Chapter of HFMADV
Spring 2017

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PA Department of Health

DAAC Landscape

CHALLENGES

Staffing –

- Current Vacancies
  - Norristown: 2 (1 long term medical leave)
  - Lionville: 1
  - Harrisburg: 2
  - Jackson Center: 2
  - Central Office – 1 Assistant Director
- Possible Staff Retirements in Next 6 Months: (Note if Early Retirement passes 45% of all of QA will be eligible to retire)
  - Harrisburg: 1
  - Johnstown: 1

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Resources for Exceptions – DSI Retirements

§ 51.31. Principle.

The Department may grant exceptions to this part when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from this part will be granted if compliance with the requirement is provided for by statue.

§ 51.32. Exceptions for innovative programs.

This part is not intended to restrict the efforts of a health care facility to develop innovative and improved programs of management, clinical practice, physical renovation or structural design. Whenever this part appears to preclude a program which may improve the capacity of the health care facility to deliver higher quality care and services or to operate more efficiently without compromising patient or resident care, the Department encourages the health care facility to request appropriate exceptions under this chapter

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Other Challenges

- New Data System Delayed
- Increase in Right to Know Requests
- Licensure Renewals taking up until the 11th Hour to be able to approve

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Protocols

Survey Priorities – Effective September 8, 2016

DAAC will handle survey priorities as follows:

1. Federal EMTALA Surveys
2. Federal Complaint Surveys
3. Federal Recertification and Validation Surveys
4. State Licensure Renewal Surveys
5. State Complaint Surveys
6. Occupancy Survey to include: New Service/Equipment/ Outpatient Facilities
7. New State Licensure
8. New CMS Certification

Time Frames were established which included permissible extensions do to other priorities

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Protocols

- Out of Service Bed Memo – Effective 9/14/16
- New Facility Licensure Surveys and CMS Initial Certifications – Effective 10/3/16
- Verification Of Registered Nurse License of DAAC HFQE Nurse Surveyors and HFQE Nurse Supervisors – Effective 10/12/16 (Important for DOH Accreditation)
- Occupancy Survey and Granting Occupancy – Effective 10/15/16
- Collecting, Entering, and Updating Facility Master (FM) -Hospital Services and Ambulatory Surgical Facilities Surgery Types – Revised 10/15/16
- New Facility Licensure, Licensure Renewal, & Password Agreements – Effective 1/29/17
- Medicare Workload Survey Due Dates – Effective 2/3/17
- Adverse Action – 03/14/17

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Other Happenings

- Hospital – Space within the hospital the hospital indicates to DAAC its not part of hospital License.
  - DSI has always considered the Hospital as a whole and assures Life Safety Requirements are met.
  - DSI Plan Review assures that plans meet the FGI Guidelines
  - FGI Guidelines are a DAAC responsibility and shall be applied to the entire hospital – Breakdown in this responsibility in the past
  - DAAC and DSI Plan Review working in partnership to assure plans meet the requirements even in areas the Hospital leases to another entity
  - DAAC will survey lease space areas to assure compliance with the FGI Guidelines.

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Other Happenings

- Revised Hospital Regulations – 1st Internal review complete. Changes are and formatting is being finalized
- Continue to work closely with Patient Safety Authority
- Behavioral Health Assessments – Several Immediate Jeopardy called at Hospitals – Facility Identified issued but did not fix
- Reviewing how we handle occupancies – Patient care area vs support areas

