What you missed while dealing with the surge:

A brief on 2020 regulatory changes

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Since the onset of the COVID-19 pandemic, hospitals faced considerable challenges keeping up with regulatory changes and updates outside of the immediate priorities posed by the coronavirus. To help you navigate **non-pandemic related** regulatory changes occurring over 2020 for acute care hospitals, we've put together this article as a "year in review." This article reviews key changes to the CMS Conditions of Participation (CoPs) along with significant changes from The Joint Commission (TJC) hospital standards that were made to align with the changes handed down by CMS, as well as other relevant TJC standard updates.

Most of the revisions will have little impact on most of us. However, we draw your attention to three requirements that may be of higher interest to most hospitals:

- The new CMS requirement for a policy indicating which ambulatory care locations do not require registered nursing may be new. Greeley has developed a model [LINK] that may help you through this issue.
- CMS has also relaxed the pre-surgical history and physical requirement for ambulatory surgical centers and some outpatient procedures/populations in hospitals. This option may be of interest to some hospitals with H&P challenges. However, the rules are tricky. So we advise caution and thought before taking advantage of this alternative.
- The Joint Commission requirements related to material hemorrhage and preeclampsia have become effective. Although these topics are not new to most hospital obstetrics units, there may be some work to be done with respect to emergency departments that also occasionally attend childbirth. As with all standards, the devil is in the details.

Significant Revisions to the Medicare Conditions of Participation

We saw CMS issue two new final rules addressing burden reduction and discharge planning that became effective late 2019. The Joint Commission followed up by changing most corresponding requirements in early 2020.

- Restraint requirements were revised to enable hospital policy flexibility as to who may order, assess, and supervise restraint use (within limits established by state law) by removing independent from the term licensed independent practitioner. The term physician assistant was also removed. (§482.13(e)(5), §482.13(e)(8)(ii), §482.13(e)(10), §482.13(e)(11), §482.13(e)(12))
- The annual review of Emergency Preparedness has been changed to **every 2 years** that includes a full review of the emergency plan, communication plan, policies, procedures, training and testing, (additional training is also required whenever the plan changes). The types of exercises/drills that may be accepted were expanded so be sure to note hospitals must now conduct exercises to test the emergency plan at least **twice per year** instead of annually. (State Operations Manual (SoM) Appendix Z §482.15)
  - **TJC** Emergency Management (EM) requirements were revised to align with the CMS timeframes

(above) within the components of the Emergency Operations Plan and emergency preparedness. EM.03.01.03 requires an organization to conduct exercises to assess the adequacy and effectiveness of its plans as it relates to logistics, human resources, training, policies, procedures, and protocols. Effective in January 2021, EPs under EM.03.01.03 are consolidated, and information about the types of emergency exercises an organization can choose to perform were added.

- Quality Assessment and Performance Improvement (QAPI) language was updated to account for data from comparative data (as opposed to data from Quality Improvement Organizations). Also, hospitals are now permitted to be a node within system-wide QAPI program, as long as the program accommodates local differences. (§482.21(b)(1), §482.21(f))
- The separate rule, §482.22(d), that stated "the medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and education interest" was removed, deferring instead to state law.
- CMS now allows the medical staff to **preclude certain patients/procedures from the requirement for a pre-procedural history and physical (H&P) examination and update** in ambulatory environments. Such patients would undergo an "assessment" instead of H&P, the details of which must be defined by hospital policy. (§482.22(c)(5)) This also effects corresponding amendments to the Medical Records (§482.24(c)(4)) and Surgical Service (§482.51(b)(1)) Conditions of Participation (CoPs). While this provides some allowance (in specific instances) to forgo a formal H&P replacing this with an "assessment," the requirements for compliance with this new "allowance" can be tricky.
    - To align with CMS regulations for **Ambulatory Surgery Centers** (ASCs), **TJC** revised two requirements effective in July 2020. Standard PC.03.01.03 EP 9 now allows certified registered nurse anesthetists (CRNAs) and anesthetists to also conduct presurgical **assessments** for risks from the planned anesthesia. EP 16 was also revised to state "a physician examines the patient immediately before surgery to evaluate patient risk for the procedure to be performed" (these measures are in lieu of an H&P exam).
    - **Additional changes for ambulatory care organizations (ACO) and office-based surgery (OBS)** practices will be effective in July 2021 in PC.03.01.01 EPs 5 and 19. Requirements in the hospital standard PC.01.01.03 EP 7 are also added accordingly with the new CMS "allowance" with TJC requirements in these environments mirroring the acute hospital "allowance." (Again, we refer you to the link above to read our analysis on what moving to an assessment versus an H&P entails).
- Nursing standard changes include clarification about the Chief Nursing Officer's responsibility to ensure that all nurses are properly trained, supervised, and follow hospital policies, regardless of their affiliation (contract vs. employed vs. volunteers, etc.). (§428.23(b)(6))
- Nursing care plans: Language was added to the standard that the plan "reflects the patient's goals and the nursing care to be provided to meet the patient's needs" along with the added wording about the inclusion of "interventions toward meeting patient treatment goals" and "assessment of patient treatment goals" within the interpretive guidelines. (§428.23(b)(4))
- The hospital is now required to establish a listing of outpatient services that **do not** require the presence of a registered nurse. This listing/policy needs to be reviewed and approved by the Chief Nursing Officer at least every 3 years. (§428.23(b)(7))
- The Infection Control CoP was retitled Infection Prevention and Control and Antibiotic Stewardship Programs. We suggest a full review of these requirements since it was completely revised to incorporate requirements for an antibiotic stewardship program and otherwise modernize this condition. Highlights include that the governing body must appoint a qualified individual as the infection control professional(s) (ICP) and is also responsible and accountable to ensure all systems are in place and operational for the programs and that all issues are addressed in collaboration with hospital QAPI leadership. Responsibilities of the ICP are specifically outlined including expected communication and collaboration with the antibiotic stewardship program (ASP). Responsibilities of the ASP leader are also specifically outlined. Additionally, a hospital

