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Center for Clinical Standards and Quality/Quality, S

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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 (*Revised*)

Memorandum Summary

 Hospital Co-location Interpretive Guidance: CMS is focused on ensuring the healthand safety of patients as it relates to the use of shared space and contracted services byhospitals 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 are releasing the final guidance for the evaluation of compliance with Medicare Conditions of Participation (CoPs) related to shared space and services for hospitals co-

Background

CMS takes <u>seriously</u> our responsibility <u>seriously</u> to oversee the quality of care for all Americans who seek care from a hospital. The Medicare <u>Conditions of Participation (CoPs)</u> 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.

Page 2- State Survey Agency Directors

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 <u>and service</u> arrangements with another hospital or health care entity when assessing the hospital's compliance with the CoPs.

Discussion

Increasingly, hospitals<u>Hospitals</u> have <u>increasingly</u> co-located with other hospitals or other healthcare entities as they seek efficiencies and develop of different delivery systems of care. Co-location occurs wherewhen two <u>Medicare certified</u> hospitals or a <u>Medicare certified</u> 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 hospitals may organize shared spaces, services, personnel, and emergency services can be organized to allow the hospital to demonstrate independentto meet regulatory requirements. When hospitals choose to co-locate, they should consider the risk to 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 through any shared space or shared service arrangements.

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). The SOM Appendix A will be revised to include the co-location guidance as a component of the hospital survey process. Surveyors are expected to use this guidance to assess a hospital's compliance with the CoPs when they are co-located with another Medicare certified hospital or health care entity.

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

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

/s/ Karen TritzDavid R. <u>Wright</u>

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.Page 2 of 2

Co-located Hospitals Survey Module

Surveying Hospitals Co-Located with Other Hospitals or Healthcare Facilities

This guidance clarifies howis for surveys of a hospital can be co-located with another hospital or healthcare provider to and demonstrate independent for determining 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. (CoPs) for hospitals.

Hospitals can be co-located with other hospitals or other healthcare <u>entitiesproviders</u>. 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 <u>entitiesfacilities</u>. Common examples of co-location <u>instances</u> 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 This guidance is specific to the requirements under general-the hospital conditions of participation (CoPs) CoPs at 42 CFR Part 482 and does not address the specific location and separateness requirements of any other Medicare- participating entity, such as psychiatric hospitals, ambulatory surgical centers (ASCs), rural health clinics, Independent Diagnostic Testing Facilities (IDTFs), etc.

Additionally, for the purpose of this guidance, reference to "healthcare providers" does not include critical access hospitals (CAHs) due to specific distance and location requirements or private physician offices, including those that may be participating in a timesharing or leasing agreement.

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 independentits compliance with the hospital CoPsall applicable Medicare and Medicaid program participation requirements.

Distinct Space and Shared Space

A Medicare-participating hospital is evaluated as a whole for compliance with the CoPs and is required <u>at all times</u> 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 spaces of operation consistent with the CoPs at 42 CFR Part 482. The hospital must consider whether the hospital's spaces that are used by another co-located provider risk their compliance with these requirements. Areas of consideration when sharing space may relate to patient rights, infection prevention and control, governing body, and/or physical environment, among others. For example, both the hospital and the co-located healthcare provider should demonstrate their compliance to protect and provide a safe environment for their 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-minglingof 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 anotherentity co-located in the same building would not be considered acceptable as it could createpatient 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-locatedhealthcare entity to protect and provide a safe environment for their patients and potential riskscould 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, which could be provided <u>either directly or</u> under contract or arrangement-with another co-located hospital or healthcare entity. <u>Services</u>, such as laboratory, dietary, pharmacy, maintenance, housekeeping, and security services. It is also common for a hospital to obtain are examples of services that may be contracted or provided under arrangement in a co-located hospital.

<u>Other common examples of contracted services may include</u> food preparation and delivery services <u>under arrangement from the entity in which is it co-located, in addition to, and</u> utilities such as fire detection and suppression, medical gases, suction, compressed air, and alarm

systems, such as oxygen alarms. <u>These services are provided under the oversight of the hospital's</u> governing body (see §482.12(e)) and would be treated as any other service provided directly by the hospital.

Staffing-Contracts

Each Medicare-certified hospital is responsible for *independently*-meeting staffing requirements of the CoPs and <u>for</u> any of the services <u>for which that</u> 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 <u>entities facilities</u> that are co-located with the hospital). When <u>hospital</u> 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. there should be evidence that the hospital's staff are meeting the needs of patients for whom they are providing care. Additionally, the staffing must meet the statutory and regulatory requirements for the activity.

For instance, under section 1861(e)(5) of the Act, and 42 CFR §482.23, a hospital must be ableto-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 fromserving those roles in both hospitals, but it cannot be simultaneously. Also, Specifically, 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.the care of any patient."