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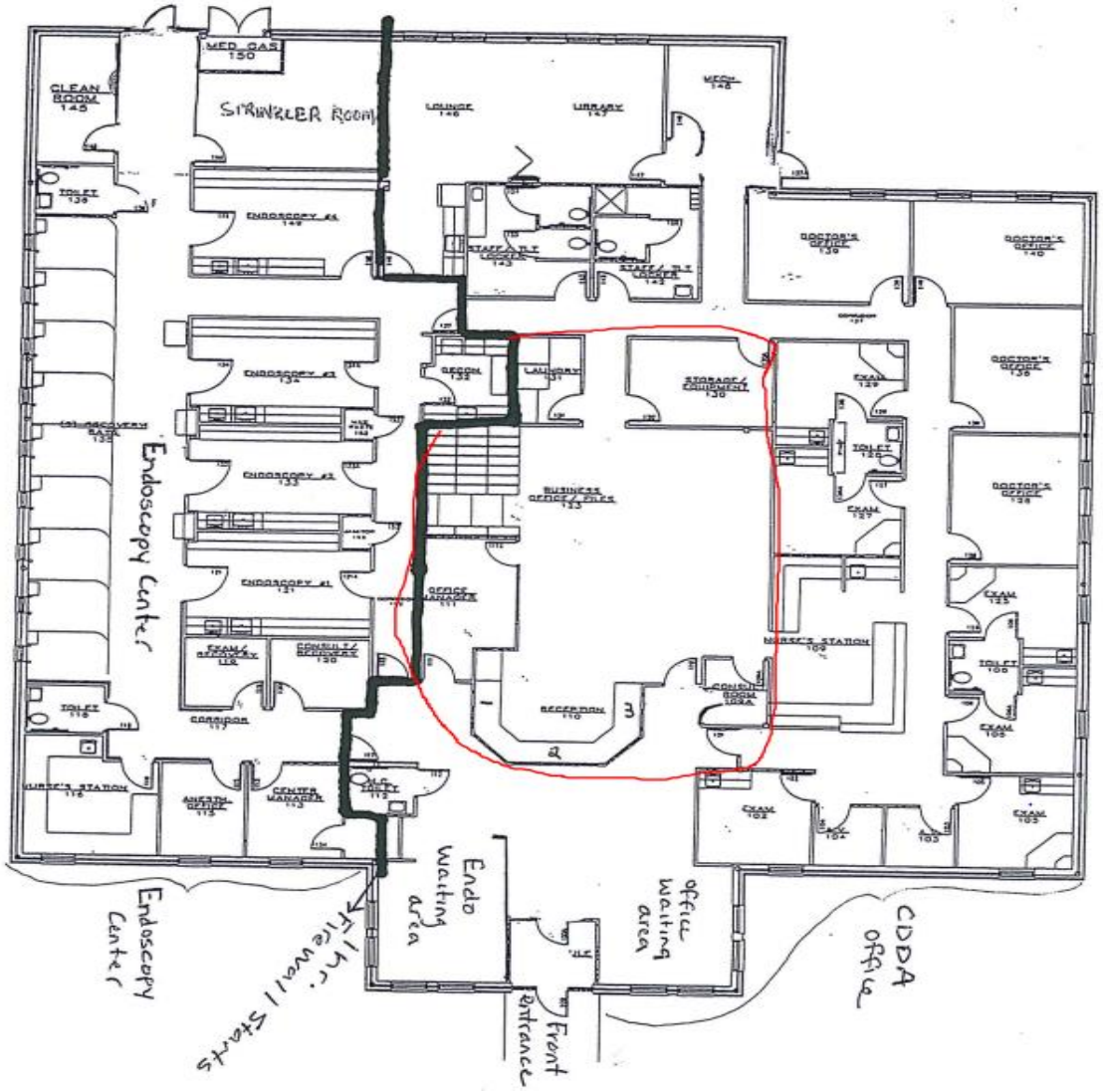
Shared Space Issues related to ASCs



The Area circled in Red is shared space and is an issue under the Conditions of Coverage for ASCs.

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CMS – ASC Distinct Entity

10.1 - Definition of Ambulatory Surgical Center (ASC)

An ASC for Medicare purposes is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients.

SCLetter10_20 Allowing for Life Safety Waiver for Shared Waiting Room only applies to the actual waiting room not to other shared spaces within the facility. Waiver can not be used for any new facility after 2010.

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CMS – ASC Distinct Entity

The regulatory definition of an ASC does not allow the ASC and another entity, such as an adjacent physician's office, to mix functions and operations in a common space during concurrent or overlapping hours of operations.

CMS does permit two different Medicare-participating ASCs to use the same physical space, so long as they are temporally separated. That is, the two facilities must have entirely separate operations, records, etc., and may not be open at the same time.

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CMS – ASC Distinct Entity

ASCs are not permitted to share space, even when temporally separated, with a hospital or Critical Access Hospital outpatient surgery department, or with a Medicare-participating Independent Diagnostic Testing Facility (IDTF).

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CMS – ASC Distinct Entity

How will it impact ASC's?

- During CMS Recerts, CMS Validation, and CMS Complaint Surveys, DAAC will be looking for any Shared Space issues. If identified a CMS deficiency will be cited as well as a State citation for § 551.52. ASF responsibilities.