system governing body may unify and integrate infection control programs across the system; the governing body is responsible and accountable that all requirements are uniquely met in each certified hospital. (§482.42) We don't expect the amended language to present new challenges, but we all know the old challenges were tough enough, not to mention COVID-19. (See The Greeley Company December 2020 webinar on Conquering Infection Control Survey Vulnerabilities to learn how your hospital can move to a mature model Infection Control program.)

  - TJC added and revised the Medication Management (MM) requirements—MM.09.01.01, EPs 9 and 10 related to antimicrobialstewardship programs. These two EPs now align with CMS requirements related to responsibilities of the governing body and an appointed leader of the ASP. Coordination and collaboration of all components is expected across hospital leadership.

- The Discharge Planning CoP was completely replaced. It is somewhat more specific, but not significantly different than the previous requirements. Highlights include that hospitals must have in effect a discharge planning process that focuses on patient goals and treatment preferences and includes the patient and support person(s) in discharge planning. Hospitals must assist patients, their family or representative, in selecting a post-acute care provider by using and sharing key performance data. This data must be relevant and applicable to the patient's goals of care and treatment preferences. (§482.43)
- Regulations for psychiatric hospitals were moved from Appendix AA (interpretive guidelines for freestanding acute psychiatric hospitals) of the State Operations Manual (SoM) to Appendix A (interpretive guidelines for hospitals in general). The ASPEN "B" tags no longer exist with new "A" tags assigned to these special conditions of participation. (§482.61)
- CMS expanded the type of practitioners who may write progress notes in psychiatric hospitals: from physicians only, to now include physicians, psychologists, and other licensed independent practitioners. (§482.61(d))

CHANGES IN TJC REQUIREMENTS AND PROCESSES

The following list includes other relevant Joint Commission requirement changes to the hospital standards effective over this past year and into 2021 that we feel are important for you to review and understand.

- TJC listened to its customers about the challenges of documenting rapidly **titrated medications.** In June 2020, new notes were added to the Record of Care, Treatment, and Services Standard RC.02.01.01, EP 2.

  Note 1: When rapid titration of a medication is necessary, the [organization] defines in policy the urgent/emergent situations in which block charting would be an acceptable form of documentation.

  Note 2: Block charting: A documentation method that can be used when rapid titration of medication is necessary in specific urgent/emergent situations as defined in organizational policy. A single "block" charting episode does not extend beyond a four-hour time frame. If a patient's urgent/emergent situation extends beyond four hours and block charting is continued, a new charting "block" period must be started. Minimum elements must be documented in each block charting episode:

  - Time of initiation of the charting block,
  - Name(s) of medications administered during the charting block,
  - Starting rates and ending rates of medications administered during the block,
  - Maximum rate (dose) of medications administered during the charting block,
  - Time of completion of the charting block,
  - Physiological parameters evaluated to determine the administration of titratable medications during the charting block.

- Effective January 2021, the Medication Management (MM) Standard MM.04.01.01, EP 2, was revised to clarify the minimum components of a **medication order.** The [organization] must follow a written policy that defines the following:

- The minimum required elements of a complete medication order, which must include medication name, dose, route, and frequency,
- When indication for use is required on a medication order,
- The precautions for ordering medications with look-alike or sound-alike names,
- Actions to take when medication orders are incomplete, illegible, or unclear,
- For medication titration orders, required elements include the medication name and route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes.

- Additionally, the following requirements were clarified related to **titration** medication:

1. In critical care/procedural settings only, for titrated vasoactive (including inotropes) medications, titrated pain infusions, and titrated sedative agents, **the nurse may select** between the ordered agents based on the patient's condition and unique physiological response if all the following criteria are met:
   - An order exists for the medication that is written in accordance with organizational policy,
   - It is not prohibited by state law,
   - It is allowed by hospital policy or the medication order,
   - Competency, as defined by the organization, is complete and documented,
   - The nurse must stay within the defined parameters of the order.

