DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

S&C Memo: 17-44-Hospitals

DATE: **September 6, 2017** **REVISED 10.27.2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy- Revisions to State Operations Manual (SOM) Hospital Appendix A

****Change to the Average Daily Census Timelines ****

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is clarifying guidance under Appendix A of the State Operations Manual (SOM) to address the following:

- The Social Security Act, (the Act) Section 1861(e) defines the statutory definition of a hospital.
- A hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Act when it is directly providing services to inpatients.
- In order to qualify for a provider agreement as a hospital under Medicare and Medicaid, an entity must meet and continue to meet all of the statutory provisions of §1861(e) of the Act, including the Condition of Participation (CoP) requirements. See also 42 CFR 488.3(a)(1) and 42 CFR 489.12.
  (*Note: This requirement does not apply to Psychiatric Hospitals or Critical Access Hospitals (CAH), as defined at section 1861(f) of the Act)*
- A hospital must have inpatients at the time of survey in order for surveyors to directly observe the actual provision of care and services to patient**s**, and the effects of that care.
- The use of benchmarks for average daily census (ADC) and average length of stay (ALOS) data for the hospital will be two factors, in addition to other factors, utilized to determine if the hospital is primarily engaged.

Background

We are issuing a revised version of the advanced copy of the Revisions to the State Operations Manual, Appendix A for Hospitals that was originally released on September 6, 2017 *and October 18, 2017*. This revision is being issued to clarify relevant questions we have received since the original release of the guidance. Substantive revisions to the original release of the advanced copy of the guidance are included in red italicized font in this memorandum.

The Social Security Act, (the Act) Section 1861(e) defines the statutory definition of a hospital.

Section 1861(e)(7) of the Act further requires that a hospital located in a state which provides for the licensing of hospitals, the hospital must be licensed in accordance with state law or approved as meeting standards for licensing as established by the agency of the State or locality responsible for the licensing of hospitals.

While a facility may have a license from a state to operate as a hospital or may have been approved by a state as a hospital under state or local standards and authorities, that facility may still not meet the Medicare definition of a hospital as per the Act. The criteria used by a State to determine that a hospital meets the requirements for State licensure as a hospital is not the same criteria used to define a hospital for the purpose of participation in Medicare, and each state has its own criteria and standards for licensure.

The definition of a hospital and determination of whether the facility is "Primarily Engaged" are not applicable to CAHs or Psychiatric Hospitals as defined by Section 1861(f) of the Act.

In order to qualify for a provider agreement as a hospital under Medicare and Medicaid, an entity must meet and continue to meet all of the statutory provisions of §1861(e) of the Act, including the Condition of Participation requirements. See also 42 CFR 488.3(a)(1) and 42 CFR 489.12. This means the entity must be 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;

Summary of Key Changes

§482.1 Basis and scope

In making a determination of whether or not a facility is primarily engaged in providing inpatient services and care to inpatients, CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality. Such factors include, but are not limited to, ADC, ALOS, the number of off-campus outpatient locations, the number of provider based emergency departments, the number of inpatient beds related to the size of the facility and scope of services offered, volume of outpatient surgical procedures compared to inpatient surgical procedures, staffing patterns, patterns of ADC by day of the week, etc. Hospitals are not required to have a specific inpatient to outpatient ratio in order to meet the definition of primarily engaged.

Generally, a hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Act when it is directly providing such services to inpatients. Having the capacity or potential capacity to provide inpatient care is not the equivalent of actually providing such care. Inpatient hospital services are defined under Section 1861(b) of the Act and in the regulations at 42 CFR Part 409, Subpart B. CMS guidance describes an inpatient as "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services …. Generally, a patient is considered an inpatient if 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." (Medicare Benefit Policy Manual, Chapter 1, §10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf) The "expectation of a two midnight stay" for an inpatient is that the intent of the physician was that the patient be admitted to the hospital for an inpatient stay as opposed to that of observation status which is an outpatient service.

