DATE: February 12, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements

***Revised to Clarify Type of Hospital when Evaluating Distance Requirements***

Memorandum Summary

CAH Recertification Checklist: In order to routinely re-evaluate the compliance of currently certified CAHs with the status and location requirements at 42 CFR 485.610, the Centers for Medicare & Medicaid Services (CMS) has revised the attached CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification for use by the CMS Regional Office (RO) staff when processing CAH recertifications. The revised checklist includes:

- Procedures on determining whether a CAH that was certified by CMS prior to January 1, 2006 had been designated by the State as a necessary provider.
- Examples of documentary evidence to demonstrate necessary provider designation prior to January 1, 2006.

Background

The Office of Inspector General (OIG) report entitled, “Most Critical Access Hospitals Would Not Meet the Location Requirements if Required to Re-enroll in Medicare,” released August 19, 2013 (OEI-05-12-00080) recommended that CMS periodically reassess CAHs’ compliance with all location-related requirements at 42 CFR 485.610. CMS concurred with the recommendation. The OIG subsequently called on CMS to maintain evidence that it is routinely re-evaluating the compliance of currently Medicare-certified CAHs with these status and location requirements. In order to facilitate this, CMS has developed the CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification for use by the CMS RO staff.

This revision is to provide more clarity on what constitutes “a hospital” for evaluation of CAH distance requirements. Section 1820(c)(2)(B) of the Social Security Act (the Act) requires CAHs to be located in a rural area (as defined in section 1886(d)(2)(D)) or is being treated as being located in a rural area pursuant to section 1886(d)(8)(E); more than a 35-mile drive (15 miles in areas with only secondary roads or mountainous terrain) from a hospital (as defined at
Section 1861(e) of the Act; or another facility as described in subsection 1820(c) of the Act. The location requirements for a CAH originally evolved from Essential Access Community Hospitals (EACH) which required that the “location [must be] more than 35 miles from another like hospital (emphasis added).” Public Law 105-33 of 1997.

The seven (7) state EACH program was replaced by the Medicare Rural Hospital Flexibility Program available in any state that chose to establish such a program. The program offered states the opportunity to designate rural nonprofit hospitals or facilities as a CAH. The legislation defines a Rural Health Network as an organization consisting of at least one CAH and at least one acute care hospital which had agreements regarding patient referrals and transfers. (Balanced Budget Act of 1997).

The rules regarding CAHs were further amended in 2004, to state that to qualify for CAH designation, a hospital must be located more than 35 miles from other “like hospitals” and be located in a rural area. (42 CFR § 412.92). Consistent with the designation of “like hospitals,” the preamble for 69 FR § 49107 states, “To qualify for CAH designation, a hospital must be located more than 35 miles from the nearest similar hospital and have an average length of stay not exceeding 4 days.” The regulations at 42 CFR 485.610(b) and 485.610(c) repeat this statutory requirement.

**Evaluation of Compliance of the Location and Distance Requirements**

Annually, the RO must request from each State Agency (SA) a list of all CAHs expected to undergo a recertification survey over the next 12 months. This list should include and identify both deemed and non-deemed CAHs. For CAHs that are deemed, the SA reviews the deemed status tab in the Automated Survey Processing Environment (ASPEN) for accreditation dates of CAHs. Prior to the date of an SA or Accrediting Organization (AO) CAH recertification survey, the RO must determine whether the CAH meets the status and location requirements. Assessing the location requirements must include evaluating the distance of any acute care facilities from that of the CAH. Psychiatric hospitals, LTCHs, or Rehabilitation hospitals would not be considered an acute care hospital and therefore would not be considered a “like or similar” hospital when evaluating the location requirements. Only acute care hospitals or CAHs are included in the definition of similar or like hospitals when evaluating location requirements. The RO must complete a CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification (copy attached) for evaluating, determining, and documenting compliance with the CAH location-related Conditions of Participation (CoPs). The CAH Checklist contains detailed procedures to be followed. The completed checklist must be placed in the CAH’s file.

