

MAINTAINING CAH STATUS



Identifying and Avoiding Traps

Idaho Hospital
Association

Kim C. Stanger

(10-22)

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RESOURCES

- CAH Conditions of Participation, 42 CFR 485.601 *et seq.*, <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485>
- CAH Interpretive Guidelines, SOM App. W (rev'd 2/21/20), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_w_cah.pdf
- CAH Certification Process, SOM Ch. 2 at § 2254 *et seq.* (rev'd 3/11/22), <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf>
- CAH Recertification Checklist, S&C 16-08-CAH (rev'd 9/2/16), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-08.pdf>
- MLN, Critical Access Hospitals (3/22), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CritAccessHospfctsht.pdf>
- RHI Hub, Critical Access Hospitals, <https://www.ruralhealthinfo.org/topics/critical-access-hospitals>

CAH REQUIREMENTS

- Designated by the State as a CAH.
- Located in a rural area (i.e., outside a metropolitan statistical area) or an area that is treated as rural.
- Located either
 - More than 35-miles from the nearest hospital or CAH, or
 - More than 15 miles in areas with mountainous terrain or only secondary roads,
 - Designated by state as a “necessary provider” prior to January 1, 2006.
- No more than 25 inpatient beds or swing-beds.
- Annual average length of stay of 96 hours or less per patient for acute inpatient care (excluding swing-beds or beds in distinct part units).
- Emergency care services provided 24/7/365.
- Complies with COPs, 42 CFR 485.601 *et seq.*

(42 CFR 485.601 *et seq.*; SOM Ch. 2 at 2254D)

CMS CHECKING CAH COMPLIANCE

- 2013:
 - OIG report found that approximately **63%** of CAHs would not meet the 35/15-mile distance requirement if required to re-enroll in Medicare. (OIG, *Most Critical Access Hospitals Would Not Meet the Location Requirements If Required to Re-Enroll in Medicare* (OEI-05-12-00080)).
 - OIG recommended that
 - CMS periodically reassess CAH's compliance with location-related criteria.
 - Do not make necessary provider status permanent.

(87 FR 40373)

- 2016: CMS guidance and checklist for evaluating CAH compliance with location and distance requirements.

(S&C 16-08-CAH (rev'd 9/2/16))

CMS CHECKING CAH COMPLIANCE

- June 6, 2022:

- “The distance requirements ... must continually be met to maintain status as a CAH... CMS anticipates certain facilities may lose eligibility for CAH designation depending on the locations of hospitals and CAHs established within relevant distance of the CAH.
- “CMS must continually verify the CAH distance requirements periodically to ensure that they are still met. CMS generally recertifies the distance requirements of CAHs every three years or upon a change of ownership as a component of initial certification or a recertification.
- “If there is a change in distance and location that does not meet the requirements, CMS notifies the provider of its options for continued enrollment in the Medicare program.”

(87 FR 40373)