Therefore, an ALOS of two midnights would be one of the benchmarks considered for certification as a hospital.

In order for surveyors to determine whether or not a hospital is in compliance with the statutory and regulatory requirements of Medicare participation, including the definition of a hospital, they must observe the provision of care. Medicare requirements at 42 CFR 488.26(c)(2) state that "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 resident**s** and/or patient**s**, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients."

Because §488.26(c)(2) and Section 1861(e) of the Act refer to patients (plural), hospitals must have at least two inpatients at the time of the survey in order for surveyors to conduct the survey. However, just because a facility has two inpatients at the time of a survey does not necessarily mean that the facility is primarily engaged in inpatient care and satisfies all of the statutory requirements to be considered a hospital for Medicare purposes. Having two patients at the time of a survey is merely a starting point in the overall survey and certification process.

If a hospital does not have at least two inpatients at the time of a survey, a survey will not be conducted at that time, and an initial review of the facility's admission data will be performed by surveyors while onsite to determine if the hospital has had an ADC of at least two and an ALOS of at least two midnights over the last 12 months. Average daily census is calculated by adding the midnight daily census for each day of the 12 month period and then dividing the total number by the number of days in the year. In order to be considered primarily engaged in providing inpatient services, prospective hospital providers and currently participating hospitals should also be able to maintain an ALOS of two midnights or greater. The ALOS is calculated by dividing the total number of inpatient hospital days (day of admission to day of discharge, including day of death) by the total number of discharges in the hospital over 12 months.

For facilities that have not been operating for 12 months at the time of the survey, an ADC calculated using 12 months as the denominator may falsely result in an ADC of less than two. Therefore, facilities that have been operating less than 12 months at the time of the survey, should calculate its ADC based on the number of months the facility has been operational but no less than *three* months. *This does not mean that a facility must be operational for at least three months before a survey can be completed. It merely means that the ADC cannot be calculated using a denominator of less than three months.*

Additionally, for facilities that have multiple campuses operating under the same CCN, the ADC is not calculated individually at each campus. All locations make up the entire facility and the ADC will be based on the total inpatient census from all campuses. This also includes PPS excluded psychiatric and rehabilitation units that are part of the facility.

- If the ADC and ALOS is two or more, the SA or AO makes the determination that a second survey will be attempted at a later date.
- If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months (or less than 12 months for facilities that have not been operational for at least 12 months), the facility is most likely not primarily engaged in providing care to inpatients and the SA or AO may not conduct the survey. The SA or AO must immediately contact the RO to inform them that a survey could not be completed and the CMS Regional Office will review additional information provided by the SA or AO to determine whether a second survey should be attempted.

When the ADC and ALOS are NOT a minimum of 2, the SA or AO do not make the final determination whether a second survey will be attempted. Instead, the SA or AO must obtain further information from the facility (other factors described below), review the information and make a recommendation to the RO regarding whether a second survey should be attempted. The SA or AO must provide its recommendation in writing to the RO along with the supporting information used to make the recommendation. The RO must review the recommendation and information and make a determination on whether a second survey will be conducted and communicate its decision to the SA or AO within 7 working days of receipt of the recommendation. AO communication to the RO must be via the current established process used for all other written communication to the RO.

If during a second survey attempt, the facility does not have two inpatients, the survey will not be conducted and the SA or AO must cite condition level non-compliance with §482.1. In addition, the SA or AO must immediately notify the RO of the situation. The RO will then proceed with either denial of certification (for initial applicants) in the Medicare program or termination of the provider agreement (for currently participating hospitals). For currently participating hospitals, the RO will base any termination action on the totality of the situation including consideration of any access to care issues.

