STATE OPERATIONS MANUAL
Appendix W – Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) And Swing-Beds in CAHs
Revisions 84, 06-07-21013

C-0151 – Physician Ownership

Required CAH Disclosure to Patients

Physician Ownership

Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.

A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to the notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.

42 CFR 489.53(c) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at 4890.20(u).

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that if there is no doctor of medicine or osteophathy present in the CAH 24 hours per day, seven days per week the DCAH must provide written notice to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24-7 do not need to issue any disclosure notice about emergency services capability.

- The notice must be provided to all inpatien5ts and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.
- The notice must be provided at the beginning of the planned or unplanned inpatient stay, or applicable outpatient visit.
- A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient's presents to the CAH.

- Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24 (b), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the CAH does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will; meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b)[the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteophathy present in the CAH. If an emergency department patient is determined to require admission, then the individual not provisions of 42 CFR 489.20(w) would apply to that patient.

- Before admitting an inpatient or providing outpatient services requiring notice, the CAH must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to him/her.

- In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.

- For a CAH that participates in Medicare with multiple campuses providing inpatient services a separate determination is made for each campus location with inpatient services as to whether the disclosure notice is required.

C-0160 – Condition of Participation: Status & Location

The CAH must meet the location requirements of 485.610(b) and 485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent full survey. If the CAH moves, its eligibility for continued CAH status must be reassured in accordance with 485.610 (d).

C-0165 – Standard: Location to Other Facilities or Necessary Provider Certification

Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive; as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer

meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.

C-0168 – Standard: Off-Campus and Co-Location Requirements for CAHs (Con't)

Does not apply to the following facilities:

- Ambulatory surgical centers (ACS's)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Home Health Agencies (HHAs)
- Skilled Nursing Facilities (SNFs)
- Hospices
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services
- ESRD Facilities
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g. laundry, or medical records department; and
- Ambulances

C-0196 – Standard: Agreements for credentialing and privileging of telemedicine physician and practitioners.

If a CAH enters into an agreement for telemedicine services with a distant-site hospital, the agreement must be in writing. Furthermore, the written agreement must specify that it is the responsibility of the distant-site hospital to conduct its credentialing and privileging process for those of its physicians and practitioners providing telemedicine services such that the distant hospital:

- Determines in accordance with State law, which categories of practitioners are eligible candidates for privileges or membership on the distant-site's hospital's medical staff.
- Appoints members and grants medical staff privileges after considering the recommendations of the existing members of the distant-site hospital's medical staff.
- Assures that the distant-site hospital's medical staff has bylaws.
- Approves the distant-site hospital's medical staff bylaws and other medical staff rules and regulations.
- Ensures that the medical staff is accountable to the distant site hospital's governing body for the quality of care provided to patients.
- Ensures the criteria for granting medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment.

- Ensures that under no circumstances is the accordance of distant-site hospital medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

The CAHs governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners . In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure that its written agreement with the distant-site hospital addresses all of the following:

- That the distant-0site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or involuntarily, at any time during the agreement, then as of the effective date of the termination, the CAH may no longer receive telemedicine services under the agreement.
- That the distant-site hospital provides a list to the CAH of all it physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current;
- That each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the CAH whose patients are receiving the telemedicine services is located must be satisfied, whatever they may b; and
- That the CAH has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site hospital for latter's use in its periodic appraisal for each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site hospital, then it must for each physician or practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

C-0197
485.616(c)(3)

The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the

agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, is accordance with 485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

485.616(c)(4)

When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decision made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians and practitioners.

Interpretive Guidelines 485.616(C)(3) & (4)

In order to exercise this alternative credentialing and privileging option, the DCAH's governing body must ensure through it written agreement with the distant-site telemedicine entity that all of the following requirements are included in the agreement and that the contractor fulfills these requirements:

- Determine in accordance with State Law, which categories of practitioners are eligible candidates for medical staff privileges or membership at the telemedicine entity;
- Appoint members and grant medical staff privileges after considering the recommendations of the existing members of its medical staff.
- Assure that its medical staff has bylaws.
- Approve it medical staff's bylaws and other medical staff rules and regulations.

- Ensure that the medical staff is accountable to the distant-0site telemedicine entity's governing body for the quality of care provided to patients;
- Ensure the criteria for granting distant-site telemedicine medical staff membership/privileges to an individual are the individual's character, competence, training, experience and judgment; and
- Ensure that under no circumstances is the accordance of medical staff membership or privileges depend solely upon certification, fellowship or membership in a specialty boy or society.

