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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-13-Hospital

DATE: May 3, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: DRAFT ONLY- Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities

Memorandum Summary

- **Hospital Co-location Interpretive Guidance:** CMS is focused on ensuring the health and safety of patients as it relates to the use of shared space and contracted services by hospitals co-located with another hospital or health care entity. CMS is committed to providing the information hospitals need to make decisions about how they partner with other providers in the health care system to deliver high-quality care.
- **This Guidance is Being Released in Draft:** To ensure that CMS is fully aware of how our guidance will impact hospital providers, we are releasing the guidance in draft and welcome comments.
- We seek comment on these draft revised policies by July 2, 2019 (60 days from the date of this release)

Background

CMS takes seriously our responsibility to oversee the quality of care for all Americans who seek care from a hospital. The Medicare Conditions of Participation (CoPs) are a key way CMS exercises that responsibility. Under the CoPs, hospitals may co-locate with other hospitals or health care entities, meaning they share certain common areas on the same campus or building.

While CMS wants to allow flexibility in these partnerships, we want to do so while simultaneously protecting the safety and quality of care for patients. In this guidance, CMS seeks to provide clarity about how CMS and State Agency surveyors will evaluate a hospital's space sharing or contracted staff arrangements with another hospital or health care entity when assessing the hospital's compliance with the CoPs.

Discussion

Increasingly, hospitals have co-located with other hospitals or other healthcare entities as they seek efficiencies and develop of different delivery systems of care. Co-location occurs where two hospitals or a hospital and another healthcare entity are located on the same campus or in the same building and share space, staff, or services.

All co-located hospitals must demonstrate separate and independent compliance with the hospital CoPs. This guidance clarifies how shared spaces, services, personnel and emergency services can be organized to allow the hospital to demonstrate independent compliance. We also clarify that sharing of staff may be done through a contractual arrangement where there are clear lines of authority and accountability. In general, under this guidance, sharing public areas such as entrances and waiting rooms would be permissible. However, due to infection control, patient management, confidentiality, and other quality and safety concerns, the use of shared clinical spaces would be limited.

CMS is issuing this guidance in draft form to solicit comments from stakeholders, which will be considered prior to the issuance of final guidance. We seek comment on these draft revised policies by July 2, 2019 (60 days from the date of this release).

Contact: For questions regarding hospital co-location, please contact HospitalSCG@cms.hhs.gov

Effective Date: This draft policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators. CMS will finalize this policy following a 60-day comment period.

/s/
Karen Tritz

Attachment (s)-Guidance Related to Hospital Co-location with Other Hospitals or Healthcare Facilities

cc: Survey and Certification Regional Office Management

This language will be added to the Survey Process Section of Appendix A.

Surveying Hospitals *Co*-Located with Other Hospitals or Healthcare Facilities

This guidance clarifies how a hospital can be co-located with another healthcare provider to and demonstrate independent compliance with the Medicare Conditions of Participation for hospitals (CoPs) for shared spaces, services, personnel and emergency services. Please note prior sub-regulatory interpretations prohibited co-location of hospitals with other healthcare entities. This guidance changes that to ensure safety and accountability without being overly prescriptive.

Hospitals can be co-located with other hospitals or other healthcare entities. These hospitals may be located on the same campus of or in the same building used by another hospital or healthcare facility. The hospital may be co-located in its entirety or only certain parts of the hospital may be co-located with other healthcare entities. Common examples of co-location instances include:

- *One hospital entirely located on another hospital's campus or in the same building as another hospital*
- *Part of one hospital's inpatient services (e.g., at a remote location or satellite) is in another hospital's building or on another hospital's campus*
- *Outpatient department of one hospital is located on the same campus of or in the same building as another hospital or a separately Medicare-certified provider/supplier such as an ambulatory surgical center (ASC), rural health clinic (RHC), federally-qualified healthcare center (FQHC), an imaging center, etc.*

Note: The following guidance is specific to the requirements under general the hospital conditions of participation (CoPs) and does not address the specific location and separateness requirements of any other Medicare-participating entity, such as psychiatric hospitals, ASCs, rural health clinics, Independent Diagnostic Testing Facilities (IDTFs), etc.

Regardless of the situation, when a hospital is in the same location (campus or building) as another hospital or healthcare entity, each entity is responsible for demonstrating separate and independent compliance with the hospital CoPs.