   Situations where similarly acting agents are ordered or medications are ordered for the same indication for the same patient; organizations should have a process where all care providers are aware of the intent for multi-modal therapy versus unintended therapeutic duplication. We recommend your Pharmacy and Therapeutics Committee discuss and identify this process and communicate it throughout the organization.
2. It is now acceptable to intermittently pause the infusion of a titrated medication if the patient no longer meets criteria for the infusion based on assessed physiological parameters. Pausing the infusion is not the same as discontinuing the infusion. If the paused infusion needs to be restarted based on assessed physiological parameters, a physician order must be present specifying how to restart the infusion or the organization must have a policy defining how to restart it. For example, an organization may consider restarting at the last infusion rate, restarting the infusion at the rate listed in the order for the start, or receiving a new order from the provider.

- There were no new National **Patient Safety Goals** (NPSG), however, there were minor editorial revisions and some requirements moved to the standards as follows:
  - NPSG.01.03.01 addressing transfusion errors moved to Standard PC.02.01.01
  - NPSG.07.03.01 addressing multidrug-resistant organisms moved to "Infection Prevention and Control" (IC) Standard IC.02.05.01 and "Performance Improvement" (PI) Standard PI.02.01.01
  - NPSG.07.04.01 addressing central line–associated bloodstream infections to Standards IC.02.05.01 and PI.02.01.01
  - NPSG.07.05.01 addressing surgical site infections to Standards IC.02.05.01 and PI.02.01.01
  - NPSG.07.06.01 addressing catheter-associated urinary tract infections to Standard IC.02.05.01
- Critical Access Hospitals must also now meet NPSG 15.01.01 requirements to reduce the risk of suicide (CAHs were previously excluded from this NPSG).
- We suggest fully reviewing the standards for behavioral health care organizations that provide substance use disorder treatment services. Requirements were added and revised that focus on the following topics: Thorough assessments addressing key aspects of the individual's history, placing the individual in an appropriate level of care, treatment and discharge planning, collecting toxicological specimens, safety measures for those on medication-assisted therapy, and disclosure of estimated costs for programs.

- In September changes were made for **behavioral health** care and human services organizations.
  - The behavioral health program manual was renamed the "Comprehensive Accreditation Manual for Behavioral Health Care and Human Services" along with the addition of more than 90 requirements related to child welfare services.
- The role of the Life Safety Code (LSC) surveyor for on-site surveys at hospitals was expanded. LSC surveyors will now evaluate the physical environment and LSC requirements at all off-site emergency department and hospital-based ambulatory surgery locations. For all other off-site locations, **clinical surveyors** will continue to evaluate the physical environment and LSC requirements, **with an enhanced focus on business occupancy requirements of the LSC.** Additionally, in July 2021, business occupancy standards will be added to the Life Safety (LS) chapter for hospitals and behavioral health care and human services agencies. *(Greeley member subscription clients may access a document highlighting the differences between hospital, ambulatory, and business occupancies.)*

THE FOLLOWING REQUIREMENTS BECAME EFFECTIVE AS OF JANUARY 2021:

- The new perinatal safety standards became effective (delayed from the original effective date of July 2020): Standard PC.06.01.01 EPs 1–7, to reduce the harm related to maternal hemorrhage in perinatal care and PC.06.03.01 EPs 1–6, to reduce the harm related to maternal severe hypertension/preeclampsia in hospitals. Although many hospitals have implemented these requirements, the standards should be reviewed to ensure current compliance with each EP. *Note: If your hospital does not provide obstetrical services, but you do have the capacity to receive patients in your Emergency Department who may be pregnant, you are responsible to meet elements of both maternal hypertension and hemorrhage requirements.*
- The Sentinel Events (SE) chapter was revised to add fall event to the list considered sentinel to help staff understand whether a fall should be reviewed as a sentinel event for all programs: *A fall resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury; or a patient with coagulopathy who receives blood products as a result of the fall; death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).*
- The Infection Prevention and Control Standard IC.02.04.01, EP 5, was deleted for all programs regarding an incremental annual influenza vaccination goal of 90% for health care personnel 18 years of age or older by 2020 to align with revised Healthy People 2030 goals.
- The Environment of Care (EC) Standard EC.02.04.03, EP 34, was revised for all institutions providing fluoroscopy services. The maximum exposure rate testing is now required **only** in fluoroscopic mode.
- The EC survey process was modified that eliminates the one-hour EC sit-down discussion with members of the safety or EC committee. Content from this session will be integrated into the document review and building tours conducted by the Life Safety Code surveyors. Also, EC topics will be incorporated during individual tracer activities completed by the clinical surveyors.
- Additionally, in July 2021, four new EPs regarding medication orders for **office-based surgery (OBS)** practices that prescribe medications take effect as follows:

1. Following a written policy that identifies the specific types of medication orders deemed acceptable for use,
2. Following a written policy that defines specific components of a medication order,
3. Using current evidence and practice if preprinted medication order sheets are used,
4. Prohibiting summary (blanket) orders to resume previous medications.

Stay tuned.

We expect the survey process, and perhaps even the underlying requirements, to undergo significant changes throughout 2021. We will do our best to keep you informed.

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