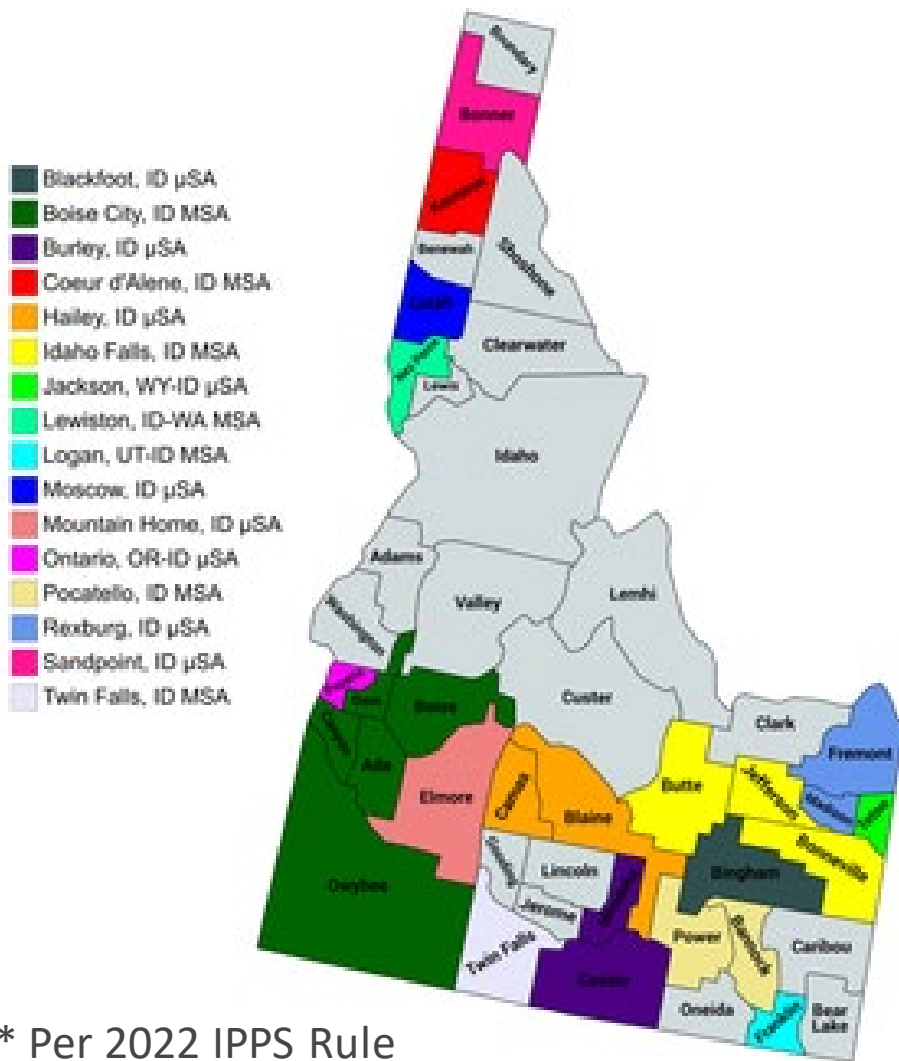
LOCATION: RURAL AREA



- CAHs, including necessary provider CAHs, must either be:
 - Located in a rural area, i.e.,
 - Outside a Metropolitan Statistical Area (MSA) as determined by OMB; and
 - Not classified as urban.
- or
- Treated as rural in accordance with 42 CFR 412.103.

(42 CFR 485.610(b))

LOCATION: IDAHO MSAs*



MSA	Counties
Boise	Ada Canyon Gem Owyhee Boise
Coeur d'Alene	Kootenai
Idaho Falls	Bonneville Jefferson Butte
Lewiston	Nez Perce
Logan	Franklin
Pocatello	Bannock Power
Twin Falls	Twin Falls Jerome

* Per 2022 IPPS Rule

LOCATION: NOT CLASSIFIED AS “URBAN”

- Even if located outside an MSA, must also confirm that CAH is not classified as “urban”, i.e.,
 - Located in an area that has been recognized as urban in accordance with 42 CFR 412.64(b), excluding §412.64(b)(3);
 - Classified as an urban hospital in accordance with 42 CFR 412.230(d); or
 - Redesignated to an adjacent urban area in accordance with 42 CFR 412.232.

(SOM Ch. 2 at 2256A)

LOCATION: TREATED AS RURAL

- CAH within an MSA may be treated as “rural” if it has been reclassified as rural in accordance with 42 CFR 412.103, *i.e.*,
 - It is located in an area designated under Idaho law or regulation as a rural area or has been designated as a rural hospital under Idaho law or regulation; or
 - It is located in a rural census tract of a MSA per the most recent version of the Goldsmith Modification or the Rural-Urban Commuting codes; or
 - It would qualify as a rural referral center or a sole community hospital if it were located in a rural area.

(42 CFR 485.610(b) and 412.103; SOM Ch. 2 at 2256)

➤ *Work with Stephanie Sayegh at Bureau of Rural Health & Primary Care.*

LOCATION: TREATED AS RURAL

- Counties treated as “rural” even though in MSA:
 - Boise
 - Butte
 - Franklin
 - Gem
 - Jefferson
 - Jerome
 - Owyhee
 - Power
 - Twin Falls

*May want to confirm with
Idaho Bureau of Rural
Health*

(From the Federal Office of Rural Health Policy, "Non-Metro Counties (Micropolitan and non-core based counties) and Eligible Census Tracts in Metropolitan Counties," <https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files>)

LOCATION: RURAL AREA

- **All CAHs must satisfy the rural area requirement,** including necessary provider CAHs.
- If CAH is no longer in a rural area:
 - Has 2 years from date CMS adopted OMB MSA delineation that changed rural status to either:
 - Establish that it should be treated as “rural”, or
 - Convert to Medicare-certified hospital status.
 - 2-year time period runs from the date CMS adopted the OMB’s MSA determination, not from recertification in which CAH is determined to be outside rural area.
- CAH has responsibility to monitor compliance and respond appropriately.

