussing diversion, a discrepancy was found in the Pyxis that remained unresolved from 7/31. **Note -ED:** Unsecured sharp (IV catheter in peds cart) in public corridor. **Wound Care:** In patient room, there was a scalpel in an unlocked drawer.
EP 7 All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.	✓			**5S:** Two red emergency medication transport boxes that were in the medication room did not have Expiration Tags which are generally on all boxes. **Note-ED:** Recommend organization of medication refrigerator. During survey medications were found in mislabeled boxes and vaccines scattered throughout.

	RFI	CNSLTVE	PF	
MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders for meds to be dispensed in the hospital.				
EP 4 All medication orders are reviewed for the following: - Patient allergies or potential sensitivities - Existing or potential interactions between the medication ordered and food and medications the patient is currently taking - The appropriateness of the medication, dose, frequency, and route of administration - Current or potential impact as indicated by laboratory values - Therapeutic duplication - Other contraindications	✓			**Mother/Baby Unit:** Benadryl, Decadron, Reglan, Zofran all ordered for the same indication PRN nausea/vomiting. **PACU/2 Center:** Post surgical patients had a one time standing order for IV Tylenol for all pain. This order does not provide specific instructions on when this medication should be given. The patient had other pain medications ordered for all levels of pain. Recommend review of the order to indicate specific timing of administration of medications such as "IV Tylenol given first" and oral medication to follow based on pain score.
MM.06.01.01 Safely administers medications.				
EP 3 Before administration, the individual administering the medication does the following: - Verifies that the medication selected matches the medication order and product label - Visually inspects the medication for particulates, discoloration, or other loss of integrity - Verifies that the medication has not expired - Verifies that no contraindications exist - Verifies that the medication is being administered at the proper time, in the prescribed dose, and by the correct route - Discusses any unresolved concerns about the medication with the patient's licensed independent practitioner, prescriber (if different from the licensed independent practitioner), and/or staff involved with the patient's care, treatment, and services	✓		✓	**Likelihood to Cause Harm: High** **Scope: Limited** **ICU:** Upon review of order for Cardene drip, titration goal stated systolic blood pressure less than 140. Upon discussion with nursing, it was left up to clinical judgement as to the lower systolic blood pressure that would require titration. During tracer of another patient who received precedex continuous infusion, the provider order stated, "subsequent titration 0.05 MCG/kg/hour every 15 minutes toward a goal of 0-(-1)". It was noted that multiple titrations were made without documentation of supporting RASS score to support titration. (7/31 at 2139 and 2200).
National Patient Safety Goals (NPSG)				
NPSG.01.01.01 Use at least two patient identifiers when providing care, treatment, and services.				
EP 1 Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient's room number or physical location is not used as an identifier.	✓			**Mother/Baby Unit:** During tracer of infant receiving donor milk, there was no documentation supporting completion of a required two person check. Upon review of administration process, recommend re-education of staff to ensure overall process is completed as designed in policy.

	RFI	CNSLTVE	PF	
NPSG.02.03.01 Report critical results of tests and diagnostic procedures on a timely basis.				
EP 1 Develop written procedures for managing the critical results of tests and diagnostic procedures that address the following: - The definition of critical results of tests and diagnostic procedures - By whom and to whom critical results of tests and diagnostic procedures are reported - The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures		✓		**ASU**: The current process for critical value is the lab calls the unit and speaks with secretary to inform only that there is a critical value on a patient. The critical value will be faxed to the unit. The RN does not speak with the lab or verbalize a read back of the value. Discussed need to review overall process including ensuring faxed lab results are promptly addressed. Policy reviewed and is outdated.
NPSG.03.04.01 Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.				
EP 1 In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used.	✓		✓	**Likelihood to Cause Harm: Low** **Scope: Limited** **ENDO:** Medication was drawn and put down on anesthesia cart without label.
NPSG.15.01.01 Reduce the risk for suicide				
EP 5 Follow written policies and procedures addressing the care of patients identified as at risk for suicide. At a minimum, these should include the following: - Training and competence assessment of staff who care for patients at risk for suicide - Guidelines for reassessment - Monitoring patients who are at high risk for suicide	✓			**ED:** During patient tracer, a patient s/p suicide attempt was documented in triage as an ESI 3. Although patient was seen by a provider and immediately placed on constant observation, staff verbalized that the patient should have been triaged as an ESI 2, per policy. **ED:** In another patient's record, missing documentation supporting completion of one 15 minute required safety check for a patient placed on constant observation.
EP 6 Follow written policies and procedures for counseling and follow-up care at discharge for patients identified as at risk for suicide.	✓			**Suicide risk inpatient discharge closed MR:** 1 out of 2 records reviewed did not have evidence of successful linkage via follow-up call. Patient had been noted at moderate risk during hospitalization. 2 out of 2 records did not have a scanned copy of "My Safety Plan" as required and relayed by staff. Some safety plan components were seen and incorporated into the discharge instructions.
UP.01.03.01 A time-out is performed before the procedure.				
EP 2 The time-out has the following characteristics: - It is standardized, as defined by the hospital. - It is initiated by a designated member of the team. - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.	✓			**ECT:** During observed time-out, all team members did stop activity and participate. However, the RN who led the time-out had the consent as source document and was the individual who also checked the armband. No other team member had a source document to confirm patient ID.

	RFI	CNSLTVE	PF	
Provision of Care, Treatment, and Services (PC)				
PC.01.02.01 The hospital assesses and reassesses its patients.				
EP 1 The hospital defines, in writing, the scope and content of screening, assessment, and reassessment. Patient information is collected according to these requirements.	✓			**Wound Center:** In medical record reviewed, initial assessment was incomplete.
EP 2 The hospital defines, in writing, criteria that identify when additional, specialized, or more in-depth assessments are performed.	✓			**1 South/2 South:** Staff unable to speak to process and timeline for further assessments i.e. nutrition, PT, medication management. **2 Center**: Staff were unable to communicate timeframe for follow-up for additional assessments (i.e. nutritional). Recommend staff re-education.
PC.01.02.03 The hospital assesses and reassesses the pt and his condition according to defined time frames. (Nursing and H&P)				
EP 4 The patient receives a medical history and physical examination no more than 30 days prior to, or within 24 hours after, registration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services.	✓			**ECT:** For Medical H&Ps that are greater than 30 days prior to the procedure, a complete H&P must be completed. In several instances, the H&P was over 30 days and the NP only completed an update note. **ASU/ENDO/PACU:** H&P's were noted to be older than 30 days from procedure date. **ENDO:** H&P reviewed, showed a written line through review of systems. **1 South/2 South:** In H&Ps reviewed, cranial nerves were not assessed. It was noted that cranial nerves assessed only when there was a neurology consult. **Wound Care:** In medical record reviewed, the H&P in the medical record was when the patient was an inpatient which was 30 days prior to the start of treatment. There was no recent H&P in the medical record.
EP 5 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.	✓		✓	**Likelihood to Cause Harm: Moderate** **Scope: Limited** **ENDO/IR:** H&P's within 30 days did not have an attestation within 24 hours or do not have a complete attestation. **OR/PACU/ENDO/IR:** Attestations did not include the word examination.

	RFI	CNSLTVE	PF	
PC.01.02.07 The hospital assesses and reassesses the patient's pain and minimizes the risks associated with treatment.				
EP 1 The hospital has defined criteria to screen, assess, and reassess pain that are consistent with the patient's age, condition, and ability to understand.	✓			**Mother/Baby Unit:** During tracer of patient without epidural in place, a pain score of 5 was documented on 8/4 at 0806 and Percocet was administered. No pain reassessment was documented post administration. **5S:** During patient tracer, pain assessments were noted to be incomplete and inconsistent scales were used for same patient. Currently there are several scales available to choose from for pain assessment based on patient status. Dementia, non-verbal and number scale were all used for one patient. Staff unable to clearly delineate what each scale used for and components. No visual aids, etc. able to be produced to show what staff references related to pain scale. **5N:** Inconsistent/absent documentation of pain scale used for a patient being traced with dementia. No visual aid/reference for staff in rooms, etc. to explain all available scales. **Pain management:** It was noted that the facility utilizes several different pain scales and determines the scale based on what the staff feels is appropriate.
EP 3 The hospital treats the patient's pain or refers the patient for treatment.	✓			**Infusion Center:** In MR reviewed patient noted pain during 5 out of 7 visits with no interventions offered or provided.
EP 6 The hospital monitors patients identified as being high risk for adverse outcomes related to opioid treatment.	✓			**1 South/2 South:** Staff unable to speak to process of screening to ID pts who are at high risk for adverse outcomes related to opioid treatment.

	RFI	CNSLTVE	PF	
PC.01.02.08 The hospital assesses and manages the patients' risk for falls.				
EP 1 The hospital assesses the patient's risk for falls based on the patient population and setting.	✓			**5S:** In 2 medical records reviewed during tracer activity, fall risk assessments were inconsistent. It was relayed that the facility recently adopted the Northwell Health Fall Assessment/Intervention Policy. Previous scale used was the Hendrich's scale, which appears to be in use by the ED where first assessment is completed. Conflicting documentation was also noted for same patient – patient was a "fall risk with harm" but was noted as a "fall risk" in certain EMR documents, and in others as "fall risk with harm". It was discussed with leadership during tracer that a review should occur to validate staff implementation and EMR output are occurring as expected/designed. **Mother/Baby Unit:** Utilizing Hendrich scale to assess fall risk which is not in alignment with policy provided. Per documentation, patient was assessed while in the OR (8/3 at 2000) as not a fall risk and at time of survey (8/4) pt had not been re-assessed post op (pt out of OR 8/3 at 2047.)
EP 2 The hospital implements interventions to reduce falls based on the patient's assessed risk.	✓			**ED:** Falls risk assessment in EMR is currently not in alignment with policy provided. Patient triggered fall with harm risk and did not have a yellow bracelet as required. **1 South/2 South:** In medical records reviewed, it was noted that there was inconsistent fall interventions/limited interventions documented.
PC.01.02.09 The hospital assesses the pt who may be a victim of possible abuse or neglect.				
EP 1 The hospital uses written criteria to identify those patients who may be victims of physical assault, sexual assault, sexual molestation, domestic abuse, or elder or child abuse and neglect. Patients are evaluated upon entry into the hospital and on an ongoing basis.	✓			**1 South/2 South/Infusion Center/Cancer Institute:** Staff unable to speak to ID method to identify possible victims of abuse and neglect.
PC.01.03.01 The hospital plans the patient's care.				
EP 5 The written plan of care is based on the patient's goals and the time frames, settings, and services required to meet those goals. and/or EP 23 The hospital revises plans and goals for care, treatment, and services based on the patient's needs.	✓		✓	**Likelihood to Cause Harm: Low** **Scope: Pattern** **1 South/2 South/ATS:** In charts reviewed, goals with broad objectives/little documentation throughout length of stay to revise or build off original goals. (Citation could also occur under Behavioral Health standard CTS. 03.01.03 - The organization has a plan for care, treatment, or services that reflects the assessed needs, strengths, preferences, and goals of the individual served).
PC.02.01.01 The hospital provides care, treatment, and services for each patient.				
EP 15 For hospitals that use Joint Commission accreditation for deemed status purposes: Blood transfusions and intravenous medications are administered in accordance with state law and approved medical staff policies and procedures.	✓			**Blood transfusion closed MR**: 1 out of 5 blood transfusion events did not have MD signature on paper order. In 1 out of 5 TARs (transfusion administration records), boxes were blank indicating check for consent and blood component verification. 1 out of 5 events had no indication for transfusion on the paper MD order sheet – was indicated in EMR.

