American Health Law Association
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Provider Co-Location: The Final Word or More to Come?

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Agenda

- Enforcement environment
- Stark Law and Anti-Kickback Statute
- Medicare coverage
- Provider-based regulation
- BBA, Cures Act, OPPS developments
- CoPs & other important requirements
- Supplier considerations
- Examples

Outline of Accompanying Paper

1. Overview of Key Federal Regulatory Considerations
    A. Stark Law
    B. Anti-Kickback Statute
    C. Medicare Coverage Requirements
    D. Overview of Key Hospital Considerations
    E. Hospital Conditions of Participation
    F. Provider-Based Status
    G. Changes to OPPS Payments for Certain Provider-Based Sites

Outline of Accompanying Paper

2. Under Arrangements Standards
3. Unique Standards for Certain Categories of Providers
4. Discussion of Guidance on Regulatory Restrictions
5. Ambulatory Surgery Centers
6. Independent Diagnostic Testing Facilities
7. DMEPOS Suppliers
8. Rural Health Clinics / Federally Qualified Health Centers
9. Clinical Laboratories

Enforcement Environment

- Where does the issue come from?
- Pros:
  - Higher Medicare payment
  - Coverage issues
  - Potential eligibility for 340B program drug pricing
  - DSH and medical education payments
- Cons:
  - Compliance burdens
  - Public perception / patient confusion (multiple bills!)
  - Construction and design
  - Higher prices
- Site neutrality developments

What Happens If You Get It Wrong?

- Historic enforcement?
  - Various agency reports as basis for enforcement
- Potential problems:
  - False Claims Act liability
  - OPPS payback
  - Plans of correction
  - Termination of provider agreement;
  - Additional build out costs to achieve required separation.
- What was coming?
  - “Changes to current co-location policies are under discussion”, so are when “leased space … is not shared space” and when hospital corridor is a “public path of travel”
- What ended up coming?
  - QSO-19-13-Hospital (11/21/21)

Provider Co-Location: So Can You Just Put Up a Shingle?

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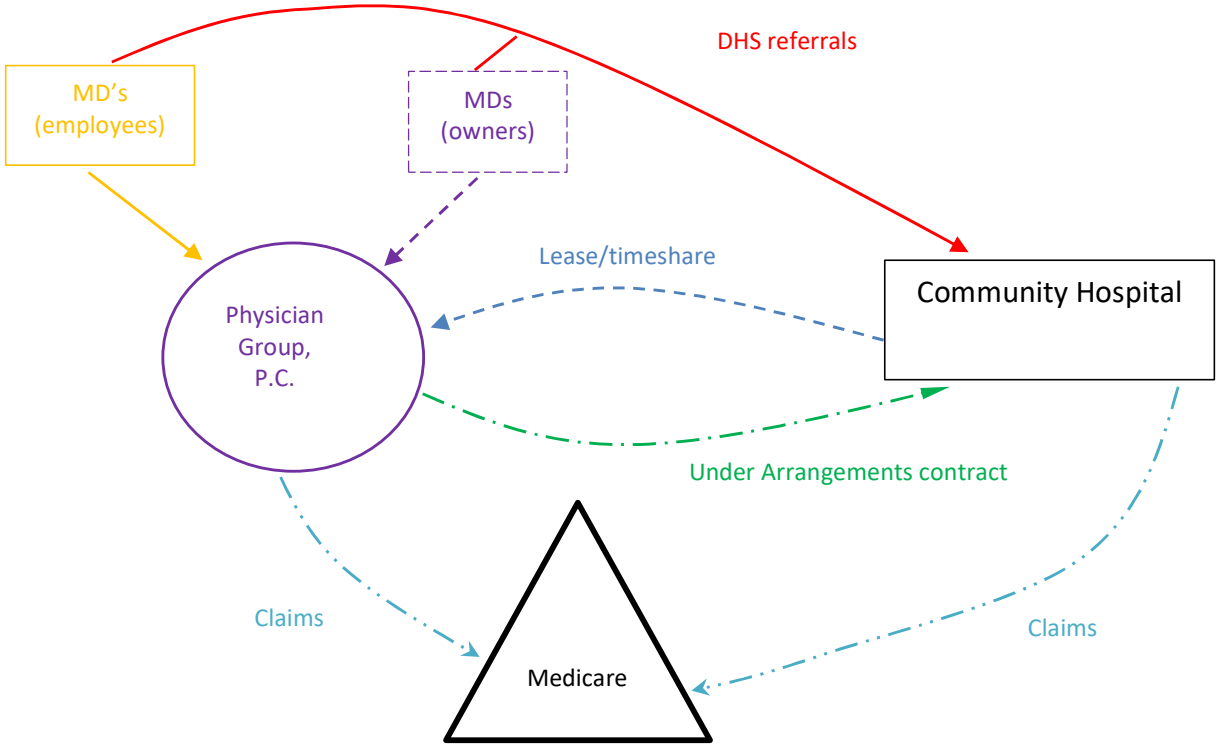
Stark Law and Anti-Kickback Statute



