Illinois Health and Hospital Association

October 25, 2019

ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M

SUBJECT: Revised Conditions of Participation, Emergency Preparedness Requirements, and Fire Safety Requirements, Final Rule

On Sept. 30, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* (FR) a final rule making a series of changes to the Medicare conditions of participation (CoP). Specifically, this rule finalizes provisions from the following proposed rules:

- Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (Sept. 20, 2018; 83 FR 47686);
- Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (June 16, 2016; 81 FR 39448); and
- Fire Safety Requirements for Certain Dialysis Facilities (Nov. 4, 2016; 81 FR 76899)

The regulations in this final rule are effective beginning Nov. 29, 2019.

Final Rules: *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* and *Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care*

These final rules revise CoPs to address a number of requirements focused on quality, infection control, and antibiotic use. Changes impact a variety of providers including hospitals, CAHs, and ambulatory surgical centers. Hospital and CAH compliance with the antibiotic stewardship requirements will be implemented March 30, 2020. CAH Quality Assessment and Performance Improvement program (QAPI) requirements will be implemented March 30, 2021. All other requirements are effective Nov. 29, 2019. Details of these final rules follow.

Hospitals

QAPI Program and Infection Control

CMS finalized new standards for a unified and integrated QAPI Program and a unified and integrated infection control and antibiotic stewardship program for multi-hospital systems. Hospital systems with a single governing body that is legally responsible for the conduct of multiple, separately certified hospitals can elect to have a unified and integrated QAPI, infection control, and antibiotic stewardship program for all member hospitals, so long as the arrangement is in accordance with all applicable state and local laws. The system's governing body is responsible and accountable for ensuring that each separately certified hospital in the

system meets all of the requirements of this new standard (42 CFR §482.21(f)). Each separately certified hospital must demonstrate that the unified and integrated QAPI program:

- Takes each member hospital's unique circumstances, patient population differences, and unique service offerings into account;
- Establishes and implements policies and procedures to ensure that the needs and concerns of each separately certified hospital are given due consideration, regardless of practice or location;
- Has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and
- Designates a qualified individual(s) at each hospital with infection prevention and control expertise to be responsible for communicating with the unified infection control program, implementing and maintaining the policies and procedures governing infection control, and providing infection prevention education and training to hospital staff.

Additionally, CMS changed QAPI data requirements such that the hospital QAPI program must incorporate quality indicator data including patient care data submitted to or received from quality reporting and quality performance programs. These requirements include data related to hospital readmissions and hospital-acquired conditions.

Hospital H&P Requirements

CMS will allow hospitals the option of establishing a policy describing circumstances under which a hospital can forgo an H&P prior to specific outpatient surgical or procedural services and instead opt for a simplified assessment. If a hospital elects to develop such a policy, it must be based on recognized guidelines and best practices as well as the clinical judgment of the hospital's medical staff, and it must be developed in accordance with applicable state and local health and safety laws.

Autopsies

CMS will no longer require hospitals to attempt to secure autopsies in cases of unusual death, medical-legal cases or educational interest. Hospitals must define a mechanism for documenting permission to perform an autopsy, and there must be a system for notifying the medical staff when an autopsy is being performed. CMS reiterated that they do not think hospitals should attempt to secure autopsies in medical-legal cases without first contacting their state's medical examiner or medical authority, and it defers to state law on this issue.

Special Requirements for LTCH and CAH "Swing-Beds"

CMS is removing the following cross-referenced requirements for long-term care hospital and CAH swing-bed providers from statute:

- Requirements that a resident has the right to refuse to perform services (i.e., work) for a facility, and the facility must not require residents to work. CMS is removing these requirements because it is referenced elsewhere in statute.