	RFI	CNSLTVE	PF	
PC.02.01.03 The hospital provides care, treatment, and services as ordered or prescribed, and in accordance with law and regulation.				
EP 7 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital provides care, treatment, and services using the most recent patient order(s).	✓			**Sleep Center:** In medical records reviewed, there was no order/prescription for the sleep study. The vendor/contractor (Persante) performs the sleep study. However, Phelps bills for the sleep study. Therefore, recommendation is to have an order/prescription for the sleep study in the medical record. **Mother/Baby unit:** Multiple orders remain active in EMR from OR. Per RN, they utilize a workaround to document dose already administered in OR (I.e.: duramorph, Pepcid, Bicitra) Recommend development of a process for timely discontinuation by provider of non-active medications. **ICU:** Verbal orders accepted on rounds to restart Cardene drip and Heparin drip. The orders had not yet been entered 6 hours post conversation on rounds. **ED:** Vital signs done randomly (q2 hours, then q12 hours) without a supporting order. Per staff, routine is every two hours in the ED per attachment B of provided policy **ED:** No order to insert PIV. **5S:** During tracer activity, central monitoring station processes were reviewed. There was an appropriate alarm limit adjustment for a patient who was consistently tachycardic. In discussion with staff and unit leadership, it was relayed that an order to change limits was required by the hospital. There was no order to support the change. The hospital policy is not prescriptive related to order requirement. Clarification of process required. Also, in patient reviewed, pain score was 5. Tylenol was given which was ordered for pain score of 1-3. There was no other order for pain available and discussion with Provider did not occur. **Dialysis:** Tracer of a 5N patient currently undergoing dialysis was conducted. Dialysis is conducted at patient's bedside. Physician orders were noted to be consistently incomplete as they do not include all HD settings, such as Dialysate flow rate. There is no standardized compliant HD template built in EMR. During observed treatment, the HD machine blood flow rate setting for this patient was 350. Order required 400. HD RN relayed she spoke with the Nephrologist who was aware of the change. Updated orders for these types of changes are generally not obtained.

	RFI	CNSLTVE	PF	
(cont'd) EP 7 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital provides care, treatment, and services using the most recent patient order(s).	✓			**Mother/Baby Unit:** Three active orders in place at time of tracer: 1. Percocet PRN mild breakthrough pain 1-3 with special instructions indicating "may be administered if epidural catheter is in place". 2. Tylenol PRN mild pain 1-3. 3. Toradol PRN moderate/severe pain 4-10 During tracer of patient without epidural in place, a pain score of 5 was documented on 8/4 at 0806 and Percocet was administered. Per orders, Toradol should have been administered.

	RFI	CNSLTVE	PF	
PC.02.01.11 Resuscitative services are available throughout the hospital.				
EP 2 Resuscitation equipment is available for use based on the needs of the population served.	✓			**OR:** Open electrodes were found on top of the anesthesia cart. **ED:** Expired (as of 8/2020) soft yankauer in bag containing manual suction on crash cart. **Special Care Nursery:** Expired pediatric defibrillators pads (as of 3/5/2021) on top of Neonatal crash cart. Neonatal crash cart log missing required daily check (8/1). **Cardiovascular Lab:** Crash cart log missing check. **Mother/Baby Unit:** Daily code cart checklist missing multiple required daily checks (8/1, 7/5, 7/6, 7/24). Maternity crash cart with two locks on cart-per staff bottom lock is for meds. Only top lock is currently tracked on log. **2 Center:** Discussed cross-outs requiring initials and documenting a change in lock number on the crash cart log. **Peds Infusion:** Unapproved cross outs on broselow cart log. Also, recommend writing "closed" on crash cart log as opposed to leaving line blank when infusion center is closed. **General:** Unable to produce or speak to Malignant Hyperthermia drills (MH). The organization has one operational MH cart. In all the other areas requiring MH cart where general anesthesia is administered they have tackle boxes containing dantrolene (managed by pharmacy.) Post survey follow up with System Periop leadership was completed. Investigation revealed there must be cold saline in addition to the Dantrolene immediately available. Therefore, MH must be available within 10 minutes. Drills required to ensure compliance. **IR**: MH education and/or drills were not performed. The emergency to go box for MH is stored in MRI instead of in IR. Recommended review of current location of the emergency to go box for MH. Suggested assessment of the safest and most at risk location for the box or potential for additional supplies.

	RFI	CNSLTVE	PF	
PC.02.01.21 The hospital effectively communicates with pts when providing care, treatments, and services.				
EP 2 The hospital communicates with the patient during the provision of care, treatment, and services in a manner that meets the patient's oral and written communication needs.	✓			**5S:** During patient tracer of a non-verbal patient whose language was Portuguese, there was no documentation related to interpretation methods needed or required. Staff relayed they were communicating with the daughter, who would then communicate with the patient in Portuguese. Documentation was absent.
PC.02.02.03 The hospital makes food and nutrition products available to its patients.				
EP 11 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.	✓			**General:** Review of patient refrigerator log revealed that temperatures were out of range with no corrective action plans. Organizational review of temperature logs, review of process and documentation when temperature is out of range is required. **Sleep Center:** Patient refrigerator temperature was out of range with no corrective action and/or new temperature check since February 9, 2021. Log indicated that an alarm was triggered several times. **5N:** Patient refrigerator log indicated log was out of range since 2017.
PC.02.03.01 The hospital provides patient education and training based on each patient's needs and abilities.				
EP 25 The hospital evaluates the patient's understanding of the education and training it provided.	✓			**5S:** In non-verbal patient whose language was Portuguese, with unclear mental status, it was indicated that the patient was taught about disease-process and symptoms. Chart indicated that teach-back was not achieved. In speaking with staff, it was relayed that teaching was occurring with the patient's family. No evidence of family teaching was documented.
PC.03.01.03 The hospital provides the patient with care before initiating operative or other high risk procedures, including those that require the admin of moderate or deep sedation or anesthesia.				
EP 1 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.	✓			**OR/ENDO/Pain/IR:** Vital sign fields are not completed on top of the pre-anesthesia assessment. Recommended review of process. **2 Center**: During chart review it was noted that the Mallampati score was not completed on pre-anesthesia record for the patient. **Mother/Baby Unit:** Incomplete documentation on two anesthesia records reviewed (epidural and c/s records) missing multiple required fields within preoperative anesthesia assessment.
EP 8 The hospital reevaluates the patient immediately before administering moderate or deep sedation or anesthesia.		✓		**ECT: Note:** Validate that the practice is to document VS before induction, during immediate pre-procedure re-evaluation, as the first time on the anesthesia record appears to be the same for medications given and VS taken. **OR/IR**: The immediate pre-anesthesia assessment section on the pre-anesthesia record was not completed.

	RFI	CNSLTVE	PF	
PC.03.01.07 The hospital provides care for the pt after operative or other high risk procedures and/or the admin of moderate or deep sedation or anesthesia.				
EP 4 A qualified licensed independent practitioner discharges the patient from the recovery area or from the hospital. In the absence of a qualified licensed independent practitioner, patients are discharged according to criteria approved by clinical leaders.	✓			**ECT:** "Discharge by criteria" is ordered on all ASU-ECT patients. Staff unable to show specific criteria used and stated it can vary based on ASU procedure. "Electroconvulsive Therapy" policy reviewed post tracer that does have a section for Post ECT treatment but indicates the patient may be discharged by order of Anesthesia provider and lists several indicators. This does not clearly indicate discharge can occur when these criteria are met. These indicators were not clearly outlined in EMR.
EP 7 For hospitals that use Joint Commission accreditation for deemed status purposes: A postanesthesia evaluation is completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services.		✓		**ENDO/PACU:** The post-anesthesia section had a written line through all elements. Recommended completing each element individually.
PC.03.05.15 The hospital documents the use of restraint or seclusion.				
EP 1 Documentation of restraint and seclusion in the medical record includes the following: - Any in-person medical and behavioral evaluation for restraint or seclusion used to manage violent or self-destructive behavior - A description of the patient's behavior and the intervention used - Any alternatives or other less restrictive interventions attempted - The patient's condition or symptom(s) that warranted the use of the restraint or seclusion - The patient's response to the intervention(s) used, including the rationale for continued use of the intervention - Individual patient assessments and reassessments - The intervals for monitoring - Revisions to the plan of care - The patient's behavior and staff concerns regarding safety risks to the patient, staff, and others that necessitated the use of restraint or seclusion - Injuries to the patient - Death associated with the use of restraint or seclusion - The identity of the physician, clinical psychologist, or other licensed independent practitioner who ordered the restraint or seclusion - Orders for restraint or seclusion - Notification of the use of restraint or seclusion to the attending physician - Consultations	✓			**Restraint Closed Medical Record Review:** In medical records reviewed it was noted 4 point restraints applied on patient described as calm and cooperative following anti-anxiety meds. It was also noted MD did not perform assessment with order, assessments were not done as policy Q15/Q30 by RN/NA.