In addition, all <u>All</u> individuals providing services <u>to a hospital patient</u>, whether directly or <u>under</u> 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 $\frac{\$482.12(e)}{\$482.12(e)}$ the contracted services standard at \$482.12(e) along with other applicable conditions and standards therein incorporated, the governing body ensures is responsible for ensuring:

- 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 With regards to medical staff-may be shared, or "float," between the_each co-located *hospitals if they are privileged and credentialed at each hospital. In the instancehospital would be responsible for meeting the medical staff requirements at §482.22. Where* 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. §482.22(b)(4) provides requirements specific to the unified medical staff.

Emergency Services

Hospitals without emergency departments While hospitals must provide care to patients in an emergency, hospitals are not required to have an emergency department. Under the CoP at §482.12(f)(2), hospitals that do not have emergency departments and are not identified as providing emergency services must have appropriate policies and procedures in place for addressing individuals' emergency care needs 24 hours per day and 7 days per weekat all times.

Hospitals should have policies and procedures to address potential emergency scenarios typical of the patient population they routinely care for and ensure staffing that would enable them to provide safe and adequate initial treatment of an emergency. 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 colocated with another hospital may not arrange to have that other hospital respond to itsemergencies 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 <u>provider</u>, <u>such as a</u> co-located facility_{*} for continuation of care. For example, a rehabilitation hospital, that is co-located with <u>a</u> separate acute care hospital; must ensure that <u>unitits rehab</u> staff are able to recognize and <u>respond toprovide an initial response to its</u> patients that may be having <u>a heart attack</u>, <u>stroke or other</u> emergencies, <u>as specified in §482.12(f)(2)</u>. It is <u>acceptablepermissible</u> that the rehabilitation hospital arranges to refer or transfer patients with emergency conditions to the co-located acute care hospital <u>if it cannot provide for</u> care beyond initial emergency treatment

(e.g. CPR and use of an AED).

Hospitals without emergency departments that contract for If the co-located hospital being surveyed is identified as providing emergency services with another hospital's or has an emergency department-are then considered to provide, the hospital would be subject to the emergency services requirements (see §482.55) and must meet the requirements of EMTALA. See §1867 of the Act and 42 CFR §§489.20-24.

Survey Procedures<mark>Distinct and Shared</mark> 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 beingsurveyed and the spaces used by the other co-located entity. The floor plan must clearly identifywhich 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 beingsurveyed. 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. Thisinformation is critically important as surveyors must know what specific space/locations to surveyand what services are being directly provided by the hospital being surveyed or are beingprovided 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 throughpublic 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 canpotentially 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 alsopotentially 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. identify any spaces used by the hospital being surveyed and any shared spaces used by the other co-located facilities. If both facilities utilize the same space, any non- compliance found in the space being surveyed would be cited for the hospital being surveyed and could trigger a complaint in the co-located facility based on the facility's regulatory requirements. Surveyors are not expected to be evaluating spaces for co-location, but rather determining if the hospital being surveyed is in compliance with the hospital CoPs, independent of its co-located provider.

For example, a co-located hospital may be sharing a supply storage room with a co-located hospital where each hospital identifies their supplies separately within the same space. The surveyor identifies that there is a water leak in the ceiling of the room that is dripping water on to the sterile packed supplies causing a breach in the package. This would be identified as a deficiency related to physical environment and infection control for the hospital being surveyed. This could also trigger a complaint for the co-located hospital because the same deficiencies would be present in the co-located hospital.

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-sitelocation. Surveyors must assess how the governing body ensures compliance with the CoPsthrough 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 spacebecause 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 intoits 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 fromthe other entity are not being simultaneously "shared" with another hospital or entity. Ask tosee 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 individualsproviding services under contract have been oriented and trained to provide care inaccordance with hospital policies and procedures.Review a sample of personnel files of individuals who provide services under contract and verify they have received requisiteeducation and training.The procedures for surveying contracted services would be the same for co-located hospitals as it would be for surveying any other hospital that has contracted services, see §482.12(e).

Emergency Services

When evaluating While surveying a co-located hospital, surveyors will need to determine if the emergency care of patients in a hospital without has 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, sterileequipment, code cart stocked?
- •Is hospital staff properly trained for appraisal of emergencies, initial treatment, and referral when appropriate?or is holding itself out as providing emergency services 24 hours a day and 7 days per week. If the hospital has no emergency department, but has its and not providing emergency services provided under a contract with surveyors should evaluate the hospital's compliance with the requirements.

<u>described in §482.12(f)(2). If the hospital has</u> an emergency department of a co-located hospital, verify that the hospital meets the, surveyors will defer to the requirements for Emergency Services at §482.55 and must determine that it meets requirements of 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. See §1867 of the Act and 42 CFR §§489.20-24.

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 during a survey of aa hospital that is co-located with another hospital or provider, the deficiency should be cited in the same manner as in other hospital surveys. The surveyor 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 undercontract 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 appropriatedata for quality control testing for the laboratory). If the other determining the scope and pervasiveness of the deficiency. If the deficient practice extends to the co-located provider, the surveyor must determine if the cited deficiency warrants a complaint investigation of the 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. Whileprovider. If so, then a complaint investigation will be performed. 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 (AOs) conducting surveys, 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 AOmust still treat the finding of non-compliance in the contracted service as a complaint in the colocated entity providing the contracted service and file the complaint as appropriate

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