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A MEDICARE LEARNING NETWORK® (MLN) EVENT

CMS Definition of a Hospital Requirements: Primarily Engaged

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Acronyms in this Presentation

- Accreditation Organization (AO)
- Ambulatory Surgery Center (ASC)
- Average Daily Census (ADC)
- Average Length of Stay (ALOS)
- Conditions of Participation (CoP)
- Emergency Department (ED)
- Medicare Administrative Contractor (MAC)
- Regional Office (RO)
- State Survey Agency (SA)
- State Operations Manual (SOM)



Agenda

- Overview of impetus for new guidance – David Wright
- Brief summary of new guidance – Marie Vasbinder
- Presentation of new guidance – Lisa Marunycz
- Question and Answer session

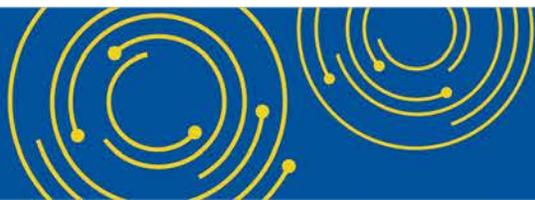


Impetus for New Guidance

- Several facility denials of participation in Medicare Program as a hospital
- Micro-hospitals
- Ambulatory Surgery Centers (ASCs) trying to enter the program as hospitals
- Section 603 (Provider-based outpatient department payment)
- Small hospitals with disproportionate number of off-campus emergency departments
- “Specialty” hospitals, such as emergency or surgical hospitals
- State licensing criteria for hospitals is not the same as CMS hospital definition



Overview of New Guidance



Definition of a Hospital

- Facilities must meet the statutory definition of a hospital to participate in Medicare as a hospital, Section 1861(e) of the Act and the regulatory requirements of part 488

§488.3 Conditions of participation, conditions for coverage, conditions for certification and long term care requirements.

(a) *Basic rules.* To be approved for participation in, or coverage under, the Medicare program, a prospective provider or supplier must meet the following:

(1) **Meet the applicable statutory definitions** in section 1138(b), 1819, 1820, 1832(a)(2)(C), 1832(a)(2)(F), 1832(a)(2)(J), 1834(e), **1861**, 1881, 1883, 1891, 1913 or 1919 of the Act.

(2) Be in compliance with the applicable conditions, certification requirements, or long term care requirements prescribed in part 405 subparts U or X, part 410 subpart E, part 416, part 418 subpart C, parts 482 through 486, part 491 subpart A, or part 494 of this chapter.

*Note that the regulation requires compliance with “applicable statutory definitions”



Definition of a Hospital (continued)

- Specifically requires that a hospital be primarily engaged in providing care to “inpatients”

1861(e) The term “hospital” (except for purposes of sections [1814\(d\)](#), [1814\(f\)](#), and [1835\(b\)](#), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, **to inpatients** (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;



Survey Requirements

- Surveyors must observe the provision of care and services to inpatients
- 488.26(c)(2) The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will **directly observe the actual provision of care and services** to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients.
- The potential or capacity to provide care to inpatients is not the same as the “actual” provision of care to inpatients.
- Facility must have at least 2 inpatients for a survey to be conducted



Appendix A New Interpretive Guidance



License Requirement

- Facility must be licensed as a hospital or approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.
- Compliance with this requirement does **not** mean that a facility meets the statutory definition of a hospital. Licensure is only one criteria in the definition.
- 1861(e)(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;



Basis and Scope §482.1

- This is not a new requirement. However, it was not previously part of appendix A of the State Operations Manual (SOM).
- Forms the basis for survey activities to determine whether or not a facility qualifies to participate in Medicare as a hospital.
- If a facility does not meet the statutory requirements of a hospital then it is not eligible to participate in Medicare as a hospital



Primarily Engaged Requirement

An entity seeking participation in Medicare as a hospital MUST:

“ **Be primarily engaged** in providing by, or under the supervision of physicians, **to inpatients** (A) diagnostic services and therapeutic services for the medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured disabled or sick persons;”



Who is Considered an Inpatient?

- An individual who is
 - Formally admitted as an inpatient,
 - With the expectation that he or she will require hospital care that is expected to span **at least two midnights** and;
 - Occupy a bed (even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight)
- Therefore...an average length of stay (ALOS) of two midnights is one benchmark for determining whether a facility is meeting the definition of a hospital
- Individuals in observation status are **not** considered inpatients



Inpatients Present at the Time of Survey

- There must be 2 inpatients present at the time of a survey for a survey to be conducted.
- If two inpatients are not present at the time of the survey, a survey will not be conducted at that time.
- A second survey may be attempted if the facility meets certain conditions (ADC, ALOS, etc.)

*This applies to **all** surveys (initial, recertification, validation and complaint)



Now What???



Second Survey Attempt

- Surveyors (to include accreditation organization (AO) surveyors) will then determine if a second survey should be attempted at a later date. This is based on the facility's ALOS and average daily census (ADC) from the previous 12 months. Surveyors must ask to see the ALOS and ADC.
- If the facility can demonstrate an ALOS of at least 2 midnights and an ADC of at least 2 inpatients from the previous 12 months, the SA or AO may attempt a second survey at a later date.
- ALOS and ADC is the **total** for all inpatient locations of the facility combined.