	RFI	CNSLTVE	PF	
PC.04.01.01 The hospital has a process that address the patient's need for continuing care, treatment, and services after discharge or transfer				
EP 22 For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital informs the patient or the patient's representative of his or her freedom to choose among participating Medicare providers and suppliers of post-discharge services and, when possible, respects the patient's or patient representative's goals of care and treatment preferences, as well as other preferences when they are expressed. The hospital does not limit the qualified providers who are available to the patient. and/or EP 25 For hospitals that use Joint Commission accreditation for deemed status purposes: The discharge plan identifies any home health agency or skilled nursing facility in which the hospital has a disclosable financial interest, and any home health agency or skilled nursing facility that has a disclosable financial interest in a hospital.	✓			**D/C to another LOC (SNF) closed MR:** Record reviewed did not indicate clearly that patient was offered choice (provided list) of SNF. **Discharge Closed Record Review:** In medical record reviewed, physical therapy and home care recommended, no list provided.
PC.04.01.05 Before the hospital discharges or transfers a patient, it informs and educates the patient about his or her follow-up care, treatment, and services.				
EP 2 Before the patient is discharged, the hospital informs the patient, and also the patient's family when it is involved in decision making or ongoing care, of the kinds of continuing care, treatment, and services the patient will need.	✓			**D/C to another LOC (SNF) closed MR:** Discharge instructions not signed by patient.
PC.06.01.01 Reduce the likelihood of harm related to maternal hemorrhage				
EP 1 Complete an assessment using an evidence-based tool for determining maternal hemorrhage risk on admission to labor and delivery and on admission to postpartum.	✓			**Mother/Baby Unit:** During tracer of patient s/p c-section one day prior to survey, OB hemorrhage risk assessment incomplete. Policy requested and this is required.
Performance Improvement (PI)				
PI.01.01.01 The hospital collects data to monitor its performance.				
EP 2 The hospital collects data on the following: Performance improvement priorities identified by leaders.		✓		**ASU:** PI board had outdated information. Recommend updating PI board.

	RFI	CNSLTVE	PF	
Record of Care, Treatment, and Services (RC)				
RC.01.01.01 The hospital maintains complete and accurate medical records.				
EP 5 The medical record includes the following: - Information needed to support the patient's diagnosis and condition - Information needed to justify the patient's care, treatment, and services - Information that documents the course and result of the patient's care, treatment, and services - Information about the patient's care, treatment, and services that promotes continuity of care among providers	✓			**ECT:** During patient tracer chart review, the Nursing preop ASU assessment was incomplete with multiple blank fields. **AC Peds Infusion:** ACP utilizing section of H&P as a progress note. Also, while patient was actively receiving GHST, it was documented under hospitalization plan -discharge plan: "patient name" was discharged to home with his mother.... " **ASU:** Review of medical record showed out of range lab values that had no indication or documentation that those values were reviewed prior to the patient being brought into the OR. Recommended review of process to improve pre-op review and communication for patient safety. **ATS:** In medical records reviewed, treatment plan did not always reflect team discussion from morning Team Meetings. Recommendation that clinicians ensure process for communicating needs of patients is communicated beyond the Team Meeting in the event of change in providers/turnover or absenteeism etc. **Closed Record Review:** One autopsy record was reviewed however, the patient requested an autopsy be performed and pathology was sent to LIJ to complete. No other information regarding the autopsy was in the record as it was stated that the consent and report would remain at LIJ. **Closed Record Review:** 1 chart reviewed for a patient on mechanical ventilation that was extubated. To note, two MRN's provided but only one could be reviewed as intubation and extubation could not be located by team member navigating the medical record. **Closed Record Review:** In 1/1 record reviewed, respiratory documented MV settings at 1811 and provider order for settings was entered at 1847. An intubation note could not be located at time of tracer. Post extubation, there was no provider order to extubate to 3L NC.
EP 7 All entries in the medical record are dated.	✓			**Restraint Closed Record Review:** Order not dated.
EP 13 For hospitals that use Joint Commission accreditation for deemed status purposes: All entries in the medical record, including all orders, are timed.	✓			**Wound Care:** In medical record reviewed, the discharge instructions were not timed by RN.

	RFI	CNSLTVE	PF	
RC.01.04.01 The hospital audits its medical records.				
EP 1 The hospital conducts an ongoing review of medical records at the point of care, based on the following indicators: presence, timeliness, legibility (whether handwritten or printed), accuracy, authentication, and completeness of data and information.	✓			**Wound Care:** In medical record reviewed, it appears that provider note was started on 6/16/21 @ 16:19 and not authenticated until 6/21/21 @ 12:42. **ENDO:** The written attestation to the H&P was illegible.
RC.02.01.03 The patient's medical record documents operative or other high risk procedures and the use of moderate or deep sedation or anesthesia.				
EP 7 When a full operative or other high-risk procedure report cannot be entered immediately into the patient's medical record after the operation or procedure, a progress note is entered in the medical record before the patient is transferred to the next level of care. This progress note includes the name(s) of the primary surgeon(s) and his or her assistant(s), procedure performed and a description of each procedure finding, estimated blood loss, specimens removed, and postoperative diagnosis.	✓			**Wound Care:** In medical record reviewed, there was no brief op or operative report.
RC.02.03.07 Qualified staff receive and record verbal orders.				
EP 1 The hospital identifies, in writing, the staff who are authorized to receive and record verbal orders, in accordance with law and regulation. EP 3 Documentation of verbal orders includes the date and the names of individuals who gave, received, recorded, and implemented the orders.	✓			**ASU:** Recommend review of process and reason for frequent use of verbal orders. **CT:** Telephone orders were obtained from physician at Lenox Hill Hospital during a cardiac CT for beta blockers. In another case, a telephone order was pre-signed with no order on the form. Recommended review of overall process for telephone orders as well as process for authenticating telephone orders from providers outside facility.

	RFI	CNSLTVE	PF	
Rights and Responsibilities of the Individual (RI)				
RI.01.03.01 The hospital honors the pt's right to give or withhold informed consent.				
EP 1 The hospital follows a written policy on informed consent that describes the following: - 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 - When a surrogate decision-maker may give informed consent	✓			**Wound Center:** In medical record reviewed, consent was not timed by the provider. In another medical record reviewed consent was not timed by the witness. **Cardiovascular Lab:** In medical record reviewed, consent was not timed by the patient. **ENDO:** The type of anesthesia on the consent form was illegible. **Closed Record Review:** In 1/1 closed record for a patient who received sedation for a reduction of the right shoulder, consent was illegible (right shoulder reduction c/ (illegible).....) and consent was not timed by surgeon.
RI.01.05.01 The hospital addresses the patient decisions about care, treatment, and services received at the end of life.				
EP 9 The hospital documents whether or not the patient has an advance directive.	✓			**Wound Care:** In medical record reviewed, there was no documentation that stated whether or not the patient has an advance directive. **Pulmonary Rehab:** In medical record reviewed, the advance directive section was blank. **5N:** A patient with dementia reviewed on tracer had several past admissions to Phelps. In review of current admission, documentation indicated patient had a MOLST. Could not be located in EMR or paper chart. Investigation revealed that the patient was registered with a new MR# for this admission, resulting in 2 MR#s for this patient. Therefore, previous admission information not available. Plan was for charts to be merged. In reviewing previous charts, the MOLST form was located; the previous EMR had noted patient as a DNR – current status did not indicate this. Clarification of advance directives was to occur. **1 South/2 South:** Records reviewed did not indicate conversation about advanced directives. **Infusion Center/Cancer Institute:** Staff not aware of out-patient role in verifying advance directives. Records reviewed does not indicate conversation about advance directives. EMR does not provide access at all outpatient areas to view inpatient advance directives.

	RFI	CNSLTVE	PF	
RI.01.07.01 The patient and his or her family have the right to have complaints reviewed by the hospital				
EP 1 The hospital establishes a complaint resolution process and informs the patient and his or her family about it.	✓			**Grievance Management Review:** One grievance record was complicated involving Risk Management input. Initial letter did not address all patient concerns and patient was then dissatisfied with response. Discussed need to acknowledge patient concerns and address in most appropriate way.
Transplant Safety (TS)				
TS.03.01.01 The hospital uses standardized procedures for managing tissues.				
EP 2 The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues.	✓			**Wound Center:** Recommendation is to ensure that staff is able to navigate the tissue log/record to provide all required documentation for the procedures for the acquisition, receipt, storage, and issuance of tissues. It was noted in medical records reviewed, that there was a delay in documentation. Staff relayed that tissue was removed and issued on 7/27/21 @ 4:03, however not documented until 7/28/21 @8:18. Time entry delay was also noted in another medical record 7/22 @1:33 surgery date/time 7/22 @ 2:05pm date/time entered. Procedural Safety Checklist time was 1:33pm.
EP 3 The hospital confirms that tissue suppliers are registered with the US Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.	✓			**Wound Center:** The license provided was not the most current tissue license. However, the most current license is posted downstairs on main floor.

Section II:

EOC/Life Safety Reports

Prepared By:
Steve Marzo, CHSP, AVP, Safety Regulation
Corporate Facilities Services

Northwell Health®

PHELPS MEMORIAL HOSPITAL
ENVIRONMENT OF CARE AND LIFE SAFETY
MOCK SURVEY

ENVIRONMENT OF CARE

EC.02.01.01

EP3
- The gate to the boiler room mezzanine was unlocked, thereby creating a fall risk to personnel or the public who could access the area.
- The access panels to generator #4, which is located outside the building, were unlocked. Consequently, unauthorized individuals could access generator controls and equipment. Note, this is a repeat finding from the most recent accreditation survey.
- An Infant Security Drill was not conducted in 2020.
- Electric panels did not have at least three feet of clearance from storage to enable quick access in an emergency. Examples of this were observed in, but not limited to Pediatrics and Endoscopy.
- A defibrillator in Pediatric Infusion was not plugged into an emergency receptacle.
- A patients CPAP machine was left unsecure on 1-South.

