PROPOSED CHANGES TO CRITICAL ACCESS HOSPITALS & RURAL EMERGENCY HOSPITALS

Emily Jane Cook, Partner
Sandra DiVarco, Partner
Caroline Reignley, Partner
Amber Arnold, Associate

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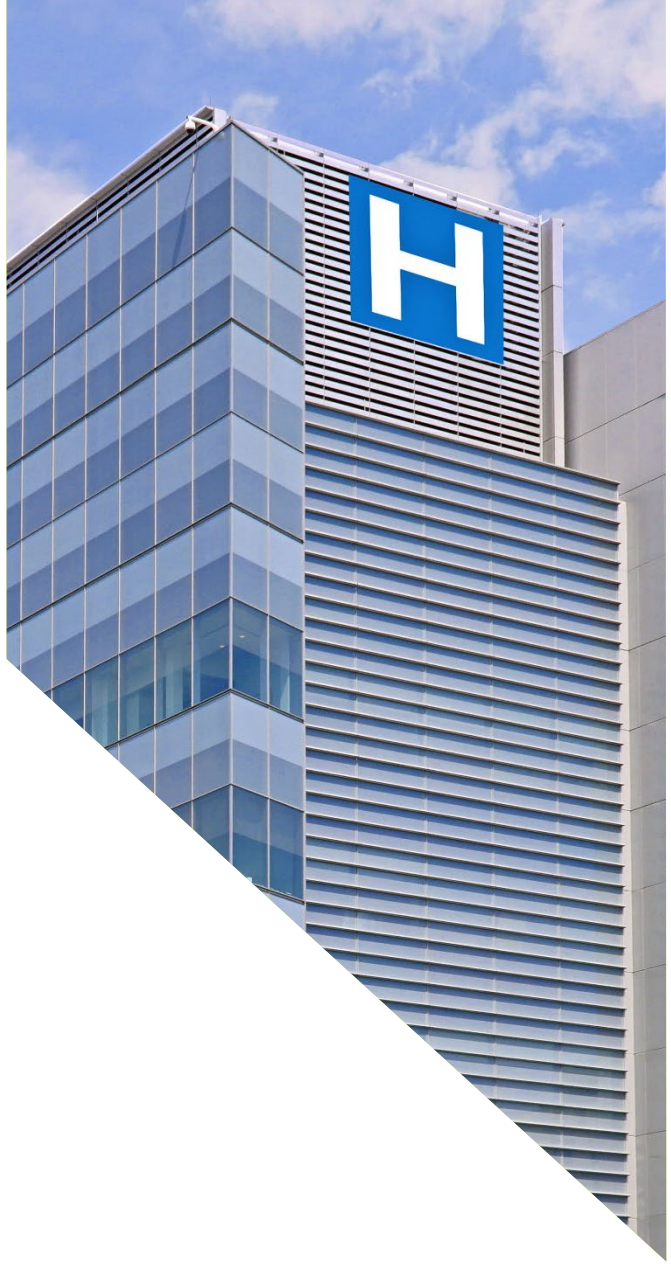

AGENDA

- A New Provider Type: Rural Emergency Hospitals (REHs)
  - Overview of REH Provider Type
  - Services
  - Proposed Rules for Medicare Participation and Payment
  - Proposed Stark Law Flexibility and Physician Ownership & Investment
  - Enrollment
  - Practical Implications
- Proposed Changes to Critical Access Hospital (CAH) Conditions of Participation
  - Location Requirements
  - Proposed Changes
  - Practical Implications

OVERVIEW

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- Rural Emergency Hospitals (REHs), a new Medicare provider type
  - Established in the Consolidated Appropriations Act of 2021
  - Provider type effective January 1, 2023
  - Proposed Rules:
    - Conditions of Participation
    - Key Payment and Service Definitions
    - Proposed Stark Law Exception

OVERVIEW

- Proposed Changes to the Conditions of Participation (CoPs) for CAHs
  - Codification of the definition of “Primary Road”
  - Conduct routine analyses of CAHs location
  - Revisions to CoPs related to medical staff, infection control and quality

A NEW MEDICARE PROVIDER TYPE: RURAL EMERGENCY HOSPITALS (REHS)

REH PROVIDER TYPE

- A new provider type under which Medicare payment is available for a provider that provides emergency department services
- Eligible for Medicare reimbursement at rates higher than Medicare Outpatient Prospective Payment System
  - Medicare payments made at the OPPS rate, plus a 5% add-on
  - Fixed monthly payment
    - Calculated by reference to 2019 payments to CAHs
    - CMS estimates add-on payment for 2023 will be $268,294
    - Monthly payment amount for future years based on 2023 payment, increased by the hospital market basket percentage increase

