

### Overview

- Summary of Past CMS Guidance
- Details on New CMS Guidance
- Review of Other Legal and Regulatory Issues

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### Why Now? New Guidance from CMS

- May 3, 2019: CMS issued national draft guidance regarding shared space arrangements after several years of uncertainty
- Guidance is available at:
   <a href="https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-13-Hospital.pdf">https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-13-Hospital.pdf</a>
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### History of Uncertainty • 2000: CMS indicated Regional Offices (ROs) would take lead on addressing questions concerning shared space and its effect on provider-based status • 2011: Chicago Regional Office letter to Indiana hospital • 2015: American Hospital Association first requested clarification from CMS about co-location

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### Advantages of Co-Location Arrangements

- Space sharing and co-location arrangements can:
   Enhance patient access and convenience

  - Improve quality of care
  - Mitigate duplication of overhead costs
  - Reduce costs overall by allowing providers the opportunity to share personnel, administrative services, and equipment expenses
- Impact of co-location in rural communities
  - Cost of regulatory compliance for rural hospitals is often higher than for larger facilities
  - Co-location arrangements help to build "critical" mass

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### **Definitions**

- CoPs: Medicare Conditions of Participation
- Co-location: Two hospitals or a hospital and another healthcare entity that are located on the same campus or in the same building and that may share space, staff, or services

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### BEFORE: CMS Disapproval of Shared Space Arrangements

- CMS signaled its disapproval of shared space arrangements through informal guidance including:
  - Revoking provider-based status or issuing nonprecedential, provider-specific decisions
    - Issued by CMS Regional Offices
  - Making statements in educational webinars that were critical of shared space arrangements
  - Responding negatively when asked for informal guidance

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### Mixed Messages

- Potential penalties for violation of providerbased rules are significant
  - May include recoupment of increased payments for all cost report periods subject to reopening or potential False Claims Act liability
  - Costs associated with correcting the problem
  - Issues associated with unutilized space if existing lease/co-location arrangements are no longer permissible

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# BEFORE: Core Concepts Hospital space required to remain hospital space at all times Co-mingling of space among separate providers prevented providers from complying with CoPs Co-located hospitals had to demonstrate separate and independent compliance with hospital CoPs

# Provider-based (hospital) space should be clearly held out to the public as hospital space and should be distinct and separate from freestanding space Separate clinical space Including exam and procedure rooms Separate patient registration space or waiting areas Limited exceptions permitted, such as shared nonclinical areas permitted Including atrium or elevator

### BEFORE: Separation of Operations Each hospital must have its own policies and procedures Separate staff including: Separate governing body Separate chief medical officer Separate medical staff Separate CEO



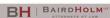
### DISTINCT AND SHARED SPACES

### Pistinct Spaces Requirement: Hospital must have defined and distinct spaces of operation for which it maintains control at all times Including clinical spaces designated for patient care Why are distinct spaces necessary for the protection of patients? Right to personal privacy Right to receive care in safe environment Right to confidentiality of patient records

### **Shared Spaces**

- Shared Spaces: Public spaces and public paths of travel utilized by both the hospital and the co-located healthcare entity are permitted
- Sharing or travel through a clinical space of a hospital by another co-located entity is **not acceptable** 
  - Clinical Space: Any non-public space in which patient care occurs

ACTION NAMED AND ADDRESS.



### **Public Space**

- Lobby
- Reception areas (but registration areas must be separate)
- Waiting rooms
- Hallways through separated clinical areas
- Public restrooms
- Cafeterias
- Gift shops
- Elevators
- Main corridors
- Main entrances
- Staff breakrooms and lounge areas

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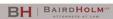


### **Clinical Space**

- · Inpatient units
- Observation units
- Hallways through inpatient/observation units
- Exam rooms
- Nurses stations
- Operating rooms
- PACU

- Emergency Department
- Therapy departments
- Imaging department
- Outpatient clinics
- "Check-in Area" (registration)

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### Survey Procedures: Distinct and Shared Space

- When surveying co-located hospitals, surveyor will consider:
  - Designated space(s) of co-located hospital and separation from other hospital or healthcare entity
  - Use of contracted services obtained from co-located entity and outside entities

### Survey Procedures: Distinct and Shared Space

- Surveyors must ask for:
  - Floor plan that clearly distinguishes space used by surveyed hospital from space used by co-located entity
  - List of all contracted services from other co-located or health care entities

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### Survey Procedures: Distinct and Shared Space

- Floor plan will be reviewed for CoP compliance:
  - Spaces within co-located hospitals are defined and identified as belonging to hospitals
  - Spaces belonging to another entity are accessed through a public path of travel (and not via travel through clinical areas)
  - Public spaces that are shared by hospital and other entities are identified as belonging to both
- Surveyor will identify locations of required and optional hospital services and departments to determine if there are any shared spaces or services

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### **Contracted Services**

- Requirement: Hospitals are responsible for providing all services in compliance with CoPs
- Services may be provided under contract by or with co-located hospital

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### **Contracted Services**

- Examples of contracted services:
  - Laboratory
  - Pharmacy
  - Radiology
  - Dietary
  - Food service
  - Maintenance
  - Housekeeping
  - Security
  - Physical plant services (oxygen, medical gas, sprinkler systems, alarm systems)

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### Survey Procedures: Contracted Services

- Surveyors must survey actual physical location where contracted services are provided if it is physically located on-site
- Surveyors must assess how the governing body ensures compliance with CoPs through QAPI activities

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### STAFFING WITH CONTRACTED STAFF

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### Staffing

- Requirement: Hospitals are responsible for independently meeting staff requirements of CoPs
- If staff is working under arrangement from another entity, must be assigned to work solely for one hospital during specific shift
  - No "floating" between hospitals/entities while on shift
  - No concurrent "on-call" duties
  - No providing services simultaneously

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### Nurse Staffing • Immediate Availability for Nurses: - §482.23(b) of Nursing Services Standard requires immediate availability of an RN for bedside care of patient if needed

### Medical Staff

- Guidance above for Hospital staff does not apply
- Physicians and non-physician practitioners permitted to move between co-located hospitals if approved medical staff are privileged and credentialed at each hospital
  - But watch for other CMS requirements that could limit this

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### Administrative Staff

- Directors of Nursing, Pharmacy, and Laboratories
- Under draft guidance, would not be able to "float," be on call, or work simultaneously
- Would patient interests be best served by having single director on these areas?