(SOM Ch. 2 at 2256)

LOCATION

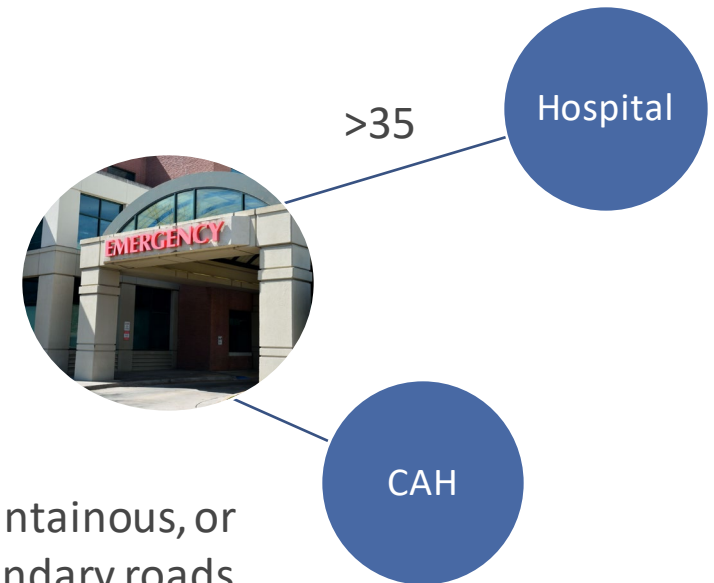
- CAH must either:
 - Be a necessary provider, or
 - Satisfy the 35/15-mile proximity requirement.



or

>15 of

- Mountainous, or
- Secondary roads



LOCATION: NECESSARY PROVIDER

- Provider that was designated by State as a “necessary provider” before **January 1, 2006** does not need to satisfy 35/15-mile proximity limit.*

(42 CFR 485.610(c))

- State agencies cannot certify necessary provider status after January 1, 2006.
- If ROs and SAs do not have the necessary provider designation in their files, they may ask the CAH to supply copies of the original necessary provider designation documents.

(CAH Interpretive Guidelines at C-0830)

- *If you don't have the necessary provider documentation readily available, check with IHA and Bureau of Rural Health.*

LOCATION: NECESSARY PROVIDERS – IDAHO*

1. Bingham Memorial Hospital
2. Caribou Memorial Hospital
3. Cascade Medical Center
4. Cassia Regional Medical Center
5. Franklin County Medical Center
6. Gritman Medical Center
7. Minidoka Memorial Hospital
8. North Canyon Medical Center
9. Power County Hospital District
10. St. Luke's Jerome
11. St. Mary's Hospital and Clinics
12. Syringa Hospital & Clinics
13. Valor Health (Walter Knox Memorial Hospital)
14. Weiser Memorial Hospital

* Per Idaho Bureau of Rural Health

LOCATION: NECESSARY PROVIDER



Beware:

- Relocation of CAH.
 - But renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation.
 - New or replacement CAH.
 - Replacement facility = relocated facility.
 - Applies to construction of a new facility that replaces the existing CAH main campus even when on the same site as the original building.
 - Off-campus provider-based depts or facilities.
 - Co-location with another hospital or CAH.
 - Termination of Medicare provider agreement.
 - Lose necessary provider status if reapply.
- (42 CFR 485.610(d); SOM Ch. 2 at 2265F; 70 FR 47472)

RELOCATION / REPLACEMENT: NECESSARY PROVIDER

- If a necessary provider CAH replaces or relocates its facility, the CAH must satisfy the following to maintain necessary provider status:
 - Serve at least 75% of the same service area that it served prior to its relocation;
 - Provide at least 75% of the same services that it provided prior to the relocation; and
 - Staffed by 75% of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.
- *See examples and instructions in SOM Ch. 2 at 2256F.*
(42 CFR 485.610(d); SOM Ch. 2 at 2256F)

RELOCATION / REPLACEMENT: NECESSARY PROVIDER

- Submit letter of attestation prior to relocation, including:
 - A copy of the CAH's original necessary provider determination from Bureau of Rural Health;
 - Documentation from the State re how the CAH at the relocation site will continue to satisfy the criteria used by the State in the original necessary provider determination.
 - Addresses of both the present location and the future location;
 - Documentation that demonstrates how the new facility/location meets the rural location requirement;
 - Documentation showing how the CAH will continue to be essentially the same provider at the new facility/location; and
 - Timetable for the relocation.
- Notify RO of changes during implementation.
- Final determination made after relocation or replacement is complete.

(SOM Ch. 2 at 2256F)

RELOCATION / REPLACEMENT: NECESSARY PROVIDER

- CAH is expected to continue to provide services based on the same criteria that the State used when initially determining that the CAH was a necessary provider.
 - For example, if the determination was based on the CAH being located in a HPSA, then the relocated CAH must continue to be located in a HPSA.

