NEW OPTIONS FOR RURAL HOSPITALS: CMS PROPOSES CONDITIONS OF PARTICIPATION FOR NEW "RURAL EMERGENCY HOSPITAL" PROVIDER CATEGORY

Date: 12 July 2022

U.S. Health Care and FDA Alert

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On 6 July 2022, the Centers for Medicare & Medicaid Services (CMS) published a rule proposing the Conditions of Participation (CoPs) for Medicare and Medicaid participation of rural emergency hospitals (REHs), to be codified in a new subpart E of 42 C.F.R. Part 485 (the REH Proposed Rule).[1] Comments on the REH Proposed Rule must be received by 29 August 2022.

In developing the proposed CoPs for REHs, CMS indicates it largely relied on the critical access hospital (CAH) CoPs,[2] but also considered relevant hospital CoPs[3] and ambulatory surgical center (ASC) Conditions for Coverage (CfCs).[4] The REH Proposed Rule also requests additional input on particular proposed REH standards; for example, CMS seeks comments as to whether REHs should be able to provide low-risk labor and delivery and the associated outpatient surgical services in the event surgical labor and delivery intervention is necessary.

This client alert focuses on certain proposed CoPs that are unique to REHs or differ in significant ways from the hospital and CAH CoPs.

BACKGROUND: RURAL EMERGENCY HOSPITALS

Section 125 of the Consolidated Appropriations Act, 2021 (CAA)[5] established a new Medicare provider category called a “rural emergency hospital.” Rural hospitals with not more than 50 beds and CAHs that were enrolled in Medicare as of 27 December 2020 may apply to convert to and enroll in Medicare as an REH. Medicare-enrolled REHs will receive payment for REH services provided on or after 1 January 2023. REH services include emergency department services and observation care and, at the option of the REH, other specified outpatient medical and health services that do not exceed an annual per patient average of 24 hours.

As with providers such as hospitals, home health agencies, hospices, and skilled nursing facilities (SNFs), REHs will be required to enter into a provider agreement to participate in Medicare and Medicaid and will have to demonstrate compliance with applicable health and safety standards established in regulation.

In regard to Medicare reimbursement for REH services, while CMS notes that proposed payment, enrollment, and quality reporting requirements for REHs will be the subject of future rulemaking, some general payment information is available now. Section 125 of the CAA stipulates that REHs providing REH services will receive a Medicare payment for those services that is equal to the amount of payment that would otherwise apply under the

Medicare Hospital Outpatient Prospective Payment System for covered outpatient department services increased by 5%.[6] In addition, the law requires the Secretary of the Department of Health and Human Services (the Secretary) to make an additional monthly facility payment to the REH.[7]

PROPOSED CONDITIONS OF PARTICIPATION FOR RURAL EMERGENCY HOSPITALS

REH Definition and Basic Requirements

CMS proposes to define an REH as "an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. The entity must not provide inpatient services, except those furnished in a unit that is a distinct part licensed as a skilled nursing facility to furnish post-REH or post-hospital extended care services."[8] In responses to the Request for Information on REHs (REH RFI),[9] commenters requested CMS increase the average length of stay in certain circumstances, such as when the REH is providing services to a patient who is need of inpatient psychiatric or inpatient rehabilitation services.[10] While CMS recognizes there may be times when patients receive services at the REH for more than 24 hours because a facility is not immediately available to provide a higher level of care, CMS states its view that this will not occur frequently enough to "seriously affect" the REH's average length of stay. Also noting the statutory requirement that the annual per patient average length of stay does not exceed 24 hours, CMS declined to propose a longer length of stay.[11]

In addition to meeting this definition, an REH must have in effect a Medicare provider agreement and meet the CoPs.[12] The ability to be certified as an REH is limited to a facility that was, as of 27 December 2020, a CAH or a hospital with not more than 50 beds (1) located in a county (or equivalent unit of local government) considered rural or treated as being located in a rural area; or (2) as proposed by CMS, located in a metropolitan county that has had an active reclassification from urban to rural status.[13]

Compliance with Federal, State, and Local Laws and Regulations

Similar to the hospital and CAH CoPs, CMS proposes to require the REH to comply with applicable federal laws related to the health and safety of patients[14] to ensure its personnel are licensed or meet other applicable standards that are required by state or local laws to provide services within the applicable scope of practice.[15] In addition, CMS proposes that the REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is

- Licensed in the state as an REH; or
- Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.[16]

Given the novelty of this category of service provider, it is likely most states or their localities, as applicable, will need to enact or revise licensing rules to recognize REHs.

Governing Body and Organizational Structure

The REH Proposed Rule proposes that an REH must have an effective governing body, or responsible individual or individuals, that are legally responsible for the conduct of the REH, which align with the CAH CoP for

organizational structure at 42 C.F.R. § 485.627(a).[17] While many of the proposed requirements in the governing body CoP similarly mirror the corresponding standards in the hospital and CAH CoPs, the proposed medical staff standard requires the REH's governing body to take a more active role in the determining of medical staff privileges. Specifically, CMS proposes that the governing body must periodically reappraise its medical staff privileges, and the scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.[18] By contrast, similar requirements in the hospital and CAH CoPs require appraisals to be conducted by the facility's medical staff.[19]

In regard to telehealth services, section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Social Security Act to add REHs to the list of permissible telehealth originating sites, and CMS has since finalized a revision to 42 C.F.R. § 410.78(b)(3) to add REH as a permissible originating site for telehealth services furnished on or after 1 January 2023. In the REH Proposed Rule, CMS proposes requirements similar to the telemedicine credentialing and privileging process requirements established for hospitals and CAHs that would allow for an optional and more streamlined credentialing and privileging process that REHs may use for practitioners providing telemedicine services for their patients.[20]