- During State Licensure and Complaint Surveys, DAAC will be looking for any Shared Space issues. If identified a State citation will be written for § 551.52. ASF responsibilities.

  – An ASF shall comply with applicable standards which are required by Federal, State and local authorities.

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Provider Based and Shared Space

- Hospital requests to add outpatient location to hospital license
- Hospital sends an attestation to CMS to add provider based location
- Recently the Department has become aware of the requirements for provider based through discussions with CMS

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CMS - Provider Based and Shared Space

- A hospital must comply with the definition of a hospital (Social Security Act (SSA) 1861(e)) which is implemented at 42 Code of Federal Regulations 482.1.
- Hospitals are recognized as “providers of service” in SSA 1861(u). Under SSA 1866(a), any provider of services may be qualified to participate in Medicare if it enters into an agreement with Medicare. Such agreements with Medicare must apply to the provider in its entirety.

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CMS - Provider Based and Shared Space

- CMS does recognize that components of hospitals may be separately housed from the main provider. In these instances, the provider agreement applies to these components in their entirety.
- Official CMS guidance on this issue is found in the State Operations Manual (SOM), Chapter 2, Section 2026.
- This guidance specifically requires the State Certification Agency to evaluate each general hospital as a whole for compliance with the Conditions of Participation and to certify the hospital as a single provider institution, including all components.
- The SOM adds that it is not permissible to certify only part of a general hospital.
- The provider-based requirements and obligations found at 42 CFR Section 413.65 lists all of the criteria for components of the hospital to be considered as parts of the hospital, whether those components are located on or off the main campus of the main provider.

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CMS - Provider Based and Shared Space

Under the provider-based status regulation at 42 CFR 413.65, a “department of a provider” means:

- a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section.
- A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility.

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CMS - Provider Based and Shared Space

SOM, Chapter 2, Section 2026A:

- It is not permissible to certify only part of a general hospital. However, the following are not considered parts of the hospital and are not to be included in the evaluation of the hospital's compliance:
- Components appropriately certified as other kinds of providers or suppliers. i.e., a distinct part SNF and/or distinct part NF, HHA, RHC or hospice; and
- Excluded residential, custodial, and non-service units not meeting the definitions in §1861(e)(1) or (j)(1) of the Act."

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CMS - Provider Based and Shared Space

SOM, Chapter 2, Section 2004 - Provider-Based Determinations (Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14) states as follows:

- "Distinct Part" and "Provider-Based" are not synonymous terms. When a location, department, remote location or satellite is established as provider-based, it is an integral part of the provider, covered by the provider's Medicare agreement, and therefore subject to the same Medicare conditions of participation as any other part of that provider.
- Unless covered by a specific exception listed in the rule, the provider-based regulations at §413.65 apply to any provider of services under the Medicare program, as well as to physicians' practices or clinics or other suppliers that are not themselves providers, but which the provider asserts are an integral part of that provider.

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Impact on State Licensure

Hospital intends to add location to the hospital CCN.

- Either before or during the occupancy survey for state licensure if shared space is identified the Department will not be able to license the location pursuant to State Regulation § 103.4. Functions. The governing body, with technical assistance and advice from the hospital staff, shall do the following:. . . (3) Take all reasonable steps to conform to all applicable Federal, State, and local laws and regulations.

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Impact on State Licensure

Hospital does not intend to add location to the hospital CCN.

- If shared space issues are identified the Department will grant the State licensure occupancy contingent upon the hospital not adding the location to the hospital CCN.

Note: With CMS definition that a Hospital has to be considered in its entirety this may still be a CMS issue

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How the Department Will Handle

- As noted the Department will evaluate outpatient locations during occupancy to assure there are no shared space issues.
- If the Department is on a complaint investigation (associated with an outpatient location under the hospital license), State licensure, recertification, or validation survey, we will be evaluating provider-based locations for possible shared space issues.
- Citations – CMS and State 103.4 Functions

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Provider Based Questions Sent to CMS – CMS Response

Is it permissible to have a door between hospital and non-hospital space that will permit providers to go back and forth between the hospital/non-hospital space (not patients), or does it have to be a wall and the providers have to go out to the main hallway to access the other area, as the patients would?

It is not permissible to have a door between hospital and non-hospital space for providers to go back and forth. A door is ok for fire escape purposes only. It should be locked at all times, and unlock electronically only when fire alarm goes off. It is not ok for use as a path of travel. To separate space between a hospital and non-hospital entity, there must be a full wall, floor to ceiling, which meets Life Safety Code requirements.