(SOM Ch. 2 at 5576F; *see* 70 FR 23453 and 70)

NECESSARY PROVIDER: IDAHO CRITERIA

If the facility is located less than

- 35-mile drive by primary highway to another hospital or CAH, or
- 15-mile drive in mountainous terrain or areas with only secondary roads,

facility may be certified as a necessary provider if it meets at least one of the following criteria:

- The hospital is located in a Primary Care Population or Geographic Health Professional Shortage Area (HPSA); *however, loss of HPSA status does not require a CAH to revert to hospital status;*

or

- Combined acute inpatient days for Medicare and Medicaid beneficiaries account for at least 50% of the hospital's total acute inpatient days in the last full year for which data is available.

(Bureau of Rural Health, *Idaho Rural Health Care Plan* at p.35-36)

LOCATION: 35/15 MILES

If the CAH is not a necessary provider, the CAH must be located more than:

- **35-mile** drive from any hospital or CAH; or
- **15-mile** drive from any hospital or CAH if either:
 - In mountainous terrain, or
 - In areas with only secondary roads available.

(42 CFR 485.610(c); SOM Ch. 2 at 2256A)



LOCATION: 35 MILES

- CAH must document that there is no driving route from the CAH to any other CAH or hospital that is 35 miles or less in length.

(SOM Ch. 2 at 2256A)

- Based on driving route, not “as the crow flies”

- Proposed rule (6/2/22): 35-mile driving distance on primary roads.

(87 FR 40373)

LOCATION: PROPOSED RULE



- “Primary roads” =
 - A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway; or
 - A numbered State highway with 2 or more lanes each way.
- CMS solicited comments on whether “primary road” should include only those Federal highways with 2+ lanes in either direction as is required for state highways.

(87 FR 40373 et seq.)

LOCATION: 15 MILES SECONDARY ROADS

- A drive of more than 15 miles without primary roads to another hospital or CAH.
- Primary road =
 - Any US highway; or
 - A numbered state highway with 2 or more lanes each way; or
 - A road shown on a map prepared in accordance with the U.S. Geological Survey's Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a "primary highway, divided by median strip."

(SOM Ch. 2 at 2256A)

LOCATION: PROPOSED RULE



- “Primary roads” =
 - A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway; or
 - A numbered State highway with 2 or more lanes each way.
 - ~~A road shown on a map prepared in accordance with the U.S. Geological Survey’s Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a “primary highway, divided by median strip.~~
- CMS soliciting comment on whether “primary road” should include only those Federal highways with 2+ lanes in either direction as is required for state highways.

(87 FR 40373 *et seq.*)

LOCATION:

15 MILES MOUNTAINOUS TERRAIN

The roads on the travel route must meet the following:

- Over 15 miles of road must be located in a mountain range identified on official maps or other public documents; and
- The road must be either:
 - Steep and winding, i.e., “[e]xtensive sections with steep grades (i.e., >5%), continuous abrupt and frequent changes in elevation or direction, or any combination of horizontal and vertical alignment that causes heavy vehicles to operate at crawl speeds for significant distances or at frequent intervals”; or
 - “[C]onsidered mountainous terrain by the State Transportation or Highway agency, based on significantly more complicated than usual construction techniques required to achieve compatibility between the road alignment and surrounding rugged terrain.”
- Requires letter from State Transportation or Highway agency to verify mountainous terrain.

(SOM Ch. 2 at 2256A)

LOCATION: NEW HOSPITAL/CAH



Beware

- CAHs that rely on the 35/15-mile limit (i.e., not necessary provider CAHs) must beware new hospital or CAH within the 35/15-mile limit.
 - New hospital/CAH may jeopardize CAH status.
 - CMS proposed rule affirms that its process will help ensure “CAHs operate under the CAH designation until, or unless, a hospital moves within 35 miles or 15 miles of the existing CAH.”

(87 FR 40374)

- Probably refers to new hospital or CAH’s main campus or inpatient services, not off-campus provider-based depts.

LOCATION: OFF-CAMPUS LOCATIONS



Beware

- Both CAHs and necessary provider CAHs must beware establishing or relocating off-campus provider-based locations, e.g.,
 - Off-campus provider-based dept.
 - Off-campus rehab or psychiatric distinct part unit.
 - Remote location of the hospital.

➤ Must satisfy 35/15-mile requirements.

(42 CFR 485.610(e)(2))

- Mileage calculated from off-campus provider-based location to main campus of other CAH or hospital.

(SOM Ch. 2 at 2256H)

LOCATION: OFF-CAMPUS LOCATIONS

- “Those CAHs seeking a provider-based determination for newly created or acquired off-campus provider-based locations must submit an attestation to the RO as specified in §2254H of the SOM.”
- Facilities that are out of compliance receive 90-day notice. They may:
 - Terminate provider agreement.
 - Terminate provider-based status of off-campus dept.
 - Transition to Medicare-certified hospital.