EC.02.03.01

EP 1 Not all surgical personnel are participating in education, training and drills associated with the prevention of and response to surgical fires. Specific reference is made to the lack of physician attendees, as evidenced by the program attendance sheets.

EC.02.03.03

EP 1 Fire drills were not being held in all high risk areas of the hospital each year. Specific reference is made to the kitchen, which did not have a fire drill in 2020.

EC.02.03.05

EP 9 While the annual fire pump flow test was conducted, the test did not indicate that the pump was operated at 150% of its rating.

EC.02.04.03

EP 2
- An expired $EtCO_2$ detector (as of 1/28/2021) was observed in the Mother/Baby unit clean utility room.
- A medication pump in the infusion center had an expired service label.

EP 3 A Detecto stand-up scale was last inspected on 4/2020.

EC.02.05.01

EP 9 Some electric panels had circuit breakers that were either unlabeled, or had spare breakers in the "on" position. Examples of this were observed in, but not limited to the operating suite and the Emergency Department.

EP 15
- Sterile Processing was under negative pressure as opposed to the positive pressure required for "clean" areas.
- Operating room temperatures were being maintained at 66° F, which is below the lower level requirement. It is recommended that the temperature be raised to a minimum of 68° F to meet the code requirement, or undertake a risk assessment that clearly justifies the need to lower the temperature, while assuring patient safety and well being.

EP 16 Soiled utility rooms in the Emergency Department and Hyperbaric services were under positive pressure, as opposed to the negative pressure required for soiled areas. It is noted that the Hyperbaric soiled utility room pressure was a finding on the recent accreditation survey.

EC.02.06.01

EP 1
- The floors of operating rooms were worn and damaged, and no longer provided an easily cleanable surface.
- The walls of some operating rooms had sections that appeared to be damaged from equipment impact.
- Ceiling tiles were noted to be stained or damaged in some areas of the building. Specific reference is made to Endoscopy, 5 North, 1 South and 2 South.
- The ultrasound bathroom emergency cord was too long and on the floor.
- The 2 Center medication room had broken cabinet doors.

LIFE SAFETY

LS.02.01.10

EP 1 Exposed structural steel was observed in the maternity construction area, as fire protection was removed during demolition and not replaced in a timely manner.

LS.02.01.20

EP 1 The C-Section room doors were equipped with dead-bolt type locking devices.

EP 14 Egress was obstructed in the maternity unit corridor and the maternity construction area.

EP 28 Suite doors in the Emergency Department were not affording a positive latch.

EP 40 The exit sign depicting the exit for the Pediatric Unit was obstructed by a duct that was recently installed.

LS.02.01.30

EP 3
- Doors to the Loading Dock and Materials Storeroom did not have labels affixed, so their fire ratings could not be determined.
- The door to the Hyperbaric storeroom was not self-closing.

NATIONAL PATIENT SAFETY GOALS

NPSG.15.01.01

EP 1 The door to the Behavioral Health dayroom/dining room was not self-closing as required for a patient occupied space with ligature risks. It is noted that the door is self-locking, as required to prevent unauthorized re-entry into the room without the presence of staff.

Section III:

Infection Prevention Report

Prepared By:

Donna Armellino RN,DNP,CIC,VP, Infection Prevention, Northwell Health

Northwell Health®

Joint Commission Infection, Prevention, and Control of Infection

Mock Survey Summary

A review of the surveillance, prevention, and control of infection program at Phelps Memorial Hospital Center located at 701 N Broadway, Sleepy Hollow, NY 10591 was conducted on August 3, 2021 Alexandra Xelas, Program Director Infection Prevention at Phelps Memorial Hospital Center accompanied Donna Armellino, Vice President Infection Prevention from Northwell Health to conduct a building tour and assess the organizations' program. Areas visited included the Sterile Processing Department, Patient Care Units (medical, surgical, critical care), Peri-Operative Services Room (OR), Radiology (interventional and ultrasound), Endoscopy, Aquatic Therapy pool and other areas within the facility. The methods of assessment included health care personnel (HCP) interviews, review of documents, plus observation of the physical environment and how HCP work within the environment. There was a focus on HCP compliance with outlined practice standards, cleaning, decontamination, and low/high-level disinfection of patient care items between patients, plus sterilization of instruments and devices.

There is an infection prevention and control program that is functioning to limit risks to reduce hospital-acquired infections (HAIs). The 2020 Surveillance, Prevention and Control of Infection Program Evaluation and 2021 Program Plan is a comprehensive review of the activities targeted at decreasing the risk for infection, as well successful initiatives. The HCP, both management and staff level on the units and within department were able to consistently answer questions related to infection prevention practices with minimal variations. Based on past reviews there appears to be consistent improvements and facility-wide engagement with the Infection Preventionist personnel.

The following are few findings that should be a priority:

- Finding: Temporary negative pressure rooms on 5 North, 5 South and intensive care unit (ICU) to allocate rooms to provide care to patients with Coronavirus Disease 2019 (COVID-19).
- Recommendation: Convert the temporary negative pressure rooms to a permanent solution, especially if there are plans to renovate units.
- Finding: Engineering/Facilities Department was not able to produce pressure monitoring data for an Airborne Infection Isolation Room (AIIR) with a patient on Airborne Precautions.
- Recommendation: Rooms with AIIR require daily monitoring and a report provided to the unit daily, when the pressure is not negative, action is taken.
- Finding: In Interventional Radiology Suite, "sterile" set up covered/draped in the corner of the procedure room with intravenous (IV) fluids spiked and hung. There was a "sterile" set up covered/draped stored within the mechanical room. The Labor and Delivery area also had a cesarean section set up opened and ready for use.
- Recommendation: The sterile field is subject to unrecognized contamination by personnel, vectors or breaks in sterile technique if left unobserved. Once created, a sterile field should not be left unattended until the operative or other invasive procedure is completed. Consider Interventional Radiology to have oversite by Perioperative Services that is familiar with the Association of Perioperative Registered Nurses (AORN) guidelines. The same applies to Labor and Delivery.
- Finding: The 5th floor solarium appeared to be mixed use: visitor waiting area, staff area and storage of damaged equipment/furniture.
- Recommendation: Consider using this area as a patient equipment storage room unless regulatory requirements require a waiting room. There was a waiting room near the ICU.
- Finding: Significant damage to walls, cabinetry, and shelving throughout the facility.
- Recommendation: Repair and ongoing maintenance of the facility.

- Finding: Intubation stylet following use was not sprayed with an enzymatic solution after use.
- Recommendation: Consider disposable stylet.

Based on the last Joint Commission Survey the following should also be a focus to minimize repeat findings:

- IC.02.02.01 EP2: 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.
    - It was observed in the sterile processing department that a bottle of test strips used for quality testing of source water used in the ultrasonic cleaner did not have the opening date documented in the space provided on the bottle label. The label stated the strips could be used for three months after opening.
    - It was observed in the OR storage area that two separate instruments that were sterilized in a double peel pack method were noted to have the inner peel pouch folded over.
- IC.02.02.01 EP4: During a tracer in the Emergency Department (ED), it was observed that a "clean" biohazard storage bin was stored in the soiled utility room. The unit technician verbalized that the storage bin would be taken to a patient room and used to transport the instruments from the patient room to the soiled utility room and then to the sterile processing department. The observation was witnessed by the unit nursing and medical leadership accompanying the surveyor.

Thank you for the opportunity to walk through the facility On August 3, 2021. If you have any questions or concerns, I can be reached at 516 472-3551 or 516 359-8613.

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Planning (A) Responsibilities (IC.01.01.01)				
Standard: IC.01.01.01. The hospital identifies the individual(s) responsible for the infection prevention and control program.				
Element of Performance:				
❑ **IC.01.01.01.01.** The hospital identifies the individual(s) with clinical authority over the infection prevention and control program.				
Element of Performance:				
❑ **IC.01.01.01.02.** When the individual(s) with clinical authority over the infection prevention and control program does not have expertise in infection prevention and control, he or she consults with someone who has such expertise to make knowledgeable decisions.				
Element of Performance:				
❑ **IC.01.01.01.03.** The hospital assigns responsibility for the daily management of infection prevention and control activities.				
Element of Performance:				
❑ **IC.01.01.01.04.** The individual with clinical authority over the infection prevention and control program is responsible for the following: o developing and implementing policies governing control of infections and communicable diseases o developing a system for identifying, reporting, investigating, and controlling infections and communicable diseases				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Planning (B) Resources (IC.01.02.01)				
Standard: IC.01.02.01. Hospital leaders allocate needed resources for the infection prevention and control program.				
Element of Performance:				
❑ **IC.01.02.01.01.** The hospital provides access to information needed to support the infection prevention and control program.		X		Surgical procedure data is being manually entered into the National Healthcare Safety Network (NHSN) and there is an option to electronically upload into the NHSN. Allocation of Information Technology to work with Corporate Infection Prevention can allow transition from paper to electronic transfer of data. Support is needed from Information Technology.
Element of Performance:				
❑ **IC.01.02.01.02.** The hospital provides laboratory resources when needed to support the infection prevention and control program.				
Element of Performance:				
❑ **IC.01.02.01.03.** The hospital provides equipment and supplies to support the infection prevention and control program.				
❑ **IC.01.03.01.01.** The hospital identifies risks for acquiring and transmitting infections based on the following: o Its geographic location, community, and population served o The care, treatment, and service it provides o The analysis of surveillance activities and other infection control data				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Planning (C) Risks (IC.01.03.01)				
Standard: IC.01.03.01. The hospital identifies risks for acquiring and transmitting infections.				
Element of Performance:				
❑ **IC.01.03.01.02.** The hospital reviews and identifies its risk at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership.				
Element of Performance:				
❑ **IC.01.03.01.03.** The hospital prioritizes risks for acquiring and transmitting infections. These priorities are documented.				
Element of Performance:				
❑ IC.01.04.01.01. The hospital's written infection prevention and control goals include the following: ○ Addressing its prioritized risks ○ Limiting unprotected exposure to pathogens ○ Limiting the transmission of infections associated with procedures ○ Limiting the transmission of infections associated with the use of medical equipment, devices, and supplies ○ Improving compliance with hand hygiene guidelines (See also NPSG.07.01.01, EP 1)	X			○ Within the Surgi-Center OR the scrub sinks had aerators in place which increase the risk of biofilm development and removal is also recommended to minimize legionella aerosols. ○ Within the ICU, touchless electronic faucets in place which are linked to promoting growth of legionella. The electric sensor on the devices do not allow for a steady stream of water. ○ Within the ED, the ice machine was leaking, causing significant damage to the cabinetry. ○ Throughout the facility, develop a process for cleaning of the ice funnel on the ice machines, it should be done monthly.