Distinct Space and Shared Space

A Medicare-participating hospital is evaluated as a whole for compliance with the CoPs and is required to meet the definition of a hospital at all times at section 1861(e) of the Act. It is expected that the hospital have defined and distinct spaces of operation for which it maintains control at all times. See SOM §2012. Distinct spaces would include clinical spaces designated for patient care and is necessary for the protection of patients, including but not limited to their right to personal privacy and to receive care in a safe environment under §§482.13(c)(1) and

(2), and right to confidentiality of patient records under §482.13(d). For example, co-mingling of patients in a clinical area such a nursing unit, from two co-located entities, could pose a risk to the safety of a patient as the entities would have two different infection control plans.

Additionally, the shared clinical space could jeopardize the patient's right to personal privacy and confidentiality of their medical records.

Shared spaces are considered those public spaces and public paths of travel that are utilized by both the hospital and the co-located healthcare entity. Both entities would be individually responsible for compliance with the CoPs in those spaces. Examples of public spaces and paths of travel would include public lobbies, waiting rooms and reception areas (with separate "check-in" areas and clear signage), public restrooms, staff lounges, elevators and main corridors through non-clinical areas, and main entrances to a building.

Travel between separate entities utilizing a path through clinical spaces of a hospital by another entity co-located in the same building would not be considered acceptable as it could create patient privacy, security, and infection control concerns. Clinical space is any non-public space in which patient care occurs. It is the responsibility of both the hospital and the co-located healthcare entity to protect and provide a safe environment for their patients and potential risks could result in non-compliance.

- A public path of travel is, for example, a main hospital corridor with distinct entrances to departments (such as outpatient medical clinics, laboratory, pharmacy, radiology). It is necessary to identify, for the public, which healthcare entity is performing the services in which department*

However, the following examples would not be public paths of travel:

- A hallway, corridor, or path of travel through an inpatient nursing unit; or*
- A hallway, corridor, or path of travel through a clinical hospital department (e.g., outpatient medical clinic, laboratory, pharmacy, imaging services, operating room, post anesthesia care unit, emergency department, etc.)*

Contracted Services

A hospital is responsible for providing all of its services in compliance with the hospital CoPs. Services may be provided under contract or arrangement with another co-located hospital or healthcare entity, such as laboratory, dietary, pharmacy, maintenance, housekeeping, and security services. It is also common for a hospital to obtain food preparation and delivery services under arrangement from the entity in which is it co-located, in addition to utilities such as fire detection and suppression, medical gases, suction, compressed air, and alarm systems, such as oxygen alarms.

Staffing Contracts

Each Medicare-certified hospital is responsible for independently meeting staffing requirements of the CoPs and any of the services for which the hospital provides, whether or not those staff are provided directly by the hospital or under arrangement or contract from another entity (including from healthcare entities that are co-located with the hospital). When staff are obtained under arrangement from another entity, they must be assigned to work solely for one hospital during a specific shift and cannot “float” between the two hospitals during the same shift, work at one hospital while concurrently being “on-call” at another, and may not be providing services simultaneously. For instance, under section 1861(e)(5) of the Act, a hospital must be able to provide nursing services at all times and if such staff are being shared between two entities at the same time, meeting this definition is not possible. This would also apply to the lab, pharmacy, and nursing director. This does not necessarily preclude these individuals from serving those roles in both hospitals, but it cannot be simultaneously.

Also, the Nursing Services standard at §482.23(b) states, “The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.” A RN could not be immediately available if the RN was working on more than one unit, building, or floor in a building, or with more than one provider (e.g., distinct part SNF, RHC, excluded unit, etc.) at the same time.

In addition, all individuals providing services under contract should receive appropriate education and training in all relevant hospital policies and procedures. The training and education should be the same training that would be provided to individuals who are direct employees of the hospital so that the quality of care and services being provided is the same.

When utilizing staffing contracts, under §482.12(e) the governing body ensures:

- Adequacy of staff levels*
- Adequate oversight and periodic evaluation of contracted staff*
- Proper training and education of contracted staff*
- Contracted staff have knowledge of and adheres to the quality and performance improvement standards of the individual hospital*
- That there is accountability of the contracted staff related to clinical practice requirements*

The governing body approved medical staff may be shared, or “float,” between the co-located hospitals if they are privileged and credentialed at each hospital. In the instance co-located hospitals are a part of a multiple hospital system, see §482.22.

Clinical Services Contract

For hospitals that provide certain clinical services under contract or arrangement from another co-located hospital or other healthcare entity, the hospital is not necessarily required to notify its patients and their representative of all services provided under contract or arrangement, as these services are provided under the oversight of the hospital's governing body and would be treated as any other service provided directly by the hospital.