Other factors that the CMS Regional Office should consider in determining whether to (1) conduct a second survey or (2) recommend denial of an initial applicant or termination of a current provider agreement, include but are not limited to:

- The number of provider-based off-campus emergency departments (EDs). An unusually large number of off-campus EDs may suggest that a facility is not primarily engaged in inpatient care and is instead primarily engaged in providing outpatient emergency services.
- The number of inpatient beds in relation to the size of the facility and services offered.
- The volume of outpatient surgical procedures compared to inpatient surgical procedures.
- If the facility considers itself to be a "surgical" hospital, are procedures mostly outpatient?
    - Does the information indicate that surgeries are routinely scheduled early in the week, and does it appear this admission pattern results in all or most patients being discharged prior to the weekend (for example does the facility routinely operate in a manner that its designated "inpatient beds" are not in use on weekends)?

- Patterns and trends in the ADC by the day of the week. For example, does the ADC consistently drop to zero on Saturdays and Sundays? Therefore suggesting that the facility is not consistently and primarily engaged in providing care to inpatients.
- Staffing patterns. A review of staffing schedules should demonstrate that nurses, pharmacists, physicians, etc. are scheduled to work to support 24/7 inpatient care versus staffing patterns for the support of outpatient operations.
- 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"?

The CMS RO should consider all of the above factors (and other factors as necessary) to make a determination as to whether or not a facility is truly operating as a hospital for Medicare purposes. A determination of non-compliance with § 482.1 will not be based on a single factor, such as failing to have two inpatients at the time of a survey.

It is important to note that CMS has the final authority to make the determination of whether or not a facility has met the statutory definition of a hospital after considering the facility's entire situation, the recommendations of the State Agency surveyors as well as the evidence submitted by the SAs and AOs. As stated previously, a facility that meets State requirements for obtaining State status as a hospital is not automatically considered a hospital for federal survey and certification purposes without further evaluation and consideration of all relevant CMS requirements. In addition, approval by the Medicare administrative contractor of an enrollment application does not convey hospital status for CMS purposes. Hospital status is only conveyed and approved by the CMS RO after a survey has been completed and the results clearly demonstrate that the facility has met all the federal requirements, including the statutory definition.

Contact: If you have any questions regarding this memorandum, please send inquiries to the hospital e-mailbox at hospitalscg@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment- Advanced Copy- State Operations Manual Appendix A

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Transmittal 169- Advanced Copy

Date:

SUBJECT: Revision to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Revisions are being made to Appendix A for Hospitals to add a current regulation with interpretive guidelines not previously included in Appendix A as well as revising interpretive guidelines defining whether a hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Social Security Act.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Month XX, 2017
IMPLEMENTATION: Month XX,, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/Table of Contents
N	Appendix A/Tag A-0008/§482.1 Basis and scope
R	Appendix A/Tag A-0022/§482.11(b) The hospital must be--

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2016 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev.)

§482.42 Condition of Participation: Infection Control
§482.43 Condition of Participation: Discharge Planning
§482.45 Condition of Participation: Organ, Tissue and Eye Procurement
§482.51 Condition of Participation: Surgical Services
§482.52 Condition of Participation: Anesthesia Services
§482.53 Condition of Participation: Nuclear Medicine Services
§482.54 Condition of Participation: Outpatient Services
§482.55 Condition of Participation: Emergency Services
§482.56 Condition of Participation: Rehabilitation Services
§482.57 Condition of Participation: Respiratory Services

A-0008
(Rev.)

§482.1 Basis and scope.

(a) Statutory basis. (1) Section 1861(e) of the [Social Security] Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.
. . .