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Stark Law and Anti-Kickback Statute

- Key Stark Law issues:
  - Does the Stark Law apply?
  - Designated health services
  - Referring physician
  - Definition of “entity”
  - “Stand in the shoes”
  - Per-click and percentage-based payment terms in leases (or timeshares)

Stark Law and Anti-Kickback Statute

- Key Stark Law issues (continued):
  - What about the exceptions?
    - Group practice / in-office ancillary services
    - Rental of office space
    - Rental of equipment
    - Personal service arrangements
    - Fair market value arrangements
    - Indirect compensation arrangements
    - Timeshare arrangements

Stark Law and Anti-Kickback Statute

- Key Anti-kickback Statute issues:
  - Does the Anti-kickback Statute apply?
  - No specific intent required
  - Safe harbors challenging to meet
  - What is a contractual joint venture and is this one of those?
  - OIG's "advisory opinions" as a roadmap to success?

Medicare Coverage Requirements

- Who can provide services?
- Where do services need to be provided?
- What needs to happen for services to be provided?
- Who can (or must) bill for the provided services?
- How does when the services are provided affect billing?
- And the same rules apply for Medicaid, right…?

Overview of "Provider" Considerations

- 42 C.F.R. § 482 (hospital conditions of participation)
- 42 C.F.R. § 488 Subpart A (accreditation and survey rules)
- 42 C.F.R. § 489 (provider agreement)
- 42 C.F.R. § 413.65 (provider-based regulation)
- Many others (e.g.):
  - 42 C.F.R. § 412.22(e)—(g) (IPPS-excluded rules)
  - 42 C.F.R. § 412.22(h) (satellite rules)

Definitions of Hospital

- Meet definition of hospital for Medicare under Social Security Act (42 U.S.C. 1395x(e))

  AND

- Meet licensing requirements for State or local licensing body

Statutory Requirements of a Hospital Under Medicare

- “Primarily engaged” in providing services to inpatients;
- Expectation inpatient will require hospital care for at least two midnights;
- Maintain clinical records on all patients;
- Have medical staff bylaws;
- Every Medicare patient must be under the care of an MD/DO;
- The hospital provides 24-hour nursing service; and
- Licensed or approved as a hospital as defined by the State.

What is “Primarily Engaged”?

- Average Daily Census (ADC)
- Average Length of Stay (ALOS)
- Number of Off-Campus Outpatient Locations
- Number of Provider-Based Emergency Departments
- Number of Inpatient Beds Relative to Size of Facility and Score of Services
- Volume of Outpatient Surgical Procedures versus Inpatient
- Staffing Patterns
- Patterns of ADC

Conditions of Participation

- Increased focus over the years on CoP compliance
- Pre-QSO-19-13 informational powerpoints
- Comments included:
  - Hospital must meet CoPs at all times.
  - Hospital may not depend upon another entity for compliance with the CoPs. Applies to:
    - All parts of the certified hospital;
    - Co-located hospitals, other providers or suppliers, or other non-hospital activities;
    - Other hospitals, or other providers or suppliers, that are not co-located with the hospital;
  - Hospital space is hospital space, 24/7; cannot be "part time" part of the hospital and "part time" another hospital, ASC, physician office, etc.
  - Co-located hospital cannot share landlord / tenant's hospital space