Emergency Services

Hospitals without emergency departments must have appropriate policies and procedures in place for addressing individuals' emergency care needs 24 hours per day and 7 days per week. *Policies and procedures should include (1) identifying when a patient is in distress, (2) how to initiate an emergency response (e.g., calling for staff assistance and the on-call physician), (3) how to initiate treatment (e.g., CPR and the use of an Automated External Defibrillator (AED)), and (4) recognizing when the patient must be transferred to another facility to receive appropriate treatment.*

Hospitals must anticipate potential emergency scenarios typical of the patient population it routinely cares for in order to develop policies, procedures and ensure staffing that would enable it to provide safe and adequate initial treatment of an emergency. Contracting with another hospital or entity for the appraisal and initial treatment of patients experiencing an emergency is permitted when the contracted staff are not working/on duty simultaneously at another hospital or healthcare entity. Hospitals without emergency departments that are co-located with another hospital may not arrange to have that other hospital respond to its emergencies in order to appraise the patient and provide initial emergency treatment. The hospital may permit the contracted emergency staff to perform other duties within the hospital and be immediately available for an emergency, but not perform duties at the other co-located entity during this time.

There may be times, however, when appraisal and initial treatment performed in one hospital requires an appropriate transfer of the patient to the other co-located facility for continuation of care. For example, a rehabilitation hospital, that is co-located with separate acute care hospital, must ensure that unit staff are able to recognize and respond to patients that may be having a heart attack, stroke or other emergencies. It is acceptable that the rehabilitation hospital arranges to refer or transfer patients with emergency conditions to the co-located acute care hospital if it cannot provide care beyond initial emergency treatment (e.g. CPR and use of an AED).

Hospitals without emergency departments that contract for emergency services with another hospital's emergency department are then considered to provide emergency services and must meet the requirements of EMTALA. See §§489.20-24.

Survey Procedures

Distinct and Shared Space

When surveying a hospital that is co-located with another hospital or healthcare entity, review the following:

- The designated space(s) of the co-located hospital and its distinct separation from the other hospital or healthcare entity*
- The use of contracted services from the co-located entity and outside healthcare entities*

Surveyors must ask for a floor plan that distinguishes the spaces used by the hospital being surveyed and the spaces used by the other co-located entity. The floor plan must clearly identify which healthcare entities use the spaces. If both entities utilize same space, then it is expected that any non-compliance found in that space could be considered non-compliance for both entities. For example, a surveyor may need to follow procedures for initiating a complaint for the other entity based on the findings of non-compliance of the healthcare entity not currently being surveyed. In addition, surveyors must ask hospital leadership to provide a list of all services that the hospital has contracted to use from the other co-located entity or healthcare entities. This information is critically important as surveyors must know what specific space/locations to survey and what services are being directly provided by the hospital being surveyed or are being provided by the other entity.

When reviewing the floor plan, look for the following and assess the hospital for compliance with CoPs:

- Spaces within the co-located hospital are defined and identified as belonging to the hospital being surveyed.*
- If spaces that belong to another entity can only be accessed by traveling through public paths of travel from within the hospital (e.g., to reach the entrance of a rehabilitation hospital that is co-located with an acute care hospital, one must not travel through the medical unit of the acute care hospital.)*
- If spaces that appear to be shared by the surveyed hospital and the other entity as public spaces are identified as belonging to both.*
- Identify where the required and optional hospital services and departments (as required in the CoPs) are located. This will help to identify if there are any shared spaces and/or services between the hospital and the other co-located entity.*

When surveying physical spaces and locations of a hospital, surveyors need to identify if any clinical care space is being shared between the hospital and the other healthcare entity with which it is co-located. In general, a hospital should not share space where patients are receiving care. This would include, but is not limited to, any space within nursing units (including hallways, nursing stations, and exam and procedure rooms located within nursing

units), outpatient clinics, emergency departments, operating rooms, post-anesthesia care units, etc.

The shared use of these clinical care areas by two or more separate healthcare entities can potentially lead to non-compliance by both entities related to other CoPs such as nursing, infection control, and patient's rights. See §482.13(c)(2), §482.23, and, §482.42. Additionally, the sharing of spaces used for medical records and patient registration/admission could also potentially pose a risk to patient privacy as an unauthorized person could have access to patient records without consent. See also §482.24(b)(3), confidentiality of medical records.