- Required provision of ongoing programs directed by qualified professionals to support residents in their choice of activities. CMS is removing these requirements because most swing-bed patients are not long-term residents of the facility. If the patients do end up being long-term residents, CMS expects the nursing care plan will be based on assessing the patient's nursing care needs and will support holistic care, including ongoing activity programs.
- Required employment of a qualified, full-time social worker in any facility with more than 120 beds. This requirement is deemed unnecessary because LTCH hospital and CAH swing-bed providers are not permitted to have more than 100 and 25 beds, respectively.
- Required provision of routine and emergency dental services to meet the needs of each resident. CMS believes hospital and CAH swing-bed providers are already considering dental needs in each patient's plan of care, so this provision is not necessary.

Special Requirements for Psychiatric Hospitals

CMS clarified that non-physician practitioners, when acting in accordance with state law and hospital policy, have the authority to document progress notes for psychiatric patients. Non-physician practitioners include physician assistants, nurse practitioners, psychologists, and clinical nurse specialists.

Critical Access Hospitals

Quality Assessment and Performance Improvement Program

CMS created a QAPI program for CAHs. This replaces the existing annual evaluation and quality assurance review requirements. CMS believes much of the work and resources necessary to implement QAPI requirements are already in place under the old evaluation requirements. CAHs must implement QAPI requirements by March 30, 2021. More information on QAPI requirements can be found at *FR* 51828.

CAH Infection Prevention and Control and Antibiotic Stewardship Programs

CAHs are required to create infection prevention and control and antibiotic stewardship programs. Both programs must have documented, facility-wide policies and procedures that ensure adherence to nationally recognized guidelines and best practices for preventing and controlling infection and improving antibiotic use. These policies and procedures must reflect the scope and complexity of services offered in the CAH setting.

The infection prevention and control program must include surveillance, prevention and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and procedures to address any infection control issues identified by public health authorities.

The antibiotic stewardship program must meet the following goals: (i) demonstrated coordination among all components of the CAH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, medical staff, and nursing and pharmacy services; (ii) documented evidence-based use of antibiotics in all departments and services of the CAH; and (iii) demonstrated, sustained improvements in proper antibiotic use, such as reductions in clostridium difficile (C. Diff.) colitis and antibiotic resistance in all departments and services of the hospital.

Program Governance: Both programs must be overseen by a governing body or responsible individual(s) deemed qualified through education, training, experience, or certified in infection prevention and control. This oversight body/individual must ensure the following:

- There is a system in place for tracking and documenting all infection surveillance, prevention and control, and antibiotic use activities in order to demonstrate the implementation, success and sustainability of such activities;
- All HAIs and other infectious diseases identified by the infection prevention and control program and antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with CAH QAPI leadership;
- Competency-based training and education on all practical applications of program guidelines, policies and procedures is provided for CAH personnel and staff including professional healthcare staff and personnel providing services in the CAH under agreement or arrangement; and
- Communication and collaboration between the prevention and control program and the antibiotic stewardship program.

Periodic Review of Clinical Privileges and Performance

Current requirements found under the "Periodic Evaluation and Quality Assurance" CoP specific to staffing and staff responsibilities are relocated to a new standard under the "Staffing and Staff Responsibilities" CoP (§485.631). This provision requires CAHs to evaluate the quality of care provided by their nurse practitioners, clinical nurse specialists, certified nurse midwives, physician assistants, doctors of medicine and/or doctors of osteopathy.

Provision of Services

In addition to the practitioners responsible for the care of patients, CMS will allow registered dieticians and any other clinically qualified nutrition professionals to order therapeutic diets for patients in accordance with state laws.

Changes to CAH Ownership Disclosure Requirements

CMS removed the requirement that CAHs disclose the names and addresses of their owners, those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5% or more ownership interest. This requirement was duplicative of the provider agreement for Medicare participation. Additionally, CMS will no longer require an

annual review of CAH policies and procedures by professional healthcare staff. This will now be required biennially (every two years).

Emergency Preparedness for Providers and Suppliers: CMS updated some elements of the Sept. 16, 2016 final rule "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" (81 FR 63860). Facilities will still be required to include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain integrated response during a disaster or emergency situation, but facilities will no longer be required to document efforts to contact these entities to participate in collaborative and cooperative planning efforts.