(CAH Interpretive Guidelines at C-0836; SOM Ch.2 at 2256H)

LOCATION: OFF-CAMPUS LOCATIONS

- Off-campus provider-based limits do not apply to:
 - Off-campus facilities in existence before January 1, 2008
 - Rural health clinics
 - Ambulatory surgical centers (ASCs)
 - Comprehensive outpatient rehabilitation facilities (CORFs)
 - Home Health Agencies (HHAs)
 - Skilled nursing facilities (SNFs)
 - Hospices
 - Independent diagnostic testing facilities (IDTFs) furnishing only services paid under a fee schedule
 - End stage renal disease (ESRD) facilities
 - Ambulances
 - Depts 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

(42 CFR 485.610(e)(2); SOM Ch. 2 at 2256H)

LOCATION: RECERTIFICATION CHECKLIST

**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 \geq 35 miles? Yes _____ No _____

If no, does the CAH qualify for the \geq 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.]

- CMS, *Critical Access Hospital (CAH) Recertification Checklist for Evaluation of Compliance with the Location and Distance Requirements, S&C 16-08-CAH (Rev'd 9/2/16)*
- Available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GenInfo/Downloads/Survey-and-Cert-Letter-16-08.pdf>

LOCATION: PROPOSED RULE

- New proposed process for evaluating CAH status:
 - CMS would use geocoding to identify all hospitals/CAHs within 50-mile radius.
 - Those CAHs with no new hospitals within 50 miles would be immediately recertified.
 - Those CAHs with new hospitals within 50 miles will receive additional review “focus[ing] primarily on expanded healthcare capacity and access to care within the 35-mile radius of the CAH being examined and less on the actual roadway designations used in making the calculations.”
 - “Those CAHs that do not meet the regulatory distance and location requirements at the time of review ... may face enforcement actions.”

(87 FR 40373)

NO MORE THAN 25 BEDS

- May be either:
 - Inpatient, or
 - Swing beds.

(42 CFR 485.620(a))

- When calculating 25 beds, include
 - Any bed used for inpatient services at anytime, and
 - Dedicated hospice beds.

(CAH Interpretive Guidelines at C-0902)



NO MORE THAN 25 BEDS

25-bed limit does not include:

- Beds used exclusively for outpatient services (e.g., observation, sleep studies, emergency services, etc.).
- Up to 10 psych distinct part unit (DPU) beds.
- Up to 10 rehab DPU beds.
- Examination tables, operating tables, etc.
- Surgical recovery beds used exclusively for such.
- Emergency department stretchers.
- Beds in OB delivery room used exclusively for patients in labor or recovery after delivery.
- Newborn bassinets used for well-baby boarders.

(CAH Interpretive Guidelines at C-0902)

NO MORE THAN 25 BEDS: OBSERVATION BEDS

- Observation beds should never be used for inpatient care.
- Observation beds are NOT appropriate:
 - As substitute for inpatient admission.
 - For continuous monitoring.
 - For medically stable patients who need diagnostic testing or outpatient procedures that are routinely provided in an outpatient setting.
 - For patients awaiting nursing home placement.
 - To be used as a convenience for patient, family or CAH.
 - For routine preop or recovery prior to or following diagnostic or surgical services.
 - As a routine stop between the ED and inpatient admission.
- CAH must be able to provide clinical criteria to justify admission to observation v. inpatient.

(CAH Interpretive Guidelines at C-0902)

NO MORE THAN 25 BEDS: SWING-BEDS

- Swing-beds
 - Certified separate from CAH.
 - Do not need to be separated from acute care.
 - Patients do not need to be moved when transitioned to swing-beds.
 - Physician order required to change patient from acute care to swing-bed.
 - Swing-beds are not included when calculating 96-hour average length of stay.
 - For Medicare patients, a 3-day qualifying stay in any hospital or CAH is required prior to admission to a swing-bed and the admission must be for treatment of the same condition.

(SOM Ch. 2 at 2259A)



AVERAGE LENGTH OF STAY 96 HOURS OR LESS

- The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

(42 CFR 485.620)

- Admitting practitioner must certify that patient may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH.

(CAH Interpretive Guidelines at C-1026).

- 96-hour average LOS does not include:

- Swing-bed
- Hospice patients
- Psych DPU
- Rehab DPU

(CAH Interpretive Guidelines at C-0902)

24/7 EMERGENCY CARE



- Emergency services available 24/7/365.
- MD, DO, PA, NP, or Clinical Nurse Specialist (CNS) is on call and immediately available on site:
 - W/in 30 minutes, or
 - W/in 60 minutes if:
 - Frontier area or remote location;
 - State determines > 30 minutes is the only feasible method of providing emergency care to residents in area; and
 - State maintains supporting documents.
 - Staff properly trained and qualified.
- RN may satisfy requirements in limited situations.
- MD, DO is immediately available 24/7 by telephone or radio.