Second Survey Attempt (continued)

- Facilities not in operation for 12 months may calculate ADC based on the number of months it has been operational but not less than 3 months.
- This does not mean that a facility must be operational for at least 3 months before a survey can be completed. It merely means that the ADC cannot be calculated using a denominator of less than 3 months.



Second Survey Attempt (continued.)

- If facility cannot demonstrate an ALOS of 2 and an ADC of at least 2 from the previous 12 months (or less for facilities not in operation for 12 months), the facility is most likely not primarily engaged in providing care to inpatients and a second survey may or may not be attempted. (SA and AO must contact the Regional Office (RO)).
- The SA or AO must then look at other factors and provide this information to the RO, so that the RO can determine whether a second survey should be attempted.
 - There is no sense in attempting a second survey if other factors demonstrate that the facility is not primarily engaged in providing care to inpatients.
- Note: there is no timeline or deadline for when the second survey attempt is to be completed. This is at the discretion of the SA or the AO.



Second Survey; Other Factors to Consider

- The number of provider-based off campus emergency departments (ED)
 - Is there an unusually large number of off campus EDs?
 - How can a hospital with more off-campus EDs than inpatient locations be primarily engaged in providing care to inpatients?
- The number of inpatient beds in relation to the size of the facility and services offered
- Volume of inpatient surgical procedures compared to volume of outpatient surgical procedures

*There is no absolute threshold for these factors when making a determination of “primarily engaged.” Each facility will be reviewed in totality before making a determination.



Second Survey; Other Factors to Consider (continued)

- Patterns and trends in the ADC by the day of the week
 - Does the ADC consistently drop to zero on Saturday and Sunday?
- Staffing patterns
 - Do staffing schedules demonstrate that nurses, pharmacists, physicians, etc. are scheduled to support 24/7 inpatient care?
- How does the facility advertise itself to the community?
 - Is it advertised as a “specialty” hospital or “emergency” hospital?
 - Does the name of the facility include terms like, clinic or center as opposed to hospital?
- There is no single factor that determines whether a facility is primarily engaged in providing care to inpatients. Surveyors and the RO must look at all factors and the totality of the facility.



Don't Forget about the Other Criteria

- The requirement to be primarily engaged in providing care to inpatients is only one of several requirements in meeting the definition of a hospital.
- Just because the “primarily engaged” requirement is met, that does not automatically mean that the facility meets the definition of a hospital



Other Statutory Definition Requirements

- Maintains clinical records on all patients;
- Has medical staff bylaws;
- Has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in section 1861(ii) of the Act) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;
- Provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times...;



Other Statutory Definition Requirements (continued)

- Has in effect a hospital utilization review plan which meets the requirements of section 1861(k) of the Act;
- Has in place a discharge planning process that meets the requirements of section 1861(ee) of the Act;
- If located in a state in which state or applicable local law provides for the licensing of hospitals, be licensed under such law or be approved by the agency of the State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;
- Has in effect an overall plan and budget that meets the requirements of section 1861(z) of the Act.



“Other” Factors Don’t Support Primarily Engaged Requirement



What Happens Next?

- A second survey will not be conducted, and;
- For initial applicants
 - The RO will deny enrollment and follow existing denial procedures
- For currently participating hospitals
 - The RO will move towards termination of the provider agreement for non-compliance with Tag A-0008, §482.1 Basis and scope, after the RO considers any access to care issues that may exist.



Things to Keep in Mind

- Medicare Administrative Contractor (MAC) approval of an enrollment application (Form CMS-855A) does **not** mean that the facility meets the definition of a hospital
- Hospital accreditation by an AO does NOT mean that the facility is truly a hospital for Medicare purposes
- Hospital status is ONLY conveyed by the CMS RO. SAs and AOs merely make a recommendation to convey hospital status to the CMS RO
- Facilities that routinely have less than 2 inpatients on any given day, run the risk of prolonging the survey and certification process and therefore prolong the granting of an effective date and Medicare reimbursement.



Things to Keep in Mind (continued)

- Previous approval to participate as a hospital in the Medicare program does not guarantee future participation in Medicare as a hospital.
- Very small rural hospitals may want to consider conversion to a critical access hospital (if appropriate)
- Surgical specialty hospitals with consistent ADCs and ALOSs of less than two may want to consider reclassifying as an ASC
- Even the smallest of hospitals (2 inpatient beds) must be in compliance with ALL of the hospital conditions of participation (CoP) in subparts A, B and C of **PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**



This is Only the Beginning

- Once the surveyor has determined that the facility meets the definition of a hospital...

The surveyor can now begin to evaluate ALL of the hospital Conditions of Participation (CoPs).



Question & Answer Session



Resources

Please send future questions to HospitalSCG@cms.hhs.gov

For additional information please refer to [Appendix A of the SOM \(https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf\)](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf)



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