Conditions of Participation, con't

- Pre-QSO-19-13-Hospital comments included:
  - Permitted for two (or more) entities to be co-located as long as each entity has distinct space which is under that entity's control at all times
  - CMS was considering
    - Another entity (physician practice, hospital, ASC.) using / leasing / renting space that is space also used by hospital A
      - For example: hospital rents space to a visiting physician one day a month. When the space is rented to the physician, the space is not hospital space.
  - Following not permitted:
    - Hospital B or ASC C leasing Hospital A's operating rooms on days or hours when Hospital A not using their OR
    - Hospital A leasing surgical space from another entity on a "part-time" basis
    - [At present] Another entity (physician practice, hospital, ASC, etc.) using / leasing / renting space that is also used by hospital A

2011 RO Enforcement Letter: Radiology Co-Location

- Hospital established off-campus site to house hospital's radiology department and freestanding imaging center
- RO denied provider-based status after learning of shared space arrangement
- RO focused on following concerns:
  - Radiology department was not included on the main hospital's license
  - Insufficient integration between services at freestanding site and hospital (e.g., medical records)
  - Not financially integrated with those at the main hospital

2011 RO Enforcement Letter: Radiology Co-Location

- Provider-based space not held out as separate and distinct from freestanding space
- Indications that “purported hospital space may instead be a part of a larger component" include:
  - Shared entryway
  - Interior hallways
  - Bathroom facilities
  - Treatment rooms
  - Waiting rooms
  - Registration areas
- RO took issue with the “ownership and control” and “administration and supervision” standards

QSO-19-13-Hospital May 2019 (Proposed)

- *Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities*
- Key principles:
  - Independent compliance with CoP
  - Expected to have defined and distinct spaces of operation for which hospital maintains control at all times
  - Distinct space includes clinical spaces designated for patient care
  - Shared space = public spaces, paths of travel that are used by both co-located entities
    - Public lobbies, waiting rooms and reception areas (with separate check-in and clear signage), public restrooms, staff lounges, elevators and main corridors through non-clinical areas and main building entrances
  - Not acceptable to travel between separate entities using path through clinical space
  - Surveyors directed to review floor plans
  - CMS requested comments on implications of guidance

QSO-19-13-Hospital 2021 (Revised)

- Key Principles
  - Eliminated most examples of prohibited / permitted arrangements from draft
    - Discussion of “distinct space” and “public paths of travel” removed
    - No discussion of restrooms, waiting rooms, lobbies, entrances, etc.
  - Hospitals evaluated as whole for CoP; required at all times to meet definition of “hospital” under SSA
  - Co-location permitted; up to hospital to assess whether co-location presents risks of noncompliance with CoPs
    - Examples of types of CoP considerations include patient rights, infection prevention and control, confidentiality, governing body, physical environment
  - Different focus for surveyors than in draft
  - Addresses contracted services, emergency services, staffing

Provider-Based Status

- Becoming provider-based
- Location, location, location:
  - Definition of “campus”
    - Does 250 yards = 250 yards?
    - Who gets to decide?
  - How far away can one be, while still being “off campus”?
    - 35 miles
    - 75% tests

Becoming Provider-Based

- Both “on” and “off-campus” must comply with the following:
  - Same license, ownership, and control as the main provider (if allowed by state law)
  - Clinical services integrated with main provider (e.g., medical records, oversight, privileges. etc.)
  - Financial operations of the facility integrated with main provider
  - Facility held out to the public as part of the main provider (the public awareness test)
  - Hospital outpatient departments and hospital-based entities must meet certain additional requirements

“Off-Campus” Requirements

- Meet the “on campus” requirements
- Ownership and control
- Administration and supervision
- Additional obligations include:
  - EMTALA
  - Physician services billed appropriately
  - Medicare patients treated as hospital outpatients
  - Comply with provider agreement
  - DRG 3-day payment window applies
  - Non-discrimination
  - Applicable CoPs and Life Safety Code
  - Notice of beneficiary coinsurance

“Special” Provider-Based Rules!