(42 CFR 485.618)

STAFFING

CAH COPs

- Med staff must have at least one MD/DO.
- May also have PAs, NPs, or CNSs.
- Professional staff must be available to furnish patient care services at all times the CAH is in operation.
- RN, CNS or LPN on duty whenever there is an inpatient.

(42 CFR 485.631)

Idaho Requirements

- All patients must be under the care of an MD/DO.
- For emergency services, an MD/DO must be in the hospital or on call 24/7 and available to see emergency patients as needed.
- PAs may only practice within scope of collaborating physician's practice.

(IC 39-1395; IDAPA 16.03.14.200.01 and .370)

NOTICE TO PATIENTS IF NO MD/DO ONSITE 24/7

- If MD/DO (including resident) is not onsite 24/7, must provide notice to:
 - Inpatients, whether planned or unplanned; and
 - Outpatients under observation or having surgery or other procedure under anesthesia.
- Provide notice at beginning of encounter.
 - For planned encounter, this is the provision of package of info re planned visit, registration, etc.
- Obtain patient's signed acknowledgement.
- For ED patients, post notice in emergency department along with info concerning how hospital will provide emergency care when no MD/DO onsite.

(42 CFR 489.20(w); CAH Interpretive Guidelines at C-0812)

COMPLY WITH 45 CFR 485.601 et seq.



- ✓ Comply with federal and state laws
- ✓ Organizational structure
- ✓ Staffing and personnel, including licensure
- ✓ Physical plant and environment
- ✓ Agreements w/network hospitals, quality assurance, credentialing, etc.
- ✓ Patient care policies
- ✓ Emergency preparedness
- ✓ Clinical records
- ✓ Surgical services
- ✓ Infection control
- ✓ Quality assessment and performance improvement (QAPI)
- ✓ Discharge planning
- ✓ Organ tissue and procurement

PROPOSED RULE: ADD PATIENT RIGHTS

- Notice of patient rights
- Grievance process
- Informed consent and advance directives
- Care in safe and private setting
- Confidentiality of and access to patient records
- Restraints and seclusion
 - Use of restraints or seclusion
 - Staff training
 - Death reporting
- Patient visitation rights

(87 FR 40374-76, 40401-03)

PROPOSED RULE: MULTI-FACILITY SYSTEMS

Creates new options for CAHs in a multi-facility system to address:

- Staffing and staff responsibilities
- Infection prevention and control
- Quality assessment and performance improvement programs

(87 FR 40374-76, 40403-04)

CO-LOCATION OR SHARED SPACE



Beware

- Co-locating with hospital or CAH
- Co-locating or sharing space with other healthcare entity, e.g.,
 - Physician offices
 - Ancillary service provider

May violate

- Requirements to maintain CAH status (42 CFR 485.610(e))
- Conditions of Participation (42 CFR 485.601 et seq.)
- Provider-Based Status rules (42 CFR 413.65)

CO-LOCATION/SHARED SPACE: OTHER HOSPITAL OR CAH

Necessary Provider CAH

- May not co-locate with other hospitals or CAHs unless the co-location was in effect prior to **January 1, 2008**.

(42 CFR 485.610(e))

- CAHs that co-locate are placed on 90-day termination track.

(Interpretive Guidelines at C-0832)

Regular CAH

- May not co-locate with other hospitals or CAHs because it would not satisfy 35/15-mile rule.

(42 CFR 485.610(e))

CO-LOCATION / SHARED SPACE



St. Peter's Hospital (Helena, MT)

- Hospital leased space in provider-based clinic to visiting specialists on a part-time basis for outreach clinics.
- In 2015, CMS determined shared space did not satisfy the provider-based rules, including requirements that:
 - The department operates under the same license, ownership, and control as the main provider.
 - The facility is held out to the public as part of the main provider.
- Consequences
 - Hospital clinic in which leased space was located did not qualify as provider-based.
 - CMS demanded \$1.5 million in repayment for past services that were billed as provider-based.

CO-LOCATING / SHARED SPACE: OTHER HEALTHCARE ENTITIES

Evolution of CMS position

- 2011-17: CMS suggested in decisions and comments--
 - Hospital space must be used exclusively as a hospital.
 - Leases within hospital or provider-based space would require:
 - Fulltime exclusive lease, not shared or part-time use;
 - Entrance that did not pass through hospital space (an exterior door or an entrance from an atrium that was not a waiting room); and
 - Signage indicating that it was not hospital space.
- 2018-2019: CMS seemed to suggest that leases and timeshares are okay so long as hospital maintains control of space as necessary to comply with COPs.