Once the RO has made the determination that a particular CAH is in current compliance with the rural status and distance requirements, it must contact the SA/AO to advise them that a recertification or reaccreditation survey may be conducted. There is no standard regarding the amount of advance notice the RO needs to give the AO or the SA prior to their next survey; however, adequate notice should be given so that resources are not used unnecessarily. The SA and AO may not conduct a recertification/reaccreditation survey of a CAH that does not meet the rural status and location requirements.

A CAH may request review of its CMS’ determination that a CAH is not a necessary provider if, within 60 days of the date of a CMS letter that communicates the agency’s determination that the
CAH distance requirements have not been met, it submits supplementary evidence to the CMS RO for CMS’ consideration. The burden is on the CAH to provide qualifying evidence demonstrating that necessary provider designation was made by the state prior to January 1, 2006, and that the designation was applicable to the specific facility in question.

In the event that the CAH is not compliant with the rural status and distance requirements, the RO will send the CAH a letter notifying the CAH of its options. The CAH will be allowed time to attempt to reclassify as rural, convert to hospital status, or have its Medicare participation terminated.

**Contact:** Questions concerning this memorandum should be addressed to CAHSCG@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(s): Critical Access Hospital Recertification Checklist: Rural and Distance or Necessary Provider Verification and A Case Study- Reconsideration

cc: Survey and Certification Regional Office Management

*The contents of this letter support actions to improve patient safety and increase quality and reliability of care and promote better outcomes.*
CRITICAL ACCESS HOSPITAL (CAH) RECERTIFICATION CHECKLIST:
Rural and Distance or Necessary Provider Verification

Date: ________________   CCN: ___________________

CAH Name: ________________________________________________________________

Address: ___________________________________________________________________

City/State/Zip/County: ________________________________________________________

Administrator: ______________________________________________________________

Last Survey Date: ________________

If deemed: Accrediting Organization (AO): __________________

Accreditation expiration date: ________________________________

Rural Status:

Does the Office of Management and Budget (OMB) Metropolitan Statistical Area (MSA) List
adopted by the CMS indicate that the county is designated as rural? Yes_____ No_____

If no, does the Division of Financial Management (DFM) confirm alternative rural status?
Yes_____ No_____ Date confirmed by the DFM: __________

Distance from other CAHs or Hospitals:

Necessary Provider Designation:  Yes_____ No______    [Source: ______________________]

If NO, conduct a distance analysis to all nearby CAHs/Hospitals.

Driving Distance ≥ 35 miles?  Yes_____ No______

If no, does the CAH qualify for the ≥ 15 mile standard, based on secondary
roads/mountainous terrain? Yes_____ No______    [Source: ______________________]

Describe why the 15 mile standard does/does not apply:

List name(s) and address(es) of all other CAHs and/or hospitals considered in the analysis:
[Psych, LTCH, and Rehabilitation hospitals are not considered an acute care hospital and should not be
included in the location analysis.]
PROCEDURES:

1. Annually the Regional Office (RO) designee contacts the State Agency (SA) to request a list of all Medicare-certified CAHs that are scheduled for a recertification survey over the next 12 months. The list should include and identify both deemed and non-deemed CAHs. For CAHs that are deemed, the SA consults the deemed status tab in ASPEN for the accreditation end dates of those CAHs. NOTE: AOs conduct reaccreditation surveys every 3 years.

2. Prior to the survey, the RO must:
   a. Follow the guidance in SOM Section 2256A for determining rural status.
      i. If the CAH is located outside a Metropolitan Statistical Area (MSA), as determined by consulting the latest Office of Management and Budget (OMB) MSA list adopted by CMS, the CAH has rural status.
      ii. If the CAH is located in an MSA but the Division of Financial Management (DFM) has reclassified it as rural, place a copy of DFM’s determination in the CAH’s file. The CAH is considered to have rural status.
      iii. If the CAH’s location was previously outside an MSA, but subsequently CMS adopted a revised OMB MSA list that places the CAH inside an MSA, the CAH has two years from the effective date of CMS’s adoption of the OMB MSA list to attempt to reclassify as rural. Alternatively, the CAH may convert to Medicare IPPS hospital status.
      iv. If the CAH’s location was previously outside an MSA, but was not determined during the prior recertification, consult with RO management on the length of time to be provided to the CAH to either attempt to reclassify or convert to hospital status. (Generally up to one year can be provided.)