- Joint ventures:
  - Not permitted for “off campus” arrangements
- “Under arrangements” arrangements
- Management contracts:
  - Off-campus facilities subject to an added set of requirements if they are operated under a “management” contract
  - Restrictions on employment of personnel who are involved in patient care but cannot bill

Potential Provider-Based Challenges in Co-Location

- HOPDs required to comply with CoPs. But meeting CoP does not mean payment rules (e.g., provider-based requirements) are met.
- Defining a “department” of a provider
- Public awareness
- Notice of coinsurance provided to beneficiaries
- All Medicare patients to be treated as hospital outpatients

No one said it would last forever…

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No one said it would last forever… Changes to OPPS Payments

- 3 Important laws:
  - 2015 Bipartisan Budget Act
  - 21st Century Cures Act
  - 2017 OPPS rulemaking
- As of 1/1/17, no “new” off-campus dept. can bill under OPPS unless they are:
  - “Dedicated emergency departments”
  - “Grandfathered”
- Limited exception for facilities in “mid build” status
- On-campus clinics are exempt

No one said it would last forever… Changes to OPPS Payments cont.

- Relocation only in “extraordinary” circumstances
- Hospitals are permitted to add new services (expand clinical service families) without losing OPPS rates
- Limitations on transactions
- 2019 OPPS stabilization of rates at excepted off-campus PBDs with non-excepted off campus PBDs
- Federal court decision struck down cuts
- Court of appeals reverses and upholds site neutrality

Other Provider Co-Location Ideas/Concepts/Options:

- Under arrangements
- Hospital within hospital
- Distinct part units
- Co-located hospitals
- Critical access hospitals
- Leased therapy pools
- Separately certified entities on hospital campus
- CORFs
- What about provider-based time shares?

“Under Arrangements” Arrangements

- Medicare guidelines permit “under arrangements” relationships
  - But what are they?
  - And do they always work?
- Achieving a valid under arrangements contract
- Provider-based rule prohibits all patient care services from being provided “under arrangements”
- Different rules for different services:
  - Therapeutic services
  - Diagnostic services

Hospital within Hospital ("HwH")

- At least one hospital excluded from IPPS
- Hospitals to operate separately or IPPS excluded hospital will lose its exclusion
- Must be a:
  - Separate governing body
  - Separate chief medical officer
  - Separate medical staff
  - Separate CEO
- Maintain compliance with Medicare CoPs like any other hospital