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Planning (E) Activities (IC.01.05.01)				
Standard: IC.01.05.01. The hospital has an infection prevention and control plan.				
Element of Performance:				
❑ **IC.01.05.01.01.** When developing infection prevention and control activities, the hospital uses evidence-based national guideline or expert consensus.				
Element of Performance:				
❑ **IC.01.05.01.02.** The plan includes a written description of the activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.				
Element of Performance:				
❑ **IC.01.05.01.05.** The hospital describes, in writing, the process for investigating outbreaks of infectious disease.				
Element of Performance:				
❑ **IC.01.05.01.06.** All hospital components and functions are integrated into infection prevention and control activities.				
Element of Performance:				
❑ **IC.01.06.01.02.** The hospital obtains current clinical and epidemiological information from its resources regarding new infections that could cause and influx of potentially infectious patients.				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Planning (F) Influx (IC.01.06.01)				
Standard: IC.01.06.01. The hospital prepares to respond to an influx of potentially infectious patients.				
Element of Performance:				
❑ **IC.01.06.01.03.** The hospital has a method for communicating critical information to licensed independent practitioners and staff about emerging infections that could cause an influx of potentially infectious patients.				
Element of Performance:				
❑ **IC.01.06.01.04.** The hospital describes, in writing, how it will respond to an influx of potentially infectious patients.				
Implementation (B) Medical Equipment, Devices, and Supplies (IC.02.02.01)				
Standard: IC.02.02.01. The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.				
Element of Performance:				
❑ **IC.02.02.01.01.** Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.	X		X	○ Low-level disinfection of the computer on wheels between patient use was not performed. RN was observed keyboarding with gloves on. Gloves removed, hand hygiene performed and then she continued documentation with keyboard. ○ Within the Surgi-Center OR, in-between case cleaning and disinfection of the invasive procedure room, staff were observed performing low-level disinfection of equipment from low to high with the same EPA-approved disinfecting wipe. In addition, there was no observation of the wet time. ○ In the Surgi-Center OR procedure room, a vinyl OR table mattress was torn. ○ In the Surgi-Center OR, a gel positioning pillow was stored within a Clean Supply Room and the outer protective layer was torn. ○ Tape on multiple surfaces and equipment within all patient care areas. ○ On 5 South, glue residue was found on the door latch to the medication room. ○ Within the 5 South unit, medication cart with significant tape. ○ On 5 North, patient care equipment (sequential stocking) positioned on the floor in a patient room.

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Implementation (B) Medical Equipment, Devices, and Supplies (IC.02.02.01)				
Standard: IC.02.02.01. The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.				
Element of Performance:				
❑ **IC.02.02.01.01.** Cleaning and performing low-level disinfection of medical equipment, devices, and supplies. *Continued*	X			○ On Ambulatory Surgery Unit (ASU) and Post Anesthesia Care Unit (PACU) there were cloth chairs in patient care area. ○ Transport stretcher located in the 5th floor lobby appeared to have dust in the lower area.
Element of Performance:				
❑ **IC.02.02.01.02.** Performing intermediate and high-level disinfection and sterilization of medical equipment, device, and supplies.	X		X	○ In the Surgi-Center OR, Intubation stylet following use was not sprayed with an enzymatic solution after use. ○ In the Surgi-Center OR, there were surgical instruments with inconsistent use of enzymatic spray after use. ○ Within the Labor and Delivery, a vaginal delivery tray was set up in the hallway immediately adjacent to an open garbage can. Staff were interviewed, the tray was set up for a period of 24 hours. ○ Within the Labor and Delivery, a case cart was positioned in the hallway, no flip sign indicating clean or biohazardous. ○ The Vascular Access Team Sonosite ultrasound probe was cracked. High-level disinfection of the ultrasound probes is required. ○ Within the Endoscopy Suite, the Medivators were not capable of creating a printable report to support all high-level parameters were met. ○ Within the Endoscopy Suite, open Rapicide container was dated with open and expiration date. However, the 21-day expiration count was incorrect.
Element of Performance:				
❑ **IC.02.02.01.03.** Disposing of medical equipment, devices, and supplies.				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Implementation (B) Medical Equipment, Devices, and Supplies (IC.02.02.01)				
Standard: IC.02.02.01. The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.				
Element of Performance:				
❑ **IC.02.02.01.04.** Storing medical equipment, devices, and supplies.	X		X	○ Within the ED, storage of sterilized instruments was within the various areas of the department. ○ Within the Labor and Delivery unit, there was storage of linen on open shelving without a cover. ○ Within the Surgi-Center OR Core, storage of sterile supplies on racks positioned against an exterior wall. ○ Within the ICU, supplies were stored within the drawers with cardboard dividers. ○ Within many patient care units, patient care supplies were stored within the nursing station. ○ Within 5 South unit, Personal Protective Equipment (PPE) supplies found in a plastic bag stored on the floor of the nursing station. ○ Within the 5 South medication room, storage shelving with IV fluids with significant dust and debris. ○ Within 5 South unit, medication cart unsecured with open IV fluid bag with outer wrapper removed. ○ Within the ICU an abundance of supplies stored within the patient rooms.
Element of Performance:				
❑ **IC.02.02.01.05.** When reprocessing single-use devices, the hospital implements infection prevention and control activities that are consistent with regulatory and professional standards.				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Implementation (C) Transmission of Infections (IC.02.03.01)				
Standard. **IC.02.03.01.** The hospital works to prevent the transmission of infectious disease among patients, licensed independent practitioners, and staff.				
Element of Performance:				
❑ **IC.02.03.01.01.** The hospital makes screening for exposure and/or immunity to infectious disease available to licensed independent practitioners and staff who may come in contact with infections at the workplace.				
Element of Performance:				
❑ **IC.02.03.01.02.** When licensed independent practitioners or staff have, or are suspected of having, an infectious disease that puts others at risk, the hospital provides them with or refers them for assessment and potential testing,				
Element of Performance:				
❑ **IC.02.03.01.04.** When patients have been exposed to an infectious disease, the hospital provides them with or refers them for assessment and potential testing prophylaxis/treatment, or counseling.				
Element of Performance:				
❑ **IC.02.04.01.01.** The hospital establishes an annual influenza vaccination program that is offered to licensed independent practitioners and staff.				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Implementation (D) Influenza Vaccinations (IC.02.04.01)				
Standard. IC.02.04.01. The hospital offers vaccination against influenza to licensed independent practitioners and staff.				
Element of Performance:				
❑ **IC.02.04.01.02.** The hospital educates, at a minimum, the influenza vaccine; non-vaccine control and prevention measures; and the diagnosis, transmission, and impact of influenza.				
Element of Performance:				
❑ **IC.02.04.01.03.** The hospital provides influenza vaccination at sites accessible to licensed independent practitioners and staff.				
Element of Performance:				
❑ **IC.02.04.01.04.** The hospital includes in its infection control plan the goal of improving influenza vaccination rates.				
Element of Performance:				
❑ **IC.02.04.01.05.** The hospital sets incremental influenza vaccination goals, consistent with achieving the 90% rate established in the national influenza initiatives of 2020.				
Element of Performance:				
❑ **IC.02.04.01.06.** The hospital has a written description of the methodology used to determine influenza vaccination rates.				

Standards and Elements of Performance	Requirement for Improvement (RFI)	Consultative	Previous Finding (PF)	Comments/Notes
Implementation (D) Influenza Vaccinations (IC.02.04.01)				
Standard. IC.02.04.01. The hospital offers vaccination against influenza to licensed independent practitioners and staff.				
Element of Performance:				
❑ **IC.02.04.01.07.** The hospital evaluates the reasons given by the staff and licensed independent practitioners for declining the influenza vaccination. This occurs at least annually.				
Element of Performance:				
❑ **IC.02.04.01.08.** The hospital improves the vaccination rates according to its established goals at least annually.				
Element of Performance:				
❑ **IC.02.04.01.09.** The hospital provides influenza vaccination rate data to key stakeholder which may include leaders, licensed independent practitioners, nursing staff, and other staff at least annually.				
National Patient Safety Goal #7: Reduce the Risk of Health Care-Associated Infections.				
❑ **NPSG.07.01.01.** Meeting hand hygiene guidelines	X			○ Hand hygiene sinks located within all unit based Soiled Utility Rooms were blocked by Environmental Services garbage receptacles. ○ Within Endoscopy suite scope processing area, hand hygiene sinks had no hot water.
❑ **NPSG.07.03.01.** Preventing multidrug-resistant organism infections				
❑ **NPSG.07.04.01.** Preventing central-line associated bloodstream infections				
❑ **NPSG.07.05.01.** Preventing surgical site infections				
❑ **NPSG.07.06.01.** Preventing indwelling catheter-associated urinary tract infections				

Section IV :

Emergency Management Report

Prepared By:

Glenn Schaefering, Director, Corporate Emergency Management, Northwell Health

Northwell Health®

Phelps Memorial Hospital

Emergency Management JC Mock Survey

Summary

July 28, 2021

Documents Reviewed/Discussed:

- Emergency Operations Plan
- Hazard Vulnerability Assessment - 2020
- Emergency Preparedness Meeting Agendas, Minutes and Sign-In Sheets
- Communications Plan
- Emergency Credentialing and Privileging
- 96-hours Sustainability
- Exercises and After Action Reports
- Policies and Procedures required by CMS

Summary:

- Phelps Memorial Hospital has a well-established Emergency Management program, with participation from key staff members and some active physician involvement.

- The facility has a comprehensive Emergency Operations Plan which is based upon its annual Hazard Vulnerability Assessment (HVA). The plan is reviewed annually and is forwarded to the Medical Board for their review and approval.

- The facility involves their local community partners to discuss their HVA, including the police department, local fire departments, various utilities, and their local chamber of commerce.