All facilities, save long-term care facilities, are now required to update their emergency preparedness program biennially. They are also required to train their staff on this plan biennially. Long-term care facilities must continue to update their program annually and providing training on their plan annually. CMS cited public comment and detailed analysis on the lack of emergency response in nursing homes following recent emergency events as rationale for not modifying long-term care requirements.

In terms of emergency preparedness testing, providers are required to test their emergency plan at least annually. For inpatient providers, CMS retained existing requirements to conduct two emergency preparedness testing exercises annually. One must be a community-based full-scale exercise or an individual facility-based functional exercise. The other is the provider's choice: either a community-based full-scale exercise, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

For outpatient providers, CMS will require only one testing exercise per year. Every other year, this must be either a community-based full-scale exercise or an individual facility-based functional exercise. In the opposite years, providers can conduct a testing exercise of their choice: either a community-based full-scale exercise, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. Organ procurement organizations have the option of providing either a tabletop exercise or a workshop every year.

If a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required community-based full-scale exercise or individual facility-based functional exercise following the onset of the actual event.

CMS wants facilities to make every attempt to conduct community-based full-scale exercises whenever possible; however, when not possible, they allow for individual facility-based functional exercises.

Ambulatory Surgical Centers (ASCs)

Transfer Agreements with Hospitals

CMS removed requirements that ASCs have a written hospital transfer agreement or hospital physician admitting privileges with the local hospital. Instead, ASCs must periodically provide the local hospital with written notice of its operation and the patient population they serve. Additionally, ASCs must have preparations in place for patient transfers in the event of an emergency. Note, this change does not preclude ASCs and hospitals from establishing written transfer agreements.

Requirements for Comprehensive Medical History and Physical Assessment

Currently, ASCs are required to ensure that a physician or other qualified practitioner has provided a comprehensive medical history and physical assessment (H&P) within 30 days prior to a scheduled surgical procedure. CMS will no longer require an H&P. Instead it requires ASCs to develop and maintain a policy that identifies when a pre-surgery H&P is necessary. Once admitted, each patient must still receive a pre-surgical assessment completed by the practitioner who will be performing the surgery. The ASC's policy must be based on nationally recognized standards of practice and guidelines, and applicable state and local health and safety laws.

Hospice

Hospice Aide and Homemaker Services

CMS will no longer require hospice aide training state licensure programs to meet federal training and competency requirements. Instead, state licensure requirements will suffice unless a state does not have pre-established requirements in place.

Orientation of Skilled Nursing Facility (SNF) and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) Staff

CMS revised existing regulations to clarify that hospice organizations share responsibility with SNF, ICF or IID facilities in assuring facility staff are oriented and trained to work with hospice populations.

Transplant Centers: CMS removed requirements at 42 CFR §482.82 that transplant centers must meet all data submission, clinical experience, and outcome requirements in order to obtain Medicare re-approval, and removed requirements at 42 CFR §482.61(f)-(h) for mitigating factors and transplant systems improvement agreements for the transplant center re-approval process.

Home Health Agencies: Instead of requiring HHAs to provide verbal notification of all patient rights, HHAs will only be required to verbally discuss payment and patient financial liability information. Additionally, CMS is eliminating the requirement that HHAs conduct a full competency evaluation of home health aides, replacing it with a requirement to retrain aides on only those skills identified as deficient. Aides will only be required to complete a competency evaluation retrained skills.

CMS is also revising the language used to describe the process for conducting home health aide competency evaluations. This change will restore longstanding official CMS policy from the July 18, 1991 final rule, "Medicare Program; Home Health Agencies: Conditions of Participation." In this final rule, CMS permitted the use of pseudo-patients and laboratory environments for purposes of home health aide competency evaluations. This was not explicitly stated in, but is applicable to, the finalized Jan. 13, 2017 HHA CoP.