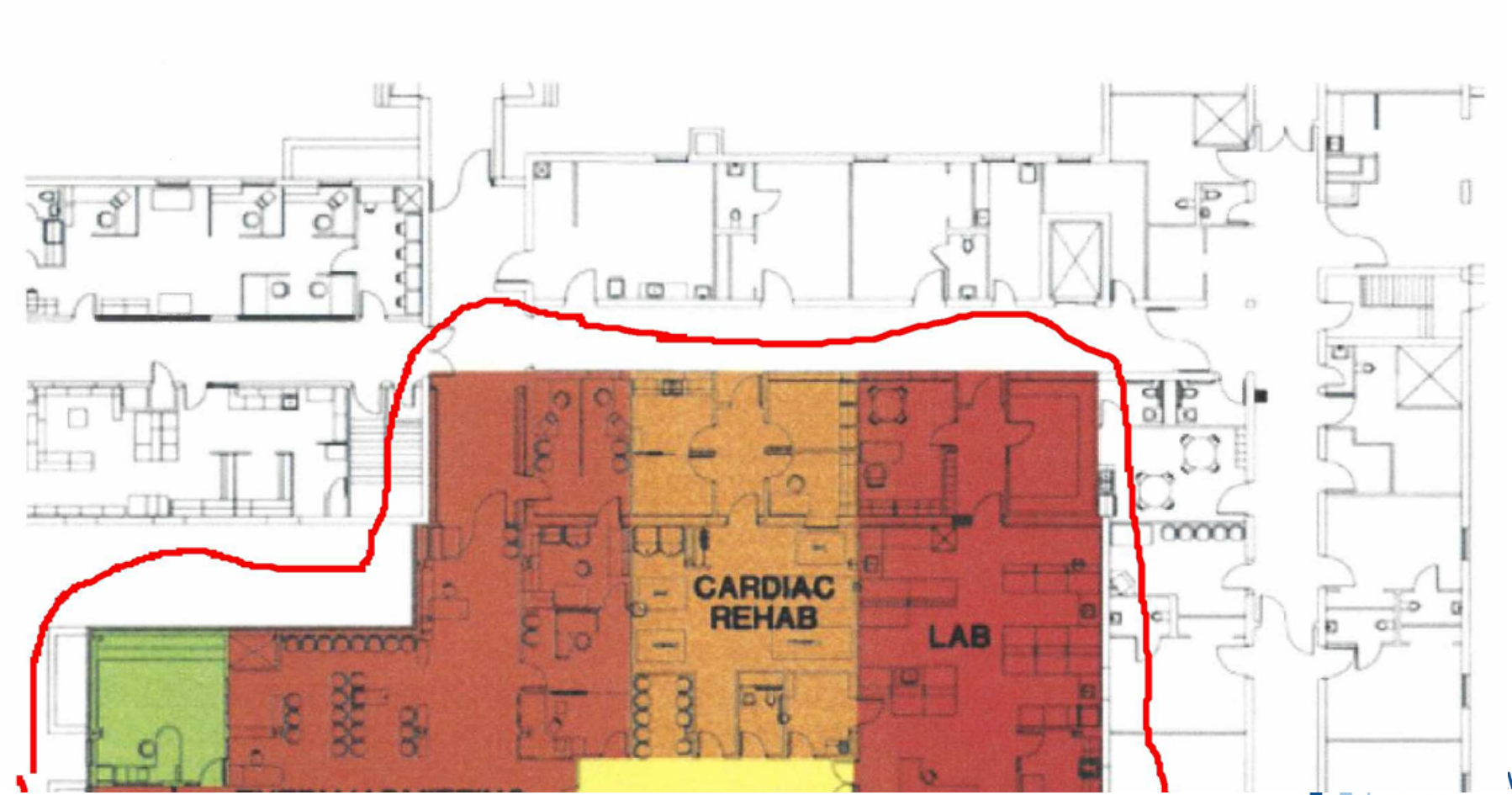
Distinct Part Unit ("DPUs")

- Specific provider excluded from IPPS and co-located with a hospital
  - Psych, rehab, skilled nursing units that are excluded from IPPS and located in hospital
- Must meet relevant CoPs as well as following:
  - Physically separate space and separate beds
  - Separate admission and discharge records
  - Separate cost center in hospital's cost report
  - Fully equipped and staffed—can share nurses and staff, but only within certain parameters

How About a Timeshare?

Co-Location Example 1: Same Floor + Separation

- Hospital has provider-based clinics on same floor of MOB as physician freestanding clinics
- Hospital patients can reach hospital clinic entry area by taking elevator from first floor lobby/common areas
- Separate entry area and elevator for freestanding clinics (also from first floor lobby/common area)


CARDIAC
REHAB
LAB

Co-Location Example 2: Same Floor + Separation?

- Provider-based and freestanding clinics in MOB
- PB and FS clinics have separate entries and waiting areas
- But patient registration happens in common area gallery, with patients then going into respective clinic entryways
- Separate waiting rooms in clinic space
- PB and FS also have “behind the scenes” resource sharing arrangement

Enforcement Examples

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Enforcement Examples

- St. Peter's Hospital (MT), Oct. 2015:
  - Hospital leased space to visiting specialty group
  - Lessee used space to operate its own practice location and bill Medicare using a physician office POS
  - 2 sites at issue:
    - 1 in the same building as the main hospital
    - 1 in clinic across the street.
  - Because one of the clinics was in the main hospital building, agency “did not believe that the public can adequately differentiate between hospital-employed physicians and the specialists that visit from out of town”
  - Repayment of approximately $1.5M from the hospital reportedly sought