- The facility maintains an extensive inventory of the assets it may need during an event. That inventory is updated regularly by various entities within the hospital and is scheduled to be reviewed on an annual basis.

Specific Areas Identified for Improvement:

- There is a lack of participation from physicians in the Emergency Management Committee and for development of their Emergency Operations Plan.

- The facility only had only a few Emergency Preparedness meetings in 2020/2021 due to the COVID-19 pandemic. Recommend that the quarterly schedule be followed and for dates to be scheduled in advance.

- The Hazard Vulnerability Assessment was last completed in January 2020 and needed to be updated. A meeting to discuss the new HVA was completed on August 2, 2021 with the goal of updating the HVA.

- While the facility maintains an inventory and list of resources available during a disaster, that inventory and resource list needs to be updated, as it has been over one year since last updated.

- Parts of the Emergency Operations Plan will need to be updated to identify how the hospital will manage a potential increase in demand for clinical services for vulnerable populations served by the hospital. Their water plan is also in the process of being updated, as is their hospital surge plan.

- The Emergency Operations Plan references several System Policies, but facility-specific plans will need to be incorporated and expanded upon to better explain and identify how certain plans will actually be implemented at the hospital.

Section V:

Sterile Compounding Report

Prepared By:

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Northwell Health℠

Phelps Hospital – TJC Mock Survey

August 3rd, 2021

Sterile Compounding Assessment

- **Overall, all paperwork is very thorough and well organized. All requirements met or exceeded based on TJC/USP Checklist. Clean room suite is clean and neat. No major concerns or risks for upcoming TJC survey.**

- **Reviewed binder of TSS reports**
  - Viable sampling:
    - All results for last 3 years readily available
    - Recommended including a corrective action plan to document steps taken in the event of an out of compliance results
    - Sample CAP document sent to Brian for future use
    - Additional triple cleans done for remediation of results were documented, and the dates corresponded accurately to the EVS cleaning logs (spot checked)
  - Room and Hood certifications:
    - Reviewed last year of recertifications – all WNL and passed
    - No hoods have been moved or serviced requiring additional recertification
    - All hoods in the facility are currently in use (i.e. there are no hoods that are in storage that need to be properly decommissioned)

- **Reviewed employee competency binder**
  - Included all competencies (completed every 6 months)
  - Included all fingertip and media fill tests, and didactic tests with passing scores
  - Last 3 years kept in the Pharmacy

- **Compounding/ storage area observations**
  - Recommend general cleaning of space outside of the ante room (floors, paperwork, remove sticker residue from bins, etc)
  - Label all bins that contain medications – even if it's temporary storage
  - Rusty cart – recommend replacing
  - Most older items in the area that need to be replaced will be discarded during upcoming main Pharmacy area renovation
  - Recommend checking dates on any guidelines/documents that are hanging on the bulletin board

- **Clean room suite observations**
    - Observed cleaning and compounding activities of Pharmacist – excellent technique
    - Recommend adding a mirror and a clock above the sink in the anteroom space to check for appropriate garb and timing of hand washing
    - Recommend reviewing the paperwork that is hanging in the buffer room – is it all currently needed? If so, laminate before hanging to make easily cleanable
    - Inventory/storage levels are currently acceptable – no excess – but recommend reviewing every 3-6 months to see if all items are still needed

- **USP 797 → USP 800**
    - Survey completed against current 2008 version of USP 797 but also considered the revision and compliance with USP 800 as well
    - Site is mostly compliant with both versions with a few exceptions for the 2019 revision:
        - System P&T hazardous policy with acknowledgement of risk form – WIP
        - Completion of hazardous drug list and all assessments of risk – WIP
        - Signage prior to entering all Pharmacy areas where hazardous drugs are stored/handled/manipulated – WIP
    - If the 2019 version of USP 797 was finalized and Phelps had to be surveyed against the revision, I feel confident that they would be more than prepared.

Surveyor Guidance Checklist for On Site Activity: Sterile Medication Compounding Assessment

Hospital Accreditation Program (HAP)

NOTE: IF AN ORGANIZATION ADOPTS THE REVISED 797 CHAPTER, THEY MUST ADOPT USP 800

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Certification/ Testing Report Evaluation (Non-Hazardous and Hazardous Sterile Compounding)						
Primary Engineering Control ISO Level	• Must be ISO 5 or Less	**For non-hazardous/hazardous:** • Must be ISO 5 or less **For hazardous (USP 800):** • Must be externally vented • C-PEC must operate continuously if used for sterile compounding • If placed near a PEC for non-sterile compounding, must be at least 1 meter apart	MM.05.01.07 EP 4	482.23(c)	X	Meets revision
Primary Engineering Control Viable Particle Testing *Surface*	• Value must be at or less than 3 CFU/plate or swab • Must be completed at least every 6 months	**For non-hazardous/hazardous:** • Completed monthly after compounding activity and before cleaning • Value must be at or less than 3 CFU/plate or swab	IC.02.01.01 EP 1	482.42	X	Meets revision - Testing completed monthly
Primary Engineering Control Viable Particle Testing *Air*	• Value must be at or less than 1 CFU/plate or swab • Must be completed at least every 6 months	**For non-hazardous/hazardous:** • Completed every 6 months • Value must be at or less than 1 CFU/cubic meter	IC.02.01.01 EP 1	482.42	X	Meets revision - Testing completed monthly
Primary Engineering Control HEPA filter leak test	• Must show passed or evidence that holes were patched	**For non-hazardous/hazardous:** • Must show passed or evidenced that leaks were repaired • Leak testing should occur after installation and every 6 months with re-certification	IC.02.01.01 EP 1	482.42	X	Meets revision - Testing occurs every 6 months with re-certification

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Primary Engineering Control Smoke Air Pattern Testing		**For non-hazardous/hazardous:** • Must be conducted initially and every 6 months • Must be tested under dynamic conditions	IC.02.01.01 EP 1	482.42	X	Completed with certifications

Secondary Engineering Control
Air Exchanges Per Hour (ACPH)
	• Must have 30/hour
	• Compounding hood can contribute up to 15 to complete the 30
		For non-hazardous/hazardous:
		• ISO 7: 30 ACPH (tested under dynamic operating conditions)
		  ○ Vendor to report ACPH from room and PEC separately and total
		  ○ No more than 15 ACPH may come from PEC (If PEC used for ACPH, cannot turn PEC off)
		• ISO 8: 20 ACPH (tested under dynamic operating conditions)
			EC.02.05.01 EP 15	482.42	X	Documented on TSS reports

Secondary Engineering Control
Air Pressure Differential
	• Buffer area=
	  ○ Non-Hazardous = (+)0.02-0.05" H_20 to unclassified space
	  ○ Hazardous = (-)0.01" H_2O
	• Ante area = positive to pharmacy area
		For non-hazardous:
		• Buffer area to ante area: > (+)0.02" water column
		• Ante area to non-classified space: >/= (+)0.02" water column
		• Must be continuously monitored and documented on days compounding occurs
			EC.02.05.01 EP 15	482.42	X	Pressures monitored continuously, alarm sounds in Pharmacy if out of range Discussed being able to speak to the escalation and threshold for alert to engineering as

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
(Secondary Engineering Control Air Pressure Differential – continued.)		○ Monitoring device must be calibrated based on IFU (EC.02.05.05 EP 6) **For hazardous medication USP 800:** • (-)0.01 to (-)0.03 inches of water column relative to adjacent areas for both buffer and ante areas • Must be continuously monitored and documented on days compounding occurs				well – what happens next? Discussed engineering should be able to speak to calibration of monitoring devices
Secondary Engineering Control ISO level	• Buffer area must be ISO 7 or less • Ante area must be ISO 8 or less	• Buffer area must be ISO 7 or less • Ante area must be ISO 8 or less (ISO 7 for hazardous)	EC.02.06.01 EP 1	482.41(a)	X	Documented on TSS Reports
Secondary Engineering Control Viable Particle Testing *Surface*	• Buffer area: at or less than 5 CFU/cubic meter • Ante area: at or less than 100 CFU/cubic meter • Must be completed at least every 6 months	**For non-hazardous/hazardous:** • Completed monthly after compounding activity and before cleaning • Buffer area value must be at or less than 5 CFU/plate or swab • Ante area value must be at or less than 50 CFU/plate or swab	IC.02.01.01 EP 1	482.42	X	Surface testing monthly
Secondary Engineering Control Viable Particle Testing *Air*	• Buffer area at or less than 10 CFU/cubic meter • Ante area at or less than 100 CFU/cubic meter	**For non-hazardous/hazardous:** • Completed at least every 6 months • Buffer area value must be at or less than 10 CFU/cubic meter	IC.02.01.01 EP 1	482.42	X	Surface testing monthly

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
	• Must be completed at least every 6 months	• Ante area value must be at or less than 100 CFU/cubic meter				
Secondary Engineering Control HEPA filter	• Must show passed or evidence that holes were patched	**For non-hazardous/hazardous:** • Must show passed or evidence that leaks were patched • Leak testing should occur after installation and every 6 months with recertification	IC.02.01.01 EP 1	482.42	X	HEPA filter testing on TSS reports – every 6 months with recertification
Evidence of action taken by organization when any item is out of range	• There must be evidence of remediation actions taken when items do not pass and subsequent testing to ensure compliance. If this is not present, then must be scored.	**For non-hazardous/hazardous:** • If levels exceed action levels, the cause must be investigated, and corrective action taken based on organization policy. Action must be documented. ○ Highly pathogenic organisms MAY NOT require remediation, it is based on policy	LD.01.02.01 EP 4	482.42 (b)(2)	X	Remediation actions are documented (triple clean dates with initials/ signature with follow-up testing) Discussed completing a corrective action plan document in addition to current process
Primary Engineering Control Certification/ Testing Frequency	• Each component listed above must be tested and certified every 6 months. • Also, any time PEC is moved or relocated	**For non-hazardous/hazardous:** Certification must be done: • Initially and recertification at least every 6 months **or** • If changes to area such as redesign, construction, replacement or relocation of any PEC **or** • Alterations in configuration of room that could affect airflow or air quality	EC.02.04.01 EP 4	483.41 (d)(2)	X	Certification is done every 6 months or if there are any changes to the area – TSS reports for certifications reviewed