(b) Scope. Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

Interpretive Guidelines §482.1(a)(1)

Hospital Definition and Regulatory Enforcement Authorities

In order to qualify for a provider agreement as a hospital (other than a psychiatric hospital as defined at section 1861(f) of the Act) under Medicare and Medicaid, an entity must meet and continue to meet all of the statutory provisions of §1861(e) of the Act, including the Condition of Participation (CoP) requirements. See also 42 CFR 488.3(a)(1) and 42 CFR 489.12. This means the entity must:

- *Be 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;*

- *Maintain clinical records on all patients[addressed in 42 CFR 482.24, Medical Records];*

- *Have medical staff bylaws [42 CFR 482.12, Governing Body, and 42 CFR 482.22, Medical Staff];*

- *Have a requirement that every patient with respect to whom payment may be made under Title XVIII 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 [42 CFR 482.12, Governing Body];*

- *Provide 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…[42 CFR 482.23, Nursing Services];*

- *Have in effect a hospital utilization review plan which meets the requirements of section 1861(k) of the Act [42 CFR 482.30, Utilization Review];*

- *Have in place a discharge planning process that meets the requirements of section 1861(ee) of the Act [42 CFR 482.43, Discharge Planning];*

- *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 [42 CFR 482.11, Compliance with Federal, State, and Local Laws];*

- *Have in effect an overall plan and budget that meets the requirements of section 1861(z) of the Act [42 CFR 482.12, Governing Body]; and*

- *Meet any other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution [42 CFR Parts 482 and 489, among others].*

Primarily Engaged

Generally, a hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Act when it is directly providing such services to inpatients. Having the capacity or potential capacity to provide inpatient care is not the equivalent of actually providing such care. Inpatient hospital services are defined under section 1861(b) of the Act and in the regulations at 42 CFR Part 409, Subpart B. CMS guidance describes an inpatient as "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services …. Generally, a patient is considered an inpatient if 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." (Medicare Benefit Policy Manual, Chapter 1, §10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf) The "expectation of a two midnight stay" for an inpatient is that the intent of the physician was that the patient be admitted to the hospital for an inpatient stay as opposed to that of observation status which is an outpatient service.*

Therefore, an average length of stay (ALOS) of two midnights would be one of the benchmarks considered for certification as a hospital.

- *In making a determination of whether or not a facility is primarily engaged in providing inpatient services and care to inpatients, CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality. Such factors include, but are not limited to, average daily census (ADC), average length of stay (ALOS), the number of off-campus outpatient locations, the number of provider based emergency departments, the number of inpatient beds related to the*

size of the facility and scope of services offered, volume of outpaient surgical procedures compared to inpatient surgical procedures, staffing patterns, patterns of ADC by day of the week, etc. Hospitals are not required to have a specific inpatient to outpatient ratio in order to meet the definition of primarily engaged.

*In order for surveyors to determine whether or not a hospital is in compliance with the statutory and regulatory requirements of Medicare participation, including the definition of a hospital, they must observe the provision of care. Medicare requirements at 42 CFR 488.26(c)(2) state that "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 resident**s** and/or patient**s**, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients."*

Because §488.26(c)(2) and section 1861(e) of the Act refer to patients (plural) hospitals must have at least two inpatients at the time of the survey in order for surveyors to conduct the survey. However, just because a facility has two inpatients at the time of a survey does not necessarily mean that the facility is primarily engaged in inpatient care and satisfies all of the statutory requirements to be considered a hospital for Medicare purposes. Having two patients at the time of a survey is merely a starting point in the overall survey and certification process.

If a hospital does not have at least two inpatients at the time of a survey, a survey will not be conducted at that time and an initial review of the facility's admission data will be performed by surveyors while onsite to determine if the hospital has had an ADC of at least two and an ALOS of at least two midnights over the last 12 months. Average daily census is calculated by adding the midnight daily census for each day of the 12 month period and then dividing the total number by the number of days in the year. For facilities that have multiple campuses operating under the same CMS Certification Number (CCN), the ADC is not calculated individually at each campus. All locations make up the entire facility and the ADC will be based on the total inpatient census from all campuses. This also includes PPS excluded psychiatric and rehabilitation units that are part of the facility.