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Provider Based Questions Sent to CMS – CMS Response

Can the following areas be “shared” within contiguous hospital/non-hospital space?

a. **Janitorial closet.** **Generally ok. A landlord may furnish housekeeping for both entities, or one may contract from the other for housekeeping services.**

b. **Conference rooms used by hospital and non-hospital at different times** **No. If the conference room is part of hospital which claims that space it must meet the Medicare cost reporting requirements. If a non-hospital entity, for example a doctor’s office owns the conference room, it may allow another entity to use that conference room. That does not apply the other way around if the hospital owns that conference room.**

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Provider Based Questions Sent to CMS – CMS Response

Can the following areas be "shared" within contiguous hospital/non-hospital space?

c. **Staff locker room and bathrooms -** **Shared bathrooms are ok. For locker rooms it depends on the situation. For example, an ASC can't use hospital's OR or the locker rooms for the OR. If the staff locker room belongs to physician's office, it's ok to allow hospital staff to use it. We would need a floor plan to look at for specifics.**

d. **American Cancer Society room -** **As long as it's truly not within hospital space and does require traveling through hospital space to get to that room. Square footage must be set-up on the Medicare Cost Report as non-reimbursable cost center.**

e. **Library area located in hospital space – can it be used by non-hospital patients as a quiet place or to research something?** **No, as it's part of the hospital. Must be set-up on the cost report as a non-reimbursable cost center.**

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Provider Based Questions Sent to CMS – CMS Response

Can you please confirm my understanding that the same shared space concerns would arise if a hospital and non-hospital provider (physician group) shared space within a singular component, notwithstanding whether the hospital leased the space within that component to the physician group, or if the physician group leased the space within that singular component to the hospital?

If I am understanding what you are describing is one unit (self-contained) in which the hospital and the non-hospital provider would be sharing. It would not matter who was leasing this scenario would still be shared space and not permitted.

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Provider Based Questions Sent to CMS – CMS Response

What impact does this new guidance have on two (2) separately licensed acute care hospitals that were approved by the DOH to use the same space at different times to operate a provider-based department (one week the department is operated by one hospital and the next week the department is operated by the other hospital)? This appears to be distinguishable to me from the guidance issued by the DOH as there are two hospitals involved (not a hospital and a freestanding facility) and the hospitals are not using the same at the same time. Do those hospitals now have a "shared space" issue?

CMS Response: CMS does see a shared space issue. CMS treats a hospital as a hospital 24/7, meaning that it can't be shared with another entity, even if separated by time. The space should be part of Hospital A or Hospital B, but cannot be part of both hospitals at one time or another. Instead of being allowed since it's not a 'free-standing entity', it will actually cause both hospitals to be in violation.

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Provider Based Questions Sent to CMS – CMS Response

If you see the waiting area as having a shared space issue, would that shared space issue be relieved through use of the following types of dividers (separate waiting room on each side with separate registration desks)?

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NO


NO


NO


No
No
No
No
No
No

DAAC Inspection Process

- Deviation from the approved/stamped plans, or not having the plans available when you arrive for the occupancy survey.
- The argument that if the project has been approved at Plans review, there can be nothing missing from the FGI requirements.
- Assuming that exceptions are a given in the event something is missing/ non-compliant.
- Facilities that will call and ask about a renovation project or change in use of an area, DAAC references something from FGI and it is like dear and deadlights

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DAAC Inspection Process

- There is probably another item that should be addressed, patient flow. While they may have all the components required by FGI, if the patient flow is wrong, i.e., causes an infection control issue, DAAC staff are looking at that as well.
  - One item that springs to mind is a “hot” patient in nuclear medicine. The flow and exposure of the other patients in the area sometimes causes a problem. They might have all the required rooms, but how that patient is moving thru the unit can sometimes be an issue.

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DAAC Inspection Process

- Some facilities that think DAAC can override recommendations made by Plan Review. Facilities need to be reminded that at the end of the day – DAAC and Plan Review support each other's decisions.
- DAAC surveys related to FGI guidelines—staff take that section of the FGI and survey the area against what is required, i.e., if they are doing a nursing area, they would copy the section of FGI that pertains to a nursing unit. In addition, they would be reviewing other items that would be pertinent to a nursing unit, new equipment (staff training), new staff (personnel files), etc.

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Questions?

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