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Secondary Engineering Control Certification/ Testing Frequency	• Each component listed above must be tested and certified every 6 months. Lack of 6-month interval must be scored.	**For non-hazardous/hazardous:** Certification must be done: • Initially and recertification at least every 6 months **or** • If changes to area such as redesign, construction, replacement or relocation of any PEC **or** • Alterations in configuration of room that could affect airflow or air quality	EC.02.06.01 EP 1	482.41(a)	X	TSS reports reviewed
Cleanroom Temperature and Humidity		**For non-hazardous/hazardous:** • Monitored daily in each compounding room and documented • Monitoring devices validated every 12 months or based on IFU • No required temperature or humidity level, only recommended	Not monitoring: EC.02.05.01 EP 15 No calibration: EC.02.05.05 EP 6	482.42 482.41 (d)(2)	X	Continuously monitored – see comments above
Segregated Compounding Area (SCA)		**For non-hazardous:** • No ACPH requirement • No requirements for walls, ceilings, or floors • Sink located at least 1-meter from PEC • Only Category 1 CSPs • Located away from unsealed windows, doors connecting outdoors, and traffic flow	EC.02.06.01 EP 1	482.41(a)	N/A	No segregated compounding areas – only cleanroom suite

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		• Visible perimeter must establish boundaries				
Compounding Evaluation						
Room Structure (Hazardous and Non-Hazardous Sterile Compounding in Classified Locations)						
Floors	• Must be solid and coved on corners • No rips/tears; check corners for dust	• Doors: no seals, no sweeps, no tacky mats in ISO classified areas (no prohibition of tacky mat in unclassified space) • No rips/tears; check corners for dust • Juncture between floor and wall must be sealed • Must include coving to sidewall	EC.02.06.01 EP 1	482.41(a)	X	Meets revision
Ceiling	• Must be solid material or with sealed drop in ceiling tiles (tiles must be caulked into place) • Sprinkler heads should be inset with pop outs, if not check for dust	• If ceiling consists of inlaid panels, panels must be caulked to framing • If overhangs/ledges present, they must be easily cleanable • Made of cleanable material to withstand cleaning	EC.02.06.01 EP 1	482.41(a)	X	Meets revision
Walls	• Must be smooth with no cracks • Where flooring meets walls must not have a ledge	• Must be smooth with no cracks • Joined panels must be sealed • Made of cleanable material to withstand cleaning	EC.02.06.01 EP 1	482.41(a)	X	Meets revision
Primary Engineering Control Placement	• Must be placed in an area with ISO 7 or less (if not then can	• Placement must allow for cleaning around PEC	MM.05.01.07 EP 2	482.23(c)	X	Meets revision

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
(Primary Engineering Control Placement – continued.)	only use a 12-hour BUD)	• For Category 1 Products: may be placed in unclassified SCA (restricted BUD) • For Category 2 Products: ISO 7 buffer with ISO 8 positive pressure ante-room				
Additional Structural Requirements		• Ante room must have fixed walls and doors • Buffer room must have fixed walls and doors • Air supply in ceiling with HEPA filter at ceiling level • Line of demarcation in ante area defines clean vs dirty side	EC.02.06.01 EP 1	482.41(a)	X	Meets revision
Staff Handwashing/ PPE Garbing (Hazardous and Non-Hazardous Sterile Compounding)						
Hand Hygiene	• Handwashing must occur to elbows minimum 30 seconds • Staff wear no make-up, jewelry, or outer garments (sweaters, hoodies, etc.)	• Remove visible debris under nails with nail cleaner • Handwashing up to elbows with soap and water 30 seconds- no brushes • Air hand dryers are prohibited • Dry hands and arms with low-lint disposable towel	IC.02.01.01 EP 2	482.42	X	Meets revision – recommended adding a mirror and a clock at the ante room sink for timing and to check for appropriate garb
Restricted Items		• Must wipe eyeglasses, if worn • Restricted items: personal outer garments, cosmetics, nail products, headphones ○ Designated person may grant waiver if	IC.02.02.01 EP 1	482.42	X	Meets revision

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
(Restricted items, continued.)		quality of air is not affected • Remove or cover all jewelry that could interfere with garbing/risk contamination				
Order of PPE donning	• Observe order of donning of PPE which must be from dirtiest to cleanest	• Refer to SOP of organization for order of donning PPE • Sterile gloves must be donned classified room or SCA • Non-HD gowns may be re-used within same shift if maintained in classified area or SCA- all other PPE must be discarded	IC.02.01.01 EP 1	482.42	X	Meets revision
RAB (CAI/CACI) gloves		• Sterile gloves must be worn OVER gloves attached to RAB sleeves	IC.02.01.01 EP 1	482.42	N/A	No RABs
Use of non-sterile products in preparing sterile compounded preparations	• Call central office for guidance. Prior to calling find out how they quality assure the sterilization process of the final product.	• Call central office for guidance. Prior to calling find out how they quality assure the sterilization process of the final product.			N/A	
Sterile Compounding Observation (Hazardous and Non-Hazardous Compounding)						
Item Placement	• Items are wiped down with sterile alcohol as they enter the compounding hood • Items must be placed 6 inches from all sides of the hood	• Items are wiped down with sterile 70% IPA (low lint wipes) as they enter the compounding hood • Items should be placed within the primary engineering control away from edges as described in the IFU of the PEC	MM.05.01.07 EP 2	482.23(c)	X	Meets revision

Surveyor Guidance Checklist for On Site Activity: Sterile Medication Compounding Assessment

Hospital Accreditation Program (HAP)

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Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments

Protecting Critical Sites	• The following sites can never be touched:
	  ○ Any part of the needles, septum of the vial, the sides of the plunger of syringe
	• Placement of hands must never block first air to critical point
		• Critical sites must be wiped with sterile 70% IPA prior to puncture
		• Placement of hands must never block first air to the critical sites
		• The following sites must never be touched:
		  ○ Any part of the needle, septum of the vial, the sides of the plunger of syringe
			MM.05.01.07 EP 2	482.23(c)	X	Meets revision

Single Dose Vial Use	• Single dose vials can be used for up to 6 hours if they are kept within the ISO 5 environment. If they are removed from the environment then they may be used for 1 hour from initial puncture	• May be used up to 12 hours if entered or punctured in ISO 5 • Does not have to be stored in ISO 5 environment • Vial/container must be wiped down with sterile 70% IPA upon reentry into the PEC	If wrong BUD: MM.03.01.01 EP 2 If not labeled: MM.03.01.01 EP 7 If not wiped down: IC.02.01.01 EP 1	N/a N/A 482.42	X	Multi use vials are not stored in the ISO 5 space Vials stored in the refrigerator are dated with appropriate BUDs
Large Volume Bags	• 1-liter bags of sterile water for injection are usable for up to 6 hours if kept in the hood • 2-liter bags and larger follow manufacturer IFU	• 1-liter bags of sterile water for injection are usable for up to 12 hours if punctured in the PEC unless shorter by package insert • 2-liter bags and larger follow manufacturer IFU	If not labeled: MM.03.01.01 EP 7 If used beyond MIFU: mm.03.01.07 EP 2	N/A N/A	X	Meets revision

Surveyor Guidance Checklist for On Site Activity: Sterile Medication Compounding Assessment

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Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Limited storage in classified area	• Only furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area	• Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area • No shipping carton or other corrugated or uncoated cardboard in **classified spaces**	MM.05.01.07 EP 2	482.23(c)	X	Current inventory is ok – discussed re-evaluation every 3-6 months to see if it is possible to decrease materials needed in the room Recommend reviewing paperwork in the buffer room to see if all is still needed – if it is recommend laminating
Compounder Glove Cleaning	• Should be conducted any time hands leave ISO 5 • Use sterile alcohol	• Should be conducted any time hands leave ISO 5 • Use sterile 70% IPA	MM.05.01.07 EP 2	482.23(c)	X	Observed – meets revision
CAI/CACI Glove Exchange	This should occur based on manufacturer IFU	Based on manufacturer IFU as defined in SOP	EC.02.04.01 EP 4	483.41 (d)(2)	N/A	No isolators used
Product Labeling	• If BUD is based on refrigeration, then must have a store in refrigerator (or similar sticker) label	Label must contain: • Assigned internal identification number (e.g., barcode, prescription, or lot number) • Active ingredient(s) and their amounts, activities, or concentrations • Storage conditions other than controlled room temperature • BUD	MM.05.01.09 EP 2 MM.05.01.09 EP 3 MM.05.01.09 EP 7 MM.05.01.09 EP 3	N/A	X	All products labeled appropriately with BUD For IV products returned to Pharmacy, do not cover patient labels with a blank label – you can still see through to the patient information

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Immediate Use CSP		• Does not require ISO 5 PEC • Involves no more than 3 different sterile products • Unused component from single-dose container must be discarded • Administer within 4 hours of prep	MM.05.01.07 EP 5	482.23(c)	X	Did not observe an immediate use CSP but advised on the importance especially of preparers signature and BUD
PEC/SEC Cleaning/Disinfecting/Sporicidal Application						
Cleaning Frequency for **PEC**	• At the beginning of each work shift • Before each batch preparation is started • Every 30 minutes during continuous compounding periods of individual CSPs • When there are spills • When surface contamination is known or suspected from procedural breaches	**For Non-Hazardous:** **Cleaning/Disinfecting:** • Daily and when contamination is suspected ○ Sterile 70% IPA must be used after cleaning to disinfect the surface • Apply sterile 70% IPA to horizontal surface every 30 minutes **Sporicidal:** • Monthly **For Hazardous:** **Decontamination:** • Daily, between different HD agents compounded, after a spill, before and after certification **Cleaning/Disinfection:** • After decontamination • Daily and when contamination is suspected	MM.05.01.07 EP 2	482.23(c)	X	Meets revision – cleaning is done daily and between compounding – discussed Pharmacists should be able to speak to every 30 minute cleaning of horizontal surfaces Reviewed cleaning logs – sporicidal 'triple clean' is done in both cleanrooms twice monthly