In order to be considered primarily engaged in providing inpatient services, prospective hospital providers and currently participating hospitals should also be able to maintain an ALOS of two midnights or greater. The ALOS is calculated by dividing the total number of inpatient hospital days (day of admission to day of discharge, including day of death) by the total number of discharges in the hospital over 12 months. For facilities that have not been operating for 12 months at the time of the survey, an ADC calculated using 12 months as the denominator may falsely result in an ADC of less than two. Therefore, facilities that have been operating less than 12 months at the time of the survey, should calculate its ADC based on the number of months the facility has been operational but no less than three months. This does not mean that a facility must be operational for at least three months before a survey can be completed. It merely means that the ADC cannot be calculated using a denominator of less than three months.

- *If the ADC and ALOS is two or more, the State Survey Agency (SA) or Accrediting Organization (AO) makes the determination that a second survey will be attempted at a later date.*

- *If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months (or less than 12 months for facilities that have not been operational for at least 12 months), the facility is most likely not primarily engaged in providing care to inpatients and the SA or AO may not conduct the survey. The SA or AO must immediately contact the RO to inform them that a survey could not be completed and the CMS Regional Office will review additional information provided by the SA or AO to determine whether a second survey should be attempted.*

- *When the ADC and ALOS are NOT a minimum of two, the SA or AO do not make the final determination whether a second survey will be attempted. Instead, the SA or AO must obtain further information from the facility (other factors described below), review the information and make a recommendation to the RO regarding whether a second survey should be attempted. The SA or AO must provide its recommendation in writing to the RO along with the supporting information used to make the recommendation. The RO must review the recommendation and information and make a determination on whether a second survey will be conducted and communicate its decision to the SA or AO within seven business days of receipt of the recommendation. AO communication to the RO must be via the current established process used for all other written communication to the RO.*

- *If during a second survey attempt, the facility does not have two inpatients, the survey will not be conducted and the SA or AO must cite condition level non-compliance with §482.1. In addition, the SA or AO must immediately notify the RO of the situation. The RO will then proceed with either denial of certification (for initial applicants) in the Medicare program or termination of the provider agreement (for currently participating hospitals). For currently participating hospitals, the RO will base any termination action on the totality of the situation including consideration of any access to care issues.*

Other factors that the CMS Regional Office should consider in determining whether to (1) conduct a second survey or (2) recommend denial of an initial applicant or termination of a current provider agreement, include but are not limited to:

- *The number of provider-based off-campus emergency departments (EDs). An unusually large number of off-campus EDs may suggest that a facility is not primarily engaged in inpatient care and is instead primarily engaged in providing outpatient emergency services.*

- *The number of inpatient beds in relation to the size of the facility and services offered.*

- *The volume of outpatient surgical procedures compared to inpatient surgical procedures.*

- *If the facility considers itself to be a "surgical" hospital, are procedures mostly outpatient?*

- *Does the information indicate that surgeries are routinely scheduled early in the week and does it appear this admission pattern results in all or most patients being discharged prior to the weekend (for example does the facility routinely operate in a manner that its designated "inpatient beds" are not in use on weekends)?*

- *Patterns and trends in the ADC by the day of the week. For example, does the ADC consistently drop to zero on Saturdays and Sundays? Therefore suggesting that the facility is not consistently and primarily engaged in providing care to inpatients.*

- *Staffing patterns. A review of staffing schedules should demonstrate that nurses, pharmacists, physicians, etc. are scheduled to work to support 24/7 inpatient care versus staffing patterns for the support of outpatient operations.*

- *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 such as "clinic" or "center" as opposed to "hospital"?*

The CMS RO should consider all of the above factors (and other factors as necessary) to make a determination as to whether or not a facility is truly operating as a hospital for Medicare purposes. A determination of non-compliance with § 482.1 will not be based on a single factor, such as failing to have two inpatients at the time of a survey.