Enforcement Examples

- Franciscan Health (Jan. 2021):
  - Related to 2016 OIG Report (*CMS is Taking Steps to Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain*)
  - Involved requirements that (a) physician services be billed with correct site of service and (b) that all Medicare patients be treated as hospital outpatients for billing purposes
    - 413.65(g)(2); 413.65(g)(5)
  - Apparent email from CMS related to OIG report and potential failure to comply with provider-based regulation
  - Hospital argued that physician group responsible for billing requirements because hospital not identified on claim as billing provider
  - No attestation filed:
    - "[w]hile it was not required to do so … [hospital] assumed a period of risk for providing and billing for services without the benefit of a provider-based status determination."

Enforcement Examples

- University of Miami (May 2021)
  - $22 million settlement (False Claims Act) related to failure to provide beneficiary notice of coinsurance
    - 413.65(g)(7)
    - Other allegations as well (unrelated to provider-based rules)
  - Conversion of physician practices to HOPDs
  - Hospital had received patient complaints related to the issue; also had received guidance from MAC
  - Failure to provide adequate notice meant claims could not be properly billed under hospital outpatient place of service
  - Relators included chief compliance officer and chief operating officer

Enforcement Examples

- Cleveland Clinic Foundation (Jul. 2021)
  - Hospital operates sleep testing location at off-site, unaffiliated Marriott Hotel
  - Court analyzed whether hotel rooms could qualify as a “department of a provider”
  - CMS asserted it could not qualify because department requires separation from other facilities
    - Exclusive entrance, waiting and registration areas, permanent walls and distinct suite designation recognized by USPS
  - Patients instructed to check in with hotel’s front desk staff, inform staff why patients were there
  - Commingling of space between hotel guests and sleep test patients
  - Court focused on attributes of physical facility necessary to be a “department”

Enforcement Examples

- Cleveland Clinic Foundation (Jul. 2021), con't.
  - Public awareness aspect of arrangement did not appear to be the problem
  - On issue of lack of wall / door separating sleep testing area from rest of hotel, court noted:
    - "in the absence of any authority to provide a more restrictive meaning to the phrase 'specific physical facility' the sleep center comprised separate physical space within the Marriott and that the space is sufficiently sectioned off from the rest of the hotel even if its entrance and common areas are shared with the hotel".

Do Other Providers / Suppliers Need to Worry About This?

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Ambulatory Surgery Centers ("ASCs")

- ASCs subject to their own restrictions on co-location
- Based on ASC "distinct space" concept
- CMS has articulated a range of principles on ASC co-location
- Some are general, others are specific to ASC relationships with other provider/supplier categories (e.g., other ASC, imaging, physician clinic, etc.)

Ambulatory Surgery Centers ("ASCs")

- Examples:
  - Need to be separated from other facilities or operations within the same building by walls with at least a one-hour separation
  - Does not have to be completely separate and distinct physically from another entity if temporally distinct
  - Certain common, non-clinical spaces, such as a reception area, waiting room, or restrooms can be shared , as long as they are never used by more than one entity at any given time
  - MD office may use the same waiting area, as long as MD office is closed while the ASC is open and vice-versa
  - Common space may not be used during concurrent or overlapping hours of operation of the ASC and MD office
  - Separate medical and administrative records

Ambulatory Surgery Centers ("ASCs")

- Other ASC principles (examples):
  - No non-hospital institutional healthcare entity that performs both surgeries and diagnostic imaging
  - Certain radiology services integral to surgical procedures may be provided in ASC
  - ASCs may not share space, even when temporally separated, with IDTF
  - Different ASCs may use the same physical space, including the same operating rooms, so long as they are temporally distinct
  - ASC cannot share space with a provider-based surgery department / hospital
    - "since the regulations at 42 CFR 413.65(d)(4) require that the provider-based department be held out to the public as part of the main hospital, and that patients entering the provider-based facility are aware that they are entering the hospital".