Contracted Services

When surveying a hospital that has contracted for services (such as laboratory or dietary services) from another entity, compliance with the CoPs through the use of contracted services can be evaluated by following the interpretive guidance and survey procedures under §482.21 Quality Assurance and Performance Improvement and §482.12(e) Contracted Services. Surveyors must always ask to see documentation of how the contracted services are incorporated into the hospital's QAPI program.

Surveyors are responsible for surveying the actual physical location where the contracted services (such as the laboratory or kitchen) are being provided if it is physically located and provided on-site. When a contracted service is not located or is not being provided on-site, (such as a laundry service for hospital linens), surveyors are not required to survey the off-site location. Surveyors must assess how the governing body ensures compliance with the CoPs through QAPI activities. Surveyors are responsible for assessing whether the outcomes of the contracted service are included in the hospital's QAPI program, and for surveying the point of care delivery that reaches the patient.

For example, if a rehabilitation hospital is co-located with a long term care hospital (LTCH) and contracts for laboratory services from the LTCH, surveyors should survey the actual lab space because it is on-site and is providing a direct clinical service to patients. In addition, surveyors would evaluate how the rehabilitation hospital has incorporated the contracted lab service into its QAPI program and how the rehabilitation hospital monitors and evaluates the quality and safety of the contracted lab service.

Surveyors will review the contracts for staffing services with co-located entities to ensure that they provide for the following:

- Adequacy of staff levels*
- Adequate oversight and periodic evaluation of contracted staff*
- Proper training and education of contracted staff*
- Contracted staff have knowledge of and adheres to the quality and performance improvement standards of the individual hospital*

- *That there is accountability of the contracted staff related to clinical practice requirements*

Additionally, surveyors will review staffing and schedules of staff to ensure that staff are immediately available at all times to perform services required by the hospital.

Ask the governing body to verify that any clinical services being provided under contract from the other entity are not being simultaneously “shared” with another hospital or entity. Ask to see staffing schedules to verify that individuals providing contracted services are only scheduled to work at one facility per shift.

Ask the governing body to demonstrate how the hospital monitors the performance of its contracted services.

Ask the governing body to demonstrate how the hospital ensures that all individuals providing services under contract have been oriented and trained to provide care in accordance with hospital policies and procedures.

Review a sample of personnel files of individuals who provide services under contract and verify they have received requisite education and training.

Emergency Services

When evaluating the emergency care of patients in a hospital without an emergency department that is co-located with another healthcare entity, review the following:

- *Does the hospital respond to its own in hospital emergencies, with its own trained staff (not another hospital’s or entity’s staff)?*
- *Does the hospital have proper emergency equipment in the event that a patient requires resuscitation, e.g., AED, code cart, intubation tray, medications?*
- *Is hospital staff properly trained in the use of the emergency equipment?*
- *Is the hospital’s emergency equipment properly maintained, e.g., drugs unexpired, sterile equipment, code cart stocked?*
- *Is hospital staff properly trained for appraisal of emergencies, initial treatment, and referral when appropriate?*

If the hospital has no emergency department, but has its emergency services provided under a contract with an emergency department of a co-located hospital, verify that the hospital meets the EMTALA requirements.

If the emergency services are provided by staff under contract, verify that staff are immediately available at all times and only committed to services at that hospital during those time.

Identification of Deficiency

In instances where deficiencies are identified in a contracted service, the appropriate CoP for that service should be cited. The deficiency must also be cited at the governing body CoP as the governing body is responsible for oversight of all contracted services provided in the hospital. For example, if a hospital contracts for laboratory services, and a survey found noncompliance with the laboratory services CoP, the surveyor should cite both the laboratory services CoP and the governing body CoP. A determination of noncompliance with a service that is provided under contract could also be cited under the QAPI CoP (e.g., a contracted dietary service could not produce any monthly data regarding the food temperatures, or there was a lack of appropriate data for quality control testing for the laboratory).

If the other co-located entity providing the contracted service is a CMS-certified provider or supplier, the surveyor should file a complaint with the SA or RO regarding that entity for further review if noncompliance is determined the shared or contracted service. While on-site, the SA should contact their supervisor to file the complaint and seek possible authorization to conduct a complaint survey of the other co-located facility while still on-site. These would be two separate surveys with two separate survey reports. For accreditation organizations, it is up to the AO as to whether it will conduct the complaint survey at that time or at a later date. However, the AO must still treat the finding of non-compliance in the contracted service as a complaint in the co-located entity providing the contracted service and file the complaint as appropriate