CO-LOCATION / SHARED SPACE: OTHER PROVIDER ENTITY

- 2019: CMS draft guidance for hospitals allows co-location subject to very detailed requirements.
- 2021: CMS revised guidance provides less prescriptive, more general guidance.
 - Addresses space, patient rights, infection controls, contracted or shared services, staffing, emergency services, etc.
 - No discussion of timeshares or leases.
 - Defines “healthcare providers” to exclude CAHs and physician offices.

(CMS, *Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities*, S&C QSO-19-13-Hospital (Rev'd 11/12/21), available at <https://www.cms.gov/files/document/qso-19-13-hospital-revised.pdf>)

CO-LOCATION / SHARED SPACE: OTHER PROVIDER ENTITY

So what about CAHs?

- As reported by AHA, CMS states:
 - 2019 guidance would not apply to non-necessary provider CAHs because of 35/15-mile limits.
 - “CAHs with necessary provider status (that do not otherwise have to meet the distance requirements) could co-locate with another hospital and would then be subject to [the hospital co-location] guidance.”

(<https://www.aha.org/news/headline/2022-01-26-cms-issues-statement-clarifying-updated-hospital-co-location-guidance>)

CO-LOCATION / SHARED SPACE: OTHER PROVIDER ENTITY

So, where are we?

- *Be careful when lease or share CAH space.*
- If allow other entities to use CAH space:
 - Comply with CAH COPs relevant to hospital space.
 - Consider S&C QSO-19-13-Hospital.
 - Comply with provider-based rules in 42 CFR 413.65, e.g.,
 - Maintain control of hospital space.
 - If possible, physically separate hospital from spaces used by outside entities.
 - Use signs or other means to distinguish hospital from space used by outside entities.
 - Comply with any applicable state licensure requirements.

USE OF HOSPITAL SPACE: FRAUD/ABUSE CONCERNS



- If hospital bills for the facility fee, technical fee:
 - Likely not remuneration.
- If hospital does not bill for the facility/technical fee, and provider effectively receives the reimbursement for the items or services:
 - Likely constitutes remuneration.
 - Potential liability under:
 - **Ethics in Patient Referrals Act (Stark)**, 42 CFR 411.351 et seq.
 - **Anti-Kickback Statute**, 42 USC 1320a-7b
 - **Eliminating Kickbacks in Recovery Act (EKRA)**, 18 USC 220
 - **Idaho Anti-Kickback Statute**, IC 41-348

USE OF HOSPITAL SPACE: FRAUD AND ABUSE CONCERNS

- **Stark:** potential defenses
 - No financial relationship if physician is not owner of entity receiving benefit and physician's compensation does not vary with referrals (42 CFR 411.354(c))
 - Lease safe harbor (42 CFR 411.357(a)-(b))
 - Timeshare safe harbor (42 CFR 411.357(y))
 - Payments by a physician safe harbor (42 CFR 411.357(i))
 - Limited remuneration to a physician < \$5000 (42 CFR 411.257(z))
 - Personal services safe harbor (42 CFR 411.357(d))
 - Fair market value safe harbor (42 CFR 411.357(l))
 - Other?

USE OF HOSPITAL SPACE: FRAUD AND ABUSE CONCERNS

- **AKS**, if provider will refer items or services payable by federal healthcare programs.
 - Lease safe harbor (42 CFR 1001.952(b))
- **EKRA**, if provider will refer lab services.
 - Not limited to referrals for govt healthcare programs.
 - No readily available safe harbors.
- **Idaho AKS**.
 - Not limited to referrals for govt healthcare programs.
 - No safe harbors.
 - But Idaho doesn't really enforce this.

OTHER ISSUES

- Idaho Abortion Laws
- Idaho Patient Act
- No Surprise Billing Rule
- Hospital Price Transparency Rule
- Information Blocking Rule
- Cybersecurity
- Physician assistant collaboration
- Telehealth
 - Idaho requirements
 - Medicare/Medicaid reimbursement
- COVID-19 vaccinations