Independent Diagnostic Testing Facilities ("IDTFs")

- IDTFs are subject to a range of certification standards and operational requirements that make co-location challenging:
  - Specific standards related to hours of operation, equipment calibration, beneficiary complaints, insurance, physician supervision, etc.
  - General prohibition on IDTF sharing practice location; leasing or subleasing its operations or its practice location; and sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled party
- IDTFs can share certain common space, including waiting and reception areas, with another Medicare-enrolled party
- More flexibility for hospital-based IDTFs, which are permitted to share space with a hospital, including both clinical and non-clinical space

DMEPOS Suppliers

- DMEPOS suppliers prohibited from sharing a practice location with another provider or supplier
- Limited exceptions:
  - Practitioners furnish DMEPOS items to their own patients
  - Certain providers
- Range of other specific standards apply:
  - Minimum square footage, public accessibility, staffed during posted hours, permanent signage, recordkeeping, etc.
- Consignment closets:
  - Viewed with suspicion
  - Guidance proposed several times to prohibit closets, but not finalized

RHCs / FQHCs

- Prohibitions on “commingling”
  - Sharing of RHC / FQHC space, staff (employed or contracted), supplies, equipment and / or other resources with an onsite Medicare Part B or Medicaid fee-for-service practice operated by the same RHC / FQHC physicians / NPPs.
  - Practitioners not permitted to furnish or separately bill for RHC / FQHC-covered services under Part B in the RHC / FQHC itself or in an area outside of the certified space such as a treatment room adjacent to the RHC / FQHC, during hours of operation
  - If located in same building as another entity, space must be clearly defined
  - Can share resources such as waiting rooms, telephones, receptionists, etc., with another entity; RHC / FQHC must maintain accurate records to assure that all costs claimed for Medicare reimbursement are only for the RHC / FQHC staff, space or other resources.
    - Shared inputs must be allocated appropriately between RHC / FQHC and other usage so as to avoid duplicate reimbursement.

Clinical Laboratories

- Labs subject to their own set of regulatory standards under CLIA
  - Scope of regulation depends on testing complexity
- Labs that perform high complexity testing are required to meet conditions and standards found in the following subparts of the CLIA Regulations:
  - Subpart C (for a certificate of compliance) or Subpart D (for a certificate of accreditation);
  - Subpart F (general administration);
  - Subpart H (proficiency testing for labs performing non-waived testing);
  - Subpart J (facility administration for non-waived testing);
  - Subpart K (quality system for non-waived testing);
  - Subpart M (personnel for non-waived testing); and
  - Subpart Q (Inspection).
- General rule = each lab needs its own CLIA certificate (exceptions exist)