It is important to note that CMS has the final authority to make the determination of whether or not a facility has met the statutory definition of a hospital after considering the facility's entire situation, the recommendations of the SA or AO surveyors as well as the evidence submitted by the SAs and AOs. As stated previously, a facility that meets State requirements for obtaining State status as a hospital is not automatically considered a hospital for federal survey and certification purposes without further evaluation and consideration of all relevant CMS requirements. In addition, approval by the Medicare administrative contractor of an enrollment application does not convey hospital status for CMS purposes. Hospital status is only conveyed and approved by the CMS RO after a survey has been completed and the results clearly demonstrate that the facility has met all the federal requirements, including the statutory definition.

Survey Procedures §482.1(a)(1)

- *Verify there are at least two inpatients currently in the hospital at the time of survey*

- *If yes, proceed with evaluating the whether the hospital is primarily engaged in providing the requisite services of a hospital, as well as in the Conditions of Participation.*

- *If there are currently no inpatients in the hospital, no survey is to be conducted and surveyors should ask to see the following, in order to make the proper determination of the hospital's status and to make the proper recommendations to the RO:*

- *ADC over the last 12 months (or less for facilities operational for less than 12 months)*
    - *Look for patterns and trends in the ADC by the day of the week.*
- *ALOS over the last 12 months (or less for facilities operational for less than 12 months)*
- *The number of provider-based off-campus emergency departments.*
- *The volume of outpatient surgical procedures compared to inpatient surgical procedures*
- *Staffing schedules by day of week and shift over the last 12 months (or less for facilities operational for less than 12 months)*
- *Verify the facility is providing the appropriate types and adequate numbers of staff to support 24/7 inpatient services (i.e. nursing, pharmacy, physicians, etc.)*
- *Review the number of inpatient beds in relation to the size of the facility and services offered.*
- *Determine if the number of inpatient beds could support emergency or unplanned admissions from the volumes of other services offered by the facility, such as ED patients or outpatient surgery patients?*

- *If the initial review of the above information indicates that the facility is most likely not providing care to inpatients, then a second survey will not be conducted. However, if the review of the information indicates the facility has had an ADC and ALOS of two over the last 12 months (or less for facilities operational for less than 12 months) and there are no other concerns regarding facility's eligibility to be surveyed as a hospital, then a second survey will be scheduled for a future unannounced date after consulting with the RO.*

- *Whenever the SA or AO is unable to complete a survey because the hospital did not have a sufficient number of inpatients that is a representative sample of the different types of services and patient populations that are treated at that hospital, it must immediately report this information to the RO.*

- *Determine through interview, observation, and record review that the hospital meets the statutory requirements as defined by 1861(e), including the CoPs Verify the facility does the following:*
    - *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…;*

- *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.*

A-0022
(Rev.)

§482.11(b) The hospital must be--

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

Interpretive Guidelines §482.11(b)

Hospitals applying for initial Medicare certification as a hospital or hospitals currently participating in Medicare must, among other things, meet the statutory definition of a hospital under section 1861(e) of the Act. Section 1861(e)(7) of the Act further requires that a hospital located in a state which provides for the licensing of hospitals, the hospital must be licensed in accordance with state law or approved as meeting standards for licensing as established by the agency of the State or locality responsible for the licensing of hospitals.

While a facility may have a license from a state to operate as a hospital or may have been approved by a state as a hospital under state or local standards and authorities, that facility may

still not meet the Medicare definition of a hospital as per the Act. The criteria used by a state to determine that a hospital meets the requirements for state licensure as a hospital is not the same criteria used to define a hospital for the purpose of participation in Medicare, and each state has its own criteria and standards for licensure.

The definition of a hospital and the issue of whether the facility is Primarily Engaged are issues not applicable to a Critical Access Hospital (CAH).

Survey Procedures §482.11(b)

- Prior to the survey, determine whether the hospital *has a current license by the state or local authority in which it operates, or, if it is located within a State that does not license hospitals, verify that the responsible State agency has approved the hospital as meeting the State's established standards for the licensing of hospitals.*