Comprehensive Outpatient Rehabilitation Facilities (CORFs): CMS reduced the required frequency of CORF utilization reviews from quarterly to annually.

Community Mental Health Centers (CMHCs): Instead of requiring an update to a client's comprehensive assessment every 30 days, CMS will now require CMHCs to update each client's comprehensive assessment only when changes in the client's status, responses to treatment, or goal achievement have occurred, in accordance with current standards of practice. This update must be done with the CMHC interdisciplinary treatment team and in consultation with the client's primary health care provider. CMS is retaining the minimum 30-day assessment update time frame for clients who receive partial hospitalization program services.

Portable X-Ray Services: CMS changed qualification requirements for personnel operating portable x-ray equipment. Instead of requiring specific school accreditation standards, CMS will now require operators of portable x-ray equipment to meet one of the following:

1. Successful completion of a program of formal training in x-ray technology at which the operator received appropriate training and demonstrated competence in the use of equipment and administration of portable x-ray procedures; or
2. Successful completion of 24 full months of training and experience under the direct supervision of a physician who is certified in radiology or who possesses qualifications which are equivalent to those required for such certification.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs): CMS will now require RHCs and FQHCs to review patient care policies and total program evaluation biennially instead of annually.

Licensed Independent Practitioners: CMS is removing the term "independent" from "licensed independent practitioner" regarding restraint and seclusion orders. The use of restraint or seclusion must be in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restrain or seclusion by hospital policy and in accordance with state law. CMS made it clear that this includes licensed physician assistants when allowable by facility policy and state law.

Nursing Services: CMS made several changes to the nursing services CoP to improve clarity. Specifically:

- The nursing service must provide ongoing assessment of patients' needs and ensure adequate nursing staff to meet those needs regardless of whether the patient is an inpatient or an outpatient.
- Hospitals may establish policy that specifies which, if any, outpatient departments are not required to have an RN physically present. The policy must establish alternative staffing plans and account for factors such as services delivered, the acuity of patients typically served and established standards of practice for such services. The policy must be approved by medical staff and reviewed at least once every three years.
- CMS clarified the process for creating and maintaining each patient's nursing care plan. CMS expects timely initiation and implementation of nursing care plans, which should include patient goals as part of the patient's nursing care assessment and, as appropriate, physiological and psychosocial factors, physical and behavioral health comorbidities, and patient discharge planning. CMS clarified that nursing care plans are required for inpatients, and should also be created for outpatients when appropriate. Plans must be consistent with the patient's overall medical care plan, and demonstrate evidence of reassessment of the patient's nursing care needs, response(s) to nursing interventions and revisions to the plan as needed. Plan extensiveness and detail should mirror the complexity of the patient.
- CMS clarified that all licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. Additionally, the nursing service director must provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel. This includes all licensed nurses and any non-licensed personnel such as nurse aides, orderlies, or other nursing support personnel who are under the direction of the nursing service, regardless of the mechanism through which those personnel were obtained (i.e., direct employment, contract or agency nurses, leasing agreement, etc.).

Final Rule: ***Fire Safety Requirements for Certain Dialysis Facilities***

This final rule addressed requirements for dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area. Grade level is defined as the ground or level of a building where patients do not have to go up or down stairs within the building to evacuate to the outside. Accessibility ramps in the exit area that provide ease of access between the patient treatment level and the outside ground level are not considered stairs.

Such dialysis centers are required to comply with the National Fire Protection Association (NFPA) 99® 2012 edition of the Health Care Facilities Code and NFPA 101® 2012 edition of the Life Safety Code. These materials have been previously incorporated by reference for other provider and supplier types by the final rule, "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities" published on May 4, 2016 (81 FR 26872). Above or below grade dialysis centers must also meet requirements of the Ambulatory Health Care Occupancy Chapters.

These requirements are effective Nov. 29, 2019.