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# Survey Procedures: Staffing Contracts • Surveyors review contracts for staffing services with co-located entities to ensure 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 adhere to the quality and performance improvement standards of hospital - Accountability of contracted staff related to clinical practice requirements

### Survey Procedures: Staffing Contracts Surveyors review staffing levels and schedules to ensure immediate availability for services as required by hospitals May ask for verification that services obtained under contract from co-located entity are not simultaneously furnished there as well May ask to see staffing schedules to verify individuals are not scheduled to work simultaneously for both entities May ask governing body to demonstrate that contracted staff have been oriented and trained on hospital policies and procedures May also ask how performance of contracted staff is monitored

# CONTRACTED CLINICAL SERVICES

### Contracted Clinical Services Hospital is "not necessarily required" to notify patients of all services provided under contract or arrangement from another co-located hospital or other healthcare entity BH | BAIRDHOLM\*\*

# EMERGENCY SERVICES BH BAIRDHOLM\*\*

### Requirement: Hospitals without emergency departments must have appropriate policies and procedures to address individual emergency needs at all times Policies and procedure should include: Identifying when a patient is in distress How to initiate an emergency response How to initiate treatment Recognizing when patient must be transferred to another facility to receive appropriate treatment

### Requirement: Emergency policy and procedures must reflect potential emergency scenarios typical of the patient population a hospital routinely cares for

### Contracting with a co-located hospital for code teams or rapid response teams to appraise and initiate treatment of patients in an emergency is permitted BUT ONLY when the contracted staff are not working or on duty simultaneously at that other hospital If a hospital "contracts for emergency services" with another hospital's emergency department, hospital considered to provide emergency services and must meet requirements of EMTALA

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### Appropriate Transfer in an Emergency It is acceptable for a hospital to refer or transfer patients with emergency conditions to co-located hospitals if transferring hospital cannot provide care beyond initial emergency treatment

# Survey Procedures: Emergency Services • Surveyors consider the following: - Does hospital respond to its own in-hospital emergencies, with its own trained staff? - Does hospital have emergency equipment in the event that patient requires resuscitation? - Is hospital staff properly trained in use of emergency equipment? - Is emergency equipment properly maintained? - Is hospital staff properly trained for appraisal of emergencies, initial treatment, and referral when appropriate?

### Survey Procedures: What if a Deficiency is Found?

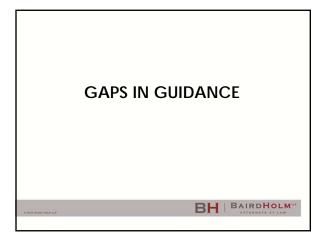
- If deficiencies are identified, deficiencies will be assessed under particular CoP <u>and</u> the governing body CoP
  - Why? Governing body is responsible for oversight of all contracted services provided in the hospital
- Could also result in deficiency under QAPI CoP

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### Survey Procedures: What if a Deficiency is Found?

 If other co-located entity providing noncompliant contracted service is CMS-provider or supplier, surveyor files complaint with state agency or regional office regarding that entity for further review

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### Leased Space/ Lessee Specialty Clinics

- CMS has stated in PowerPoint presentation on 6/5/19:
  - "A leased space is not co-location as the tenant is responsible for that space under the terms of the lease agreement with the landlord hospital"
- However, many co-location arrangements are lease arrangements

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### **Timeshare Services**

- In the same presentation, CMS also noted that sometimes visiting providers use space, equipment, and supplies within a hospital at particular times (i.e., provider-based specialty clinics staffed by visiting physicians)
- CMS stated that in these cases hospital is responsible for maintaining space and services in compliance with CoP requirements

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### Other Open Issues

- Grandfathering?
- Shared EMRs
- What services cannot be contracted (i.e., can a hospital contract for all or almost all services?)

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### OTHER REGULATORY ISSUES AFFECTING HOSPITAL LEASE ARRANGEMENTS

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### Other Regulatory Issues Affecting Hospital Lease Arrangements

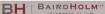
- Fraud and Abuse Laws
- Non-Profit Status
- Reimbursement Rates
- Property Tax Exemptions
- Bond-Financed Space
- State licensure requirements
- Other CMS "Separateness" Requirements

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### Comments

- Deadline July 2<sup>nd</sup>
- Submit comments via email to HospitalSCG@cms.hhs.gov
- Not clear how long CMS will take to review comments and finalize guidance
- If would like our assistance in submitting comments, please contact us





### Feedback to AHA

- AHA seeking comments and scenarios from hospitals that describe patient care issues or hardships caused by draft guidance
  - Considering requesting explicit guidance on specialty clinic arrangements
- AHA contacts:
  - Nancy Foster, Vice President of Quality and Safety Policy (Nfoster@aha.org)
  - Mark Howell, Senior Associate Director of Standards and Drug Policy (Mhowell@aha.org)