RURAL EMERGENCY HOSPITALS



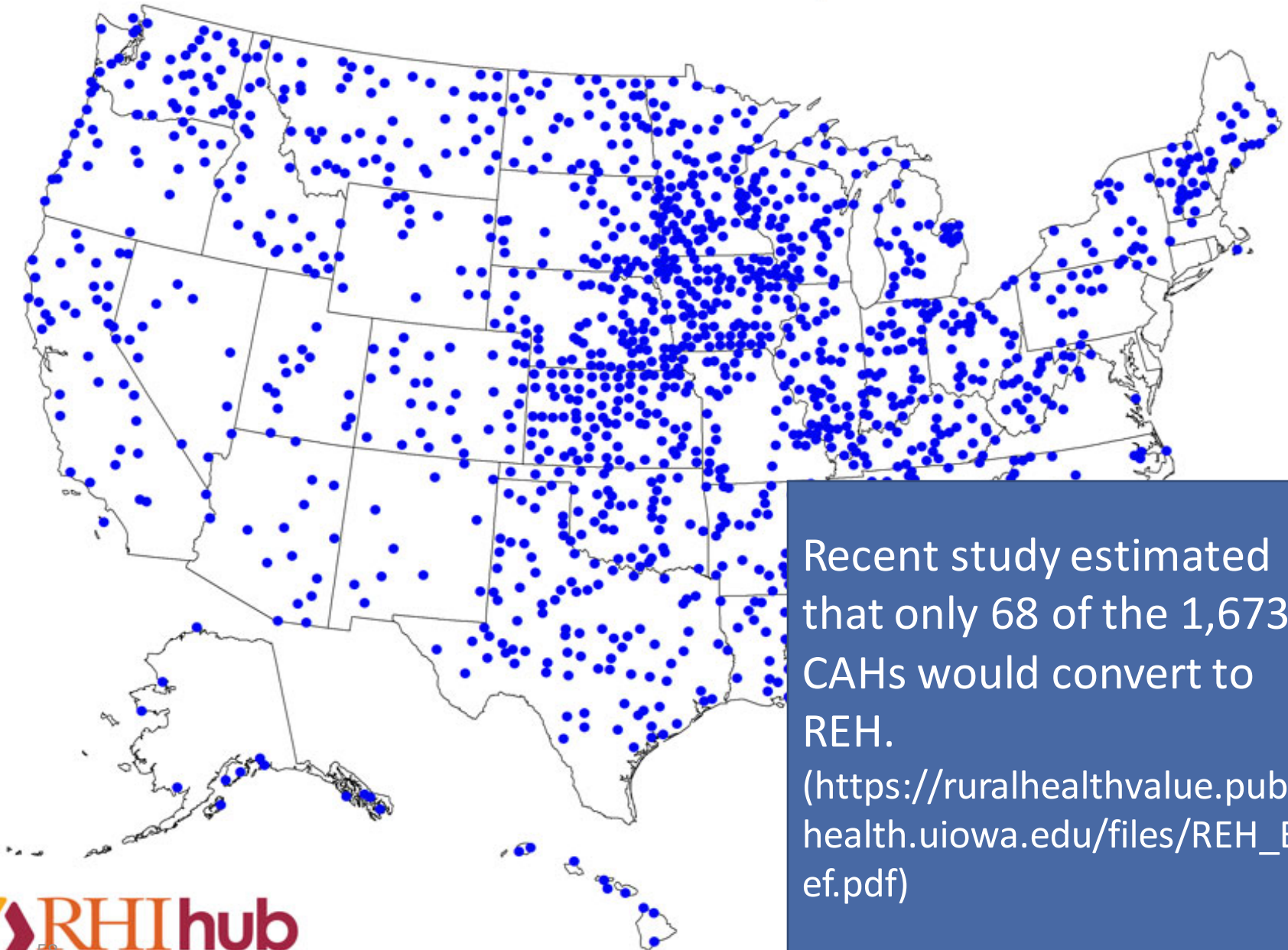
RURAL EMERGENCY HOSPITAL

- Effective January 1, 2023, CAHs may convert to Rural Emergency Hospital (REH).
 - Must provide 24/7 emergency care.
 - Must not provide inpatient services.
 - May provide extended post-acute care services through distinct part unit (DPU) skilled nursing facilities (SNF) and other outpatient services.
 - May serve as originating site for telehealth.
- Reimbursement
 - For emergency and outpatient services:
 - 105% outpatient prospective payment system (OPPS), plus fixed monthly fee
 - For all other service:
 - Traditional fee-for-services

RURAL EMERGENCY HOSPITAL

- To qualify as an REH:
 - Provide 24/7 emergency services and observation care.
 - Be staffed 24/7, and a physician, nurse practitioner, clinical nurse specialist, or physician assistant must be available to provide emergency services.
 - Annual per patient average length of stay of 24 hours or less.
 - Transfer agreement with a level I or II trauma center.
 - Meet state licensure requirements.

Critical Access Hospitals



Recent study estimated that only 68 of the 1,673 CAHs would convert to REH.
(https://ruralhealthvalue.public-health.uiowa.edu/files/REH_Brief.pdf)

QUESTIONS?



Kim C. Stanger
Office: (208) 383-3913
Cell: (208) 409-7907
kcstanger@hollandhart.com