Clinical Laboratories

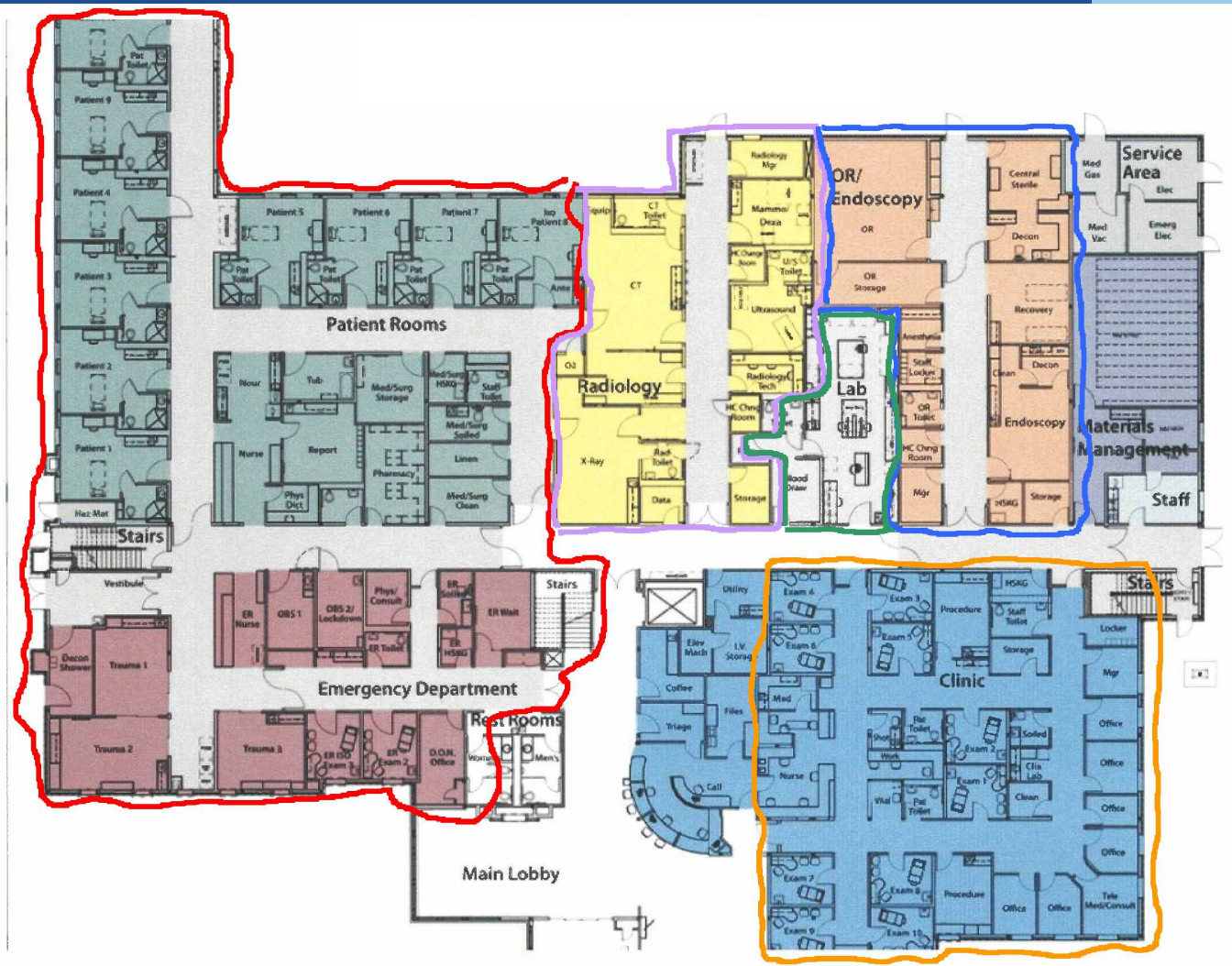
- CLIA “proficiency testing” can be trap for co-located (and other) labs:
  - Due to the potential for the two labs to refer (even inadvertently) proficiency testing samples between them (or more likely personnel purportedly working for each of the labs) for analysis
  - Or engage in “inter-laboratory communication”
- Medicare guidelines provide that a hospital can provide clinical laboratory services directly or obtain them from an independent laboratory under arrangement
- “Independent lab” = independent both of an attending or consulting physician's office and of a hospital that meets at least the requirements to qualify as an emergency hospital

Clinical Laboratories

- QSO-18-20-CLIA (Jul. 2018) (*Clarification of the Operation of Multiple Laboratories at the Same Location and the Discontinued Use of the Term "Shared Laboratory"*):
  - Multiple labs may operate at the same physical location (e.g., same building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate that it is operating as a separate and distinct entity
  - Multiple labs that operate "at the same physical location and use the same testing personnel and equipment must meet the following conditions":
    - All records separate and distinct; must clearly show each lab operating independently
    - Specified hours of operation
    - Separate and distinct hours of operation; no simultaneous or overlapping hours of testihg
  - Supersedes all prior guidance regarding the registration of shared laboratories for CLIA, including the use of the term 'shared laboratory'

Co-Location Example 3: Outpatient, Freestanding + Ancillary

- Provider-based and freestanding clinics located on same floor
- Physician group owns ancillary sites (also on that same floor):
  - IDTF
  - ASC
  - Clinical lab
- Both physician group and hospital desire to use lab and imaging. Hospital has its own surgery dept. in different location.



Thank you!

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