The distant-site telemedicine entity provides to the CAH a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity.

Each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is locates.

The CAH reviews the performance of the physicians and practitioners providing telemedicine services to its patients and provides a written review to the distant-site telemedicine entity for

the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services the agreement.

If the CAH's governing body or responsible individual does not rely on the privileging decision of the distant-site telemedicine entity, then it must for each practitioner providing telemedicine services under an agreement follow the CAHs standard process for review of the credential and granting of privileges to physicians and practitioners.

C-0221
485.623 (a) Standard: Construction
Interpretive Guidelines

The CAH's physical facilities must be constructed, designed and maintained such that patients are always accessible and the safety of patients is assured. The CAH's construction must be in accordance with applicable Federal, State and local law, as determined by the authorities having jurisdiction to enforce such law.

The CAH's physical plant must provide sufficient space to support those services the CAH provides on-site. There must also be adequate space to support all additional services the CAH offers.

C-0273
485.635(a)(3)

(1) A descrip0tion of the services the CAH furnishes, including those furnished through agreement or arrangement.

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH.

The description of the services provided may be brief, but informative. (radiologic tests and their interpretation, surgery would satisfy this requirement.)

C-0281
485.635(b) Standard: Patient Services

(1) General. The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care

delivery system, such as a low intensity hospital outpatient department or emergency department. The CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guidelines 485.635(b)(1)

This regulation addresses the minimum level of outpatient, services which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician's office or in a hospital outpatient or emergency department that furnishes low intensity services. Such services include, but are not limited to: taking a patient's medical history, conducting a physical examination of the patient; specimen collection, assessment of health status and treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients if services for basic ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week.

C-0282
485.635(b)(2) Laboratory Services
Interpretive Guidelines 485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

- Chemical examination of urine by stick or tablet method or both (including urine ketones);
- Hemoglobin or hematocrit;
- Blood Glucose;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory.

These services may be provided by the CAH staff or under arrangement or agreement, or through a combination of CAH staff and a laboratory under agreement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor,

must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's emergency services operation.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offer to patients. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at 485.638 (a)(4)(ii).

C-0283
485.635(b)(3) Radiology Services
Interpretive Guidelines 485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All modalities use some form of radiation, such as ionizing radiation which has enough energy to potentially cause damage to DNA, and other forms of radiation to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be available at all time the CAH provides services, including emergency services. The CAH has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services.

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc.

Qualified Radiologic Personnel

There should be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment and administer procedures, and which studies require interpretation by a radiologist.

When telemedicine is used to provide teleradiology services, radiologist who interprets radiological tests must satisfy the telemedicine privileging requirements 485.616(c)(3).

In addition to radiologist, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologist and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

Safety from Radiation Hazards

The CAH must adopt and implement policies and procedures that ensure safety from radiation hazards for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies should contain safety standards for at least the following:

Adequate radiation shielding for patients, personnel and facilities, which includes:

- Shielding built into the CAH's physical plant, as appropriate;
- Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;
- Types of containers to be used for various radioactive materials, if applicable, when stored in transport, in use, and when disposed;
- Clear Signage identifying hazardous radiation areas
- Clear signage identifying hazardous radiation areas;

Labeling of all radioactive materials, including waste, with clear identification of all material(s);

Transportation of radioactive materials between locations within the CAH;

Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;

Periodic testing of equipment for radiation hazards;

Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;

Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and

Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance
The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must ensure that equipment is inspected in accordance with Federal and State laws and regulations, as applicable, and hospital policy. The CAH must have a system in place to correct identified problems. The CAH must have evidence of its inspections and corrective actions.

Radiology Records
The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at 485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results and consultative findings.

C-0284
485.635(b)(4) Emergency Procedures
Interpretive Guidelines 485.635(b)(4)
Emergency services must be provided by the CAH at the CAH campus either by CAH staff or under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide initial interventions, treatment and stabilization of any patient who requires emergency services.

C-0320
485.639 Conditions of Participation: Surgical Services
If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guidelines 485.639

In accordance with acceptable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g. The American Medical Association, American College of Surgeons, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the CAH's outpatient surgical services must be integrated with the CAH's inpatient surgical services.

The scope of surgical services provided by the CAH should be defined in writing and approved by the governing body or responsible individual.