REH PROVIDER TYPE

- Proposed rule requires that facilities seeking to become REHs met the following conditions as of December 27, 2022
  - Licensed as a CAH or rural hospital with not more than 50 beds
  - Enrolled in Medicare
  - Located in a rural area or in an urban area classified as rural for Medicare payment purposes
- Facilities that closed prior to December 27, 2022 are not eligible for REH status
- Required to operate under applicable state or local licensure laws
  - May impose more stringent requirements than CMS
  - Not all states have licensure categories that will accommodate REHs

REH PROVIDER TYPE

- REH Requirements:
  - No acute care inpatient services
  - Annual per patient length of stay of 24 hours or less
  - Transfer agreement with a Level 1 or II trauma center
  - Maintain a staffed emergency department 24/7
    - Staffed by a physician, nurse practitioner, clinical nurse specialist or physician assistant immediately available to provide emergency services in the facility
  - Meet new REH CoPs

SERVICES

Required Services Under Proposed CoPs	Optional Services Under Proposed CoPs
Emergency	Outpatient services consistent with the needs of the community
Laboratory	Low-risk labor and delivery
Radiology/Imaging	Behavioral Health/Substance Use Disorder
Pharmacy	Surgical services
	Outpatient rehabilitation

MEDICARE ENROLLMENT

- REHs would enroll in Medicare through the 855A "change of information" process
- REHs would not be required to terminate the current CAH or hospital enrollment and submit a new enrollment for a REH
- Unclear how enrollment process would work for CAHs or hospitals that closed since the date of enactment
- Unclear how the effective date will be determined for REHs converting after January 1, 2023

PROPOSED CONDITIONS OF PARTICIPATION

- Generally consistent with CAH CoPs
- REHs with distinct part skilled nursing units must also comply with the skilled nursing facility CoPs
- Appears to provide for flexibility in staffing and breadth of outpatient services

PROPOSED CONDITIONS OF PARTICIPATION

- Staffing Requirements
  - Registered nurse, clinical nurse specialist or licensed practical nurse remain onsite when patients receive emergency or observations services
  - Doctor, physician assistant, nurse practitioner or clinical nurse specialist with training or experience in emergency care be on call and immediately available by telephone or radio contact
- Quality Assessment and Performance Plan (QAPI):
  - Program and scope
  - Program data collection and analysis
  - Program activities
  - Executive responsibilities
  - Unified and Integrated QAPI program for REH in a multi-hospital system

THE STARK LAW WILL APPLY TO RURAL EMERGENCY HOSPITALS

- The Stark Law prohibits a physician from referring patients for “designated health services” payable by Medicare from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies
  - The proposed Medicare CoPs require that REHs provide “designated health services”
- Physician-owned small rural hospitals and CAHs currently rely on the Rural Provider Exception and the Whole Hospital Exception

STARK LAW FLEXIBILITY AND PHYSICIAN OWNERS

- CMS is proposing to create a new exception to the Stark law
  - Proposed REH Exception
    - Will permit physicians to own and invest in REHs, provided the elements of the exception are met
- CMS is seeking comment as to whether there should be requirements for public disclosures of physician ownership and investment or an annual report to CMS in the REH Exception
  - These requirements are not included in the proposed rule

STARK LAW FLEXIBILITY AND PHYSICIAN OWNERS

- Proposed revisions to exceptions applicable to compensation arrangements to ensure REHs can qualify for certain regulatory compensation exceptions:
  - Physician recruitment
  - Obstetrical malpractice insurance subsidies
  - Retention payments in rural and underserved areas
  - Electronic prescribing items and services
  - Assistance to compensate a non-physician practitioner
  - Timeshare arrangements
- CMS is seeking comment on:
  - Medical staff incidental benefits exception
  - Physician recruitment exception

PRACTICAL IMPLICATIONS

- Preserves access to hospital emergency and outpatient services in rural areas
- Proposed rules for outpatient services would allow REHs to provide a wide variety of services
- Generally favorable approach to calculating fixed monthly payments amounts
- Less burdensome enrollment process than for other new and converting providers
- Broad proposed Stark Law exception that would permit physicians to own and invest in REHs without many restrictions generally applicable to physician-owned hospitals
- Interested providers should:
  - Continue to engage with CMS
  - Engage with state and local regulatory agencies to ensure that such authorities will permit REHs to operate

PROPOSED CHANGES FOR CRITICAL ACCESS HOSPITALS (CAHS)

LOCATION REQUIREMENTS

- Location Requirements
  - Rural area
  - Distance Requirement
- Distance Requirement is reflected in current CAH CoPs
  - Located more than a 35-mile drive from a hospital
  - In mountainous terrain, located more than a 15-mile drive from a hospital
  - In areas with only secondary roads, located more than a 15-mile drive from a hospital
- CAH CoPs do not reference or define the term “Primary Road”
  - “Primary Road” is defined in CMS Guidance- State Operations Manual- Ch. 2 2256A

CURRENT DEFINITION OF “PRIMARY ROAD”

Any US highway, including any road:

- In the National Highway System, as defined in 23 US Code §103(b); or
- In the Interstate System, as defined in US Code §103(c); or
- Which is a US-Numbered Highway (also called “US Routes” or “US Highways”) as designated by the American Association of the State Highway and Transportation Officials (AASHTO), regardless of whether it is also part of the National Highway System;

All US highways are readily identified via signage along the roads and on maps by the presence of “US” or “I” above the highway number, with the letters and number appearing on a distinctive, uniform shield background that is called the six point shield, with five points above and one below. Note: Although the National Highway System and the U.S. Numbered Highway system largely overlap, they are not identical. According to the American Association of the State Highway and Transportation Officials (AASHTO), which is responsible for designation of roads in the U.S. Numbered Highway system, the system is intended to facilitate the movement of interstate traffic in two or more States with the use of uniform markings. Given the role all US highways are intended to play in interstate commerce, they are,by definition, primary roads.

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.”

PROPOSED CHANGES: CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION

- CMS proposal to codify the definition of primary road derives from a 2013 OIG study on CAH compliance with location requirements

PROPOSED CHANGES TO CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION

- Clarifies Location Distance Requirement for CAHs
  - More than a 35-mile drive on Primary Roads
  - A 15-mile drive on mountainous terrain
  - A 15-mile drive in an area with only secondary roads available

- Proposed Definition of “Primary Road”
  - A numbered federal highway; or
  - A numbered state highway with two or more lanes each way

- CMS solicits comments regarding this description of a numbered federal highway in the proposed definition
  - Whether “Primary Road” should include numbered federal highways with two or more lanes, similar to the description of numbered state highway and exclude numbered federal highways with only one lane in each direction

PROPOSED CHANGES TO CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION

- Review of all hospitals and CAHs within a 50-mile radius of a CAH
  - During review for initial eligibility
  - Re-review each CAH on a continuous 3-year cycle
    - 3-year cycle review initially focuses on expanded healthcare capacity and access to care within the 35-mile radius of the CAH rather than roadway designations
    - Where there are no new hospitals within a 50-mile radius, CAHs will be automatically recertified
    - Where there are new hospitals within a 50-mile radius, an additional review will be conducted based on the distance and definitions for Primary Road and mountainous terrain

PROPOSED CHANGES TO CAHS

- Establish CoP for Patient Rights
  - Notice and Exercise of Rights
  - Privacy, Safety and Confidentiality of Patient Records
  - Use of Restraints and Seclusion
    - Staff Training Requirements
  - Death Reporting Requirements
  - Patient Visitation Rights
- Establish CoP for Staffing and Staff Responsibilities
- Unified and Integrated Infection Prevention and Antibiotic Stewardship Program
  - For CAHs in a multi-facility system
- Unified and Integrated Quality Assessment and Performance Improvement Program
  - For CAHs in a multi-facility system

PRACTICAL IMPLICATIONS

- So, what would the proposed regulatory definition of “Primary Road” change?
  - U.S. Highway system roads without federal highway numbers would not be “Primary Roads”
  - Roads shown on a map prepared in accordance with the US Geological Survey’s Federal Geographic Data Committee Digital Cartographic Standard for Geologic Map Symbolization as a “primary highway, divided by median strip” would not be “Primary Roads” unless they otherwise meet the proposed definition
- If the alternative approach is adopted, “Primary Road” would also exclude numbered federal highways with only one lane in each direction

PRACTICAL IMPLICATIONS

- Facilities that do not meet the mileage requirements under the current guidance should review the proposed rule to determine if they may be eligible under the proposed rules
- CAHs that may lose eligibility under the proposed re-review process may need to conduct additional review of current compliance obligations and risks, as well as advocacy beyond preparing comments
- Facilities that may be helped or harmed under the proposed rule should provide comments

PRACTICAL IMPLICATIONS

- Routine monitoring and removal of CAHs that do not meet the distance requirements upon re-review (based on the 3 year-cycle) is likely to result in de-designation
- CMS is NOT proposing to remove “Necessary Provider” as a permanent distance requirement exemption, so those providers would not be impacted
- Some CAHs may be unaware that they do not meet the criteria because of new hospitals or CAHs established within the distance limits
- Changes for CAHs that operate as part of a multi-facility system would reduce administrative burden and duplication currently required under CAH CoPs, but not under the hospital CoPs

COMMENT PERIODS

Two Separate Proposed Rules

- Conditions of Participation
  - Comments due August 29, 2022
  - CMS-3419-P
- Payment Provisions and Stark Law Flexibilities
  - Comments due September 13, 2022
  - CMS-1772-P

QUESTIONS?

SPEAKERS

EMILY COOK

Partner
Los Angeles
+1 310 284 6113 | ecook@mwe.com

SANDRA DIVARCO

Partner
Chicago
+1 312 984 2006 | sdivarco@mwe.com

SPEAKERS

CAROLINE REIGNLEY

Partner
Washington, D.C.
+1 202 756 8548 | creignley@mwe.com

AMBER ARNOLD

Associate
+1 202 951 6733 | aarnold@mwe.com

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