      NOTE – if the CAH is not located in an area that is considered rural, a termination enforcement action must be undertaken. Depending on the facts of the case, the termination action may become effective in one or two years. The CAH may opt to convert to an IPPS hospital which would require the submission of an amended CMS Form 855A and a subsequent certification survey demonstrating compliance with the hospital CoPs at CFR 482.

   b. Determine whether the CAH was certified prior to January 1, 2006, in order to determine if the CAH is a Necessary Provider (NP) CAH. (A CAH that was Medicare-certified as a CAH after January 1, 2006 is not eligible to be an NP CAH.) NP CAHs are exempt from the distance requirement.
i. If the NP CAH was certified by CMS prior to January 1, 2006, review the CAH file to confirm there is evidence of NP CAH status (for example, an NP Designation letter issued by the State prior to January 1, 2006).

ii. If there is no documentation in the CAH's file, the RO may ask the State if there is documentation of State NP designation performed prior to January 1, 2006.

iii. If the State provides the RO with a copy of the CAH’s necessary provider designation documentation demonstrating State designation prior to January 1, 2006, the CAH is an NP CAH.

iv. If the RO designee determines that the CAH is an NP CAH, proceed to step 3. Otherwise, proceed to step 2.c.

c. If the CAH is not an NP CAH, evaluate the road mileage distance and road characteristics using ASPEN (ACO) and Google Maps for each identified CAH and nearby CAHs/Hospitals and make screen-prints of the findings. The RO also checks whether the mountainous terrain criteria apply. (See Section 2256A for details.)

d. Attach all documentation from the above steps to this completed Checklist.

3. The RO saves the completed Checklist and attachments in the RO records. The RO program lead is notified of the results of the determination, so that appropriate follow-up action may be taken.

   a. If the CAH is not an NP CAH and does not meet the distance and location requirements, the RO enters the case in the RO tracking system (e.g. Auto Tally Millennium). The RO sends the CAH a letter indicating its CAH status will be terminated. The CAH may be allowed time (generally one year) to convert to hospital status in lieu of having its Medicare provider agreement terminated. The letter will include appropriate appeal rights. The letter also will provide that CMS will review the NP CAH status determination if the CAH timely submits a request that contains qualifying supplementary information to the RO within 60 days of the date of the CMS letter, consistent with the requirements and procedures in step 4 of this Exhibit. The SA and AO are copied on the letter. The RO also notifies CMS Central Office at CAHSCG@cms.hhs.gov.

   b. If the CAH is either an NP CAH or meets the distance requirements, but is located in an MSA and has not been reclassified as rural, the RO enters the case in the RO tracking system (e.g. Auto Tally Millennium). The RO sends the CAH a letter indicating its CAH status will be terminated unless it can be reclassified as rural within the applicable timeframe. If the CAH is unable to be reclassified as rural within the applicable time frame, it may choose to convert to hospital status in lieu of
having its Medicare participation terminated. The SA and AO are copied on the letter. The letter advises that CAH applications for reclassification must be submitted to the RO DFM, who evaluates and makes a determination regarding the CAH’s rural status. The RO DFM sends the Division of Survey and Certification (DSC) a copy of their determination letter.

c. If the CAH meets both the rural status and the distance and location requirements, the RO notifies the SA/AO, which may then conduct a recertification/reaccreditation survey. **No notice is provided to the CAH (to avoid announcing the survey).**

d. The RO files the above correspondence in the CAH file in the RO system of records.