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		○ Sterile 70% IPA must be used after cleaning to disinfect the surface • Apply sterile 70% IPA to horizontal surfaces every 30 minutes **Sporicidal:** • Monthly				
Cleaning Frequency for **SEC**	• Daily – floors and easily cleanable work surfaces • Monthly – walls, ceiling, storage shelves	**For non-hazardous/hazardous:** **Cleaning/ Disinfecting:** • **Daily**: pass-through, work surfaces, floors • **Monthly**: walls, doors, ceilings, storage shelves and bins, equipment outside PEC **Sporicidal Agent Application**: • **Monthly**: to all areas listed in Daily and Monthly • Evaluate process for ensuring appropriate dwell times for products based on use - Clean vs Disinfect vs Sporicidal	IC.02.01.01 EP 1	482.42	X	Cleaning logs reviewed – daily cleaning is done by both EVS and pharmacy staff, triple clean is done twice a month All staff (pharmacy and EVS) are trained by CONTEC on appropriate dwell times and use of all cleaning products Technicians clean inside storage bins monthly - documented
Cleaning products	• Organization selects agent – ensure proper dilution	• Organization selects agents – ensure proper dilution and dwell times • Sterile 70% IPA is not a cleaning agent	IC.02.01.01 EP 1	482.42	X	Meets revision – system P&T policy

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		• Cleaning agent must be EPA registered disinfectant or an equivalent				
Cleaning Order **PEC**	• Based on direction of airflow of hood • Always cleanest to dirtiest	• Direction of cleaning should be cleanest to less clean areas • Direction of cleaning depends on airflow of hood	MM.05.01.07 EP 2	482.23(c)	X	Observed hood cleaning by Pharmacist
Cleaning Order **SEC**	• Always cleanest to dirtiest	• Direction of cleaning should be cleanest to less clean areas	IC.02.01.01 EP 1	482.42	X	
Sink cleaning		• Cleaned and disinfected at least daily on days compounding occurs • Sporicidal agent applied at least monthly	IC.02.01.01 EP 1	482.42	X	Sink cleaned daily by EVS – eye wash station checked weekly by engineering and documented
Hazardous Compounding Additions (ONLY APPLIES if using USP 797 2008)						
PEC type utilized	• Must utilize either a biological safety cabinet or a CACI	N/A	MM.01.01.03 EP 2	N/A	X	BSCs used
PPE utilization	• Must wear 2 pairs of chemotherapy gloves (sterile)	N/A	MM.01.01.03 EP 2	N/A	X	
SEC Design – physical location	• Must have limited access to only those who need to access area	N/A	EC.02.02.01 EP 5	482.41(a)	X	Badge access to all Pharmacy areas, fixed walls and doors to ante room
Beyond Use Dating (unless sterility testing has been done to extend the dating listed below)						
Immediate Use	• 1 hour from start of compounding	• 4 hours from start of compounding	MM.05.01.07 EP 5	482.23(c)	X	

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
BUD: Low Risk Compounding / Category 1	**Low Risk Compounding**: • Room temperature: 48 hours • Refrigerator: 14 days • Freezer: 45 days	**Category 1 CSP:** Room Temperature: 12 hours Refrigerator: 24 days Freezer: N/A	MM.05.01.07 EP 5	482.23(c)	X	No SCA
BUD: Medium Risk Compounding / Category 2	**Medium Risk Compounding:** • Room Temperature: 30 hours • Refrigerator: 9 days • Freezer: 45 days	**Category 2 – Aseptically processed CSP:** **Without Sterility Testing:** • Room temperature: 4 days • Refrigerator: 10 days • Freezer: 45 days **With Sterility Testing:** • Room temperature: 30 days • Refrigerator: 45 days • Freezer: 60 days	MM.05.01.07 EP 5	482.23(c)	X	Following revision (without sterility testing)
Category 2: **Terminally sterilized after compounding**		**Without sterility testing:** • Room temperature: 14 days • Refrigerator: 28 days • Freezer: 45 days **With Sterility Testing:** • Room Temperature: 45 days • Refrigerator: 60 days • Freezer: 90 days	MM.05.01.07 EP 5	482.23(c)	N/A	No terminal sterilization done
Leadership Policy Requirements						
Required policies	N/A	• All compounding policies and procedures must be reviewed every 12 months	LD.04.01.07 EP 1	482.25	X	Only utilize system P&T policies for compounding

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments

(required policies – continued.)		• Garbing of PPE to include the order
		• Viable particle sampling for air and surface to include locations and time of day to conduct sampling
		• Cleaning and disinfecting processes for engineering controls
		  ○ Frequency of cleaning
		  ○ Method of cleaning
		  ○ Requirement to document application of cleaning, disinfecting, and sporicidal agents
		• Calibration, maintenance, cleaning, and use of equipment based on the manufacturer's recommendations
		• Master formulation records development and maintenance				

Compounding Staff Competency Evaluation						
Defining required competencies	**Minimum required competencies (for compounding pharmacy staff members):** • Didactic testing (organization must define "pass" score)	**Minimum required competencies (for compounding pharmacy staff members):** • **Every 12 months**: Didactic testing (organization must define "pass" score – see below for required content) • **Every 6 months:**	HR.01.06.01 EP 1	N/A	X	Didactic testing completed every 6 months along with all competencies Competencies assessments are done with trainings

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
	• Visual observation of hand washing, donning PPE • Media fill test • Gloved fingertip testing (x3 for initial)	○ Visual observation of hand washing, donning PPE ○ Media fill test ○ Gloved fingertip testing (x3 for initial) • Score here if not defined as required competencies				and all documentation is stored both hard copy and in simplifi
Media-fill test	• The test complexity must match the complexity level of compounding • Low/Medium Risk versus High Risk	• Should represent most complex compounding processes performed	Initial: HR.01.06.01 EP 5 Ongoing: HR.01.06.01 EP 6	N/A N/A	X	Meets revision
Gloved Fingertip Testing ***Initial*** Gloved Fingertip Testing ***Ongoing***	**Initial test:** • 3 separate tests required • To pass test cannot exceed "0" CFU **Ongoing test**: • Requires one sample only • To pass test cannot exceed 3 CFU	**Initial test:** • Performed 3 separate times after completing hand hygiene • To pass test cannot exceed "0" CFU **Ongoing test:** • Every 6 months within the PEC after completing the media fill test • < 3 CFU to pass **Documentation requirements:** • Name of the person evaluated • Evaluation date/time • Media and components used to include manufacturer • Expiration date and lot number	Initial: HR.01.06.01 EP 5 Ongoing: HR.01.06.01 EP 6	N/A N/A	X	Meets revision – completed every 6 months, all documentation of test complete

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		• Starting temperature for each interval of incubation • Dates of incubation • Results after incubation • Identification of the observer and the person who reads and documents the results				
Observation Competency	**Includes following items:** • Garbing of PPE • Aseptic technique	**Initially and every 6 months:** • Hand hygiene • Garbing PPE • Aseptic technique	Initial: HR.01.06.01 EP 5 Ongoing: HR.01.06.01 EP 6	N/A N/A	X	Meets revision
Didactic Written Testing	• Hazardous compounding must be incorporated if applicable to compounder reviewed	**Compounding staff didactic test with passing score to include the following items:** • Hand hygiene • Garbing • Cleaning and disinfection • Calculations, measuring, and mixing • Aseptic technique • Achieving and/or maintaining sterility and apyrogenicity • Use of equipment • Documentation of the compounding process (e.g. master formulation and compounding records) • Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area	Initial: HR.01.06.01 EP 5 Ongoing HR.01.06.01 EP 6	N/A N/A	X	Meets revision

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		• Proper use of primary engineering controls (PECs) • Principles of movement of materials and personnel within the compounding area				
Additional hazardous medication training required	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	• Initially, every 12 months, or introduction of new HD/equipment • Training must include (must be evaluated): ○ Overview of entity's list of HDs and their risks ○ Proper disposal of HDs and trace-contaminated materials ○ Review of the entity's SOPs related to handling of HDs ○ Proper use of PPE ○ Proper use of equipment and devices (e.g., engineering controls) ○ Response to known or suspected HD exposure ○ Spill management ○ Proper disposal of HDs and trace-contaminated materials	For lack of defining: HR.01.06.01 EP 1 Initial: HR.01.06.01 EP 5 Ongoing: HR.01.06.01 EP 6	N/A N/A N/A	N/A	Almost meets revision – staff are trained on appropriate handlings of hazardous drugs, HD list does not have all completed assessments of risk
Hazardous Specific Compounding Additional Items USP 800						

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
Annual evaluation of hazardous medication	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	Organization must identify all hazardous medications every 12 months and when added to formulary	MM.01.01.03 EP 1	N/A	N/A	WIP
Assessment of Risk	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	• May risk assess out for all NIOSH Table 2 and 3 medications and Table 1 medications that do not require further manipulation (e.g. tablets) • Risk assessment must be completed every 12 months • Assessment of risk must minimally contain: o Type of hazardous medication o Dosage form o Risk of exposure o Packaging o Manipulation of product	MM.01.01.03 EP 2	N/A	N/A	WIP
HD Receipt	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	Unpacked in a neutral or negative pressure area (only applies to medications where USP 800 is applicable)	MM.01.01.03 EP 2	N/A	X	Meets revision – designated space for unpacking HDs
HD Storage	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	Antineoplastic items used for compounding should be stored with the following requirements: • Separate from other agents • Externally vented area	MM.01.01.03 EP 2	N/A	X	Meets revision

Assessment Item	2008 USP 797 Chapter	Revised USP 797 / 800 Chapters	Joint Commission Standard	CMS CoP	Meets Requirement	Comments
		• Negative pressure (-0.01" to -0.03") • 12 ACPH • Refrigerated antineoplastic HD stored in dedicated refrigerator, in a room with at least 12 ACPH				
HD-PPE	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	• If reusable PPE is used, it must be decontaminated and cleaned after use • Gowns, head, hair, shoe covers, and 2 pairs of chemotherapy gloves are required	MM.01.01.03 EP 2	N/A	X	Meets revision
HD PPE gloves	*Not applicable if surveying to 2008 version of USP 797, these represent USP 800 concepts only*	• Gloves must meet ASTM D6978 rating • Outer pair must be sterile when compounding sterile CSPs	MM.01.01.03 EP 2	N/A	X	Meets revision