4. Process for Considering Supplementary Evidence of Necessary Provider Status: A CAH may request the CMS RO to review the determination of its necessary provider CAH status if, within 60 days of the date of a CMS letter that communicates the agency’s determination that the CAH distance requirements have not been met, it submits supplementary evidence to the CMS RO for consideration. The burden is on the CAH to provide qualifying evidence demonstrating that NP designation was made by the State prior to January 1, 2006 and that the designation was applicable to the specific facility in question. Note that a CAH does not need to wait before submitting supplementary evidence, but may do so before the CAH is due for a recertification survey or at any other prior time. Some examples of potentially qualifying evidence include:

a. A letter, issued before January 1, 2006, from the appropriate State authority designating the CAH by name as a necessary provider.

b. An edition of the State’s Rural Health Plan, published in 2005 or earlier, identifying the CAH by name as a necessary provider.

c. A State’s Rural Health Plan, combined with supporting documented evidence that includes all of the following:
   (i) An edition of the State’s Rural Health Plan, published in 2005 or earlier, specifying the State’s criteria for a CAH to qualify as a necessary provider; and
   (ii) At the time of its CAH certification, which must have been prior to January 1, 2006, the CAH met the State’s criteria to qualify as a necessary provider in accordance with the applicable edition of the State’s Rural Health Plan (published in 2005 or earlier). Acceptable data sources used to support the documented evidence that the CAH met the necessary provider criteria in the State’s Rural Health Plan includes, but are not limited to: Health Resources Services Administration (HRSA), U.S. Census Bureau, or data from the applicable State departments; and
   (iii) A signed statement by the appropriate State authority that the State considers the CAH to have been designated as a necessary provider before January 1, 2006. This statement may be from a date before or after January 1, 2006 when combined with the documented evidence cited above.
d. A State law or regulation with supporting documented evidence that includes **all** of the following:
   (i) The law or regulation, enacted prior to January 1, 2006, specifically describes the requirements for necessary provider designation by the State in order to become a CAH, **and**
   (ii) At the time of its CAH certification, which must have been prior to January 1, 2006, the CAH met the criteria in the law or regulation to qualify as a necessary provider, **and**
   (iii) A signed statement by the appropriate State authority that the State considers the CAH to have been designated as a necessary provider before January 1, 2006. This statement may be from a date before or after January 1, 2006.
Background
Page Memorial Hospital (Page Memorial) is a Medicare-certified critical access hospital (CAH) located in the State of Virginia that is due for its CMS recertification survey. The CMS Regional Office (RO) reviewed the CAH’s compliance with the location and distance requirements under 42 CFR 485.610 and found that the CAH does not meet the requirements under §485.610(b) due to its proximity to a nearby similar hospital. Page Memorial is located 25.8 miles from Warren Memorial Hospital and 33.1 miles from Shenandoah Memorial Hospital. The routes to these hospitals do not meet the criteria for the lesser 15 mile distance criteria for either “secondary roads” or "mountainous terrain".

CMS queried the State to obtain a list of all necessary provider CAHs in Virginia and Page Memorial was not on that list. The CMS RO does not have any documentation of Page Memorial’s necessary provider status in the CAH’s file nor was there evidence in the State’s Rural Health Plan that the CAH was specifically designated (by name) by the State as a necessary provider. As a result, Page Memorial was sent a notice letter for termination of its certification by the CMS RO.

In response to the CMS letter stating that the facility did not meet the criteria for CAH status, Page Memorial informed the CMS RO that it was indeed a necessary provider CAH, at which time the CMS RO requested additional evidence of that designation.

The State’s Rural Health Plan Criteria
While the facility Page Memorial was not able to find a letter from the State specifically naming the hospital as a CAH NP, it was able to (a) produce an edition of the State’s Rural Health Plan pre-dating January 2006 that itemized the criteria for a hospital to be a necessary provider criteria and (b) produce evidence that the hospital met the criteria at the time. In addition, the State confirmed that Page Memorial was designated by it as a necessary provider before January 1, 2006, prior to being certified by CMS as a CAH. The criteria in the State’s pre-2006 Rural Health Plan were as follows:

To be classified as a necessary provider, a hospital must be the sole provider in a county and meet two of the following conditions:

1. Located in a nonmetropolitan county that is a federally designed Medically Underserved Area (MUA) or Health Professional Shortage Area (HPSA)
2. Hospital is located in a county where the percentage of poverty exceeds the state percentage as specified in the most recent U.S. census of population.
3. The percentage of the hospital’s revenue from Medicare must exceed the state average for Medicare reimbursement.
4. Hospital is located in a county where the percentage of population 65 and older is greater than the state average as specified in the most recent U.S. census estimate of population and age.
5. Hospital is located in a county whose most recent three-year unemployment rate average exceeds the same three-year average rate for the state.
The following table lists the State’s necessary provider criteria as well as the evidence that has been provided by the CAH demonstrating that it met the state criteria for designation as a CAH NP at the time of its request for certification of CAH NP status by CMS. (as noted above, Page Memorial is only required to meet the mandatory requirement of being the sole acute care hospitals in its county and two additional requirements):

<table>
<thead>
<tr>
<th>State Necessary Provider Criteria</th>
<th>Evidence the CAH Met the State’s Necessary Provider Criteria</th>
<th>Is the Evidence Sufficient?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory for all necessary provider CAHs in the State:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital must be the sole provider in a county</td>
<td>Per the Health Resources and Services Administration (HRSA), there is only one hospital in the county in which the CAH is located (<a href="http://www.pagecounty.virginia.gov/231/Medical">http://www.pagecounty.virginia.gov/231/Medical</a>) and the closed hospital list from UNC (a HRSA contractor), which now has data back to 2005, only found one closed hospital in Virginia, Lee Regional Medical Center in Lee County, Virginia.</td>
<td>Yes</td>
</tr>
<tr>
<td>Located in a nonmetropolitan county that is a federally designed Medically Underserved Area (MUA) or Health Professional Shortage Area (HPSA)</td>
<td>Data from HRSA’s Data Warehouse indicates that the CAH was located in a nonmetropolitan county that is a Federally designated Medically Underserved Area (MUA) and a Health Professional Shortage Area (HPSA) at the time they were designated by the State as a necessary provider <a href="http://datawarehouse.hrsa.gov/GeoAdvisor/ShortageDesignationAdvisor.aspx">http://datawarehouse.hrsa.gov/GeoAdvisor/ShortageDesignationAdvisor.aspx</a></td>
<td>Yes</td>
</tr>
<tr>
<td>Hospital is located in a county where the percentage of poverty exceeds the state percentage as specified in the most recent U.S. census of population.</td>
<td>Data from the U.S. Census Bureau, Small Area Income and Poverty Estimates, 2000-2013 –indicates that the county in which the CAH was located has a poverty level above the State poverty level at the time they were designated by the State as a necessary provider <a href="http://www.census.gov/did/www/saipe/index.html">http://www.census.gov/did/www/saipe/index.html</a></td>
<td>Yes</td>
</tr>
<tr>
<td>The percentage of the hospital’s revenue from Medicare must exceed the state average for Medicare reimbursement.</td>
<td>This information must be obtained from the CAH and the State.</td>
<td>TBD</td>
</tr>
<tr>
<td>Hospital is located in a county where the percentage of population 65 and older is greater than the state average as specified in the most recent U.S. census estimate of population and age.</td>
<td>Data from the U.S. Census Bureau indicates that the CAH was located in a county in which the percentage of population 65 and older is greater than that State average at the time they were designated by the State as a necessary provider <a href="http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=CF">http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=CF</a></td>
<td>Yes</td>
</tr>
<tr>
<td>Hospital is located in a county whose most recent three-year unemployment rate average exceeds the same three-year average rate for the state.</td>
<td>Data from the Virginia Labor Market Information indicates that the CAH was located in a county whose 3-year unemployment rate average is greater than the same three year average rate for the State at the time they were designated by the State as a necessary provider <a href="https://data.virgini%D0%B0%D0%BC%D0%B8.com/vosnet/alyzer/results.aspx?session=labforce">https://data.virginiами.com/vosnet/alyzer/results.aspx?session=labforce</a></td>
<td>Yes</td>
</tr>
</tbody>
</table>
As a result of the supporting information provided, it can be concluded that Page Memorial was designated as a necessary provider CAH before January 1, 2006 and as a result, currently meets the CAH location and distance requirements under §485.610(c).