Emergency Services

Section 125 of the CAA requires that REHs comply with the CAH emergency services requirements at 42 C.F.R. § 485.618, as well as the hospital emergency services requirements at 42 C.F.R. § 482.55, as determined to be applicable.[21] In underscoring the manner in which the proposed REH CoPs are based on the existing hospital and CAH standards, CMS draws a distinction in the REH Proposed Rule to the different emergency services requirements for hospitals and CAHs.[22] Whereas CAHs are required to furnish emergency services, if a hospital does not provide emergency services, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.[23] However, one similarity in the hospital and CAH emergency services requirements is that, where emergency services are furnished, both provider types are required to have emergency services that meet the needs of their respective patients presenting at the individual facility.[24] As such, CMS proposes to require that an REH furnish the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.[25]

By extension, because the primary function of the REH is to provide emergency services, CMS proposes that the REH must have emergency services that are organized under the direction of a qualified member of the medical staff and are integrated with other departments of the REH.[26]

Laboratory Services

CMS proposes to require REHs to provide laboratory services that are determined to be appropriate and necessary based on the level of services provided at the REH, and that such services must include basic laboratory services that are essential to the immediate diagnosis and treatment of the patient.[27] These requirements align with the corresponding laboratory standards in the hospital and CAH CoPs.[28]

One notable departure from the laboratory standards for hospitals and CAHs is that CMS includes, in preamble text but not in regulation, a list of laboratory services the REH should provide that exceed the specific laboratory services that a CAH must provide.[29] CMS's basis for recommending an expanded list of services is the REH's nature of primarily providing emergency services.[30] As such, in addition to the laboratory services identified in the CAH CoPs, CMS encourages the REH to provide laboratory services that include a complete blood count, basic

metabolic panel, magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests (troponin, brain natriuretic peptide, and d-dimer), lactate, coagulation studies (prothrombin time, partial thromboplastin time, and international normalized ratio), arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology.[31]

Other Outpatient Medical and Health Services

In addition to emergency services and observation care, section 125 of the CAA authorizes REHs to provide outpatient medical and health services, as specified by the Secretary through rulemaking.[32]

CMS notes it received comments on the REH RFI recommending that REHs be allowed to provide additional outpatient services, including radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services.[33] In the REH Proposed Rule, CMS proposes to allow REHs to provide additional medical and health outpatient services that are commonly furnished in a physician's office or at another entry point into the health care delivery system, including, but not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services.[34] As such, provided that an REH demonstrates that the service is needed—based on a community health needs assessment that uses a systematic approach to ensuring the services furnished by an REH are appropriate and meet the needs of the community—the REH would be able to provide additional outpatient medical and health care services beyond those specified in regulation, without needing to wait for separate rulemaking by the Secretary to authorize the provision of such services.[35] Where an REH chooses to provide additional outpatient medical and health services, CMS proposes to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice.[36]

In recognition of the challenges many rural communities face in accessing maternal health services, CMS indicates its view is that there would be community benefit if REHs provided maternal health services, including prenatal care, low-risk labor and delivery, and postnatal care.[37] On this issue, CMS seeks comment as to whether REHs should be able to provide low-risk labor and delivery and the associated outpatient surgical services in the event surgical labor and delivery intervention is necessary.[38]

CMS notes that, in response to the REH RFI, several commenters indicated that REHs should provide behavioral health services, including substance use disorder treatment.[39] CMS states it expects that some REHs may be interested in being opioid treatment providers, and that providing these services is not prohibited by the statute so long as the treatment remains an outpatient service.[40]

Given that the scope of REH services does not include inpatient services, patients requiring a higher level of care would need to be transferred to an acute care hospital or CAH.[41] As a result of this limitation, CMS anticipates that REHs will transfer at least 20% of their patients, and proposes to require that REHs have:

- A system in place for referral from the REH to different levels of care, including follow-up care, as appropriate;
- Effective communication systems in place between the REH and the patient (or responsible individual) and their family, to ensure that the REH is responsive to their needs and preferences;
- Established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the REH; and

- Personnel providing additional outpatient medical and health services who meet the proposed regulatory requirements in 42 C.F.R. § 485.524(b).[42]

Infection Prevention and Control

The proposed CoPs associated with infection prevention and control largely mirror the requirements that apply to hospitals and CAHs to ensure facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections and other infectious diseases, and for the optimization of antibiotic use through stewardship.[43] In addition, the REH Proposed Rule introduces new CoPs for both REHs and CAHs, similar to the hospital CoPs, that would allow both REHs and CAHs to elect to utilize unified and integrated infection prevention and control and antibiotic stewardship programs that would apply to all separately certified hospitals, CAHs, or REHs that are part of the same health system.[44] The proposed conditions on utilizing a unified system include requiring each REH and CAH to ensure they have qualified individual(s) appointed at each licensed facility to communicate, implement, maintain, and provide education and training on the programs and the associated policies and procedures. In addition, the program policies and procedures must ensure that the unique needs and concerns of each separately certified facility, such as those based on differences in patient population, are met as part of the unified program.

Staffing and Staff Responsibilities

REHs will be required to be staffed 24 hours a day, 7 days per week; however, CMS believes that REHs should have flexibility in determining how to appropriately staff the emergency department.[45] At a minimum, a registered nurse, clinical nurse specialist, or licensed practice nurse must be on duty whenever the REH has one of more patients receiving emergency or observation care.[46] In addition, the REH must include one or more doctors of medicine or osteopathy on staff and the staff must be sufficient to provide the services essential to the operation of the REH.[47]

One significant departure from the CAH CoPs is that there is no requirement for a doctor of medicine or osteopathy to be available to furnish patient care services at all times that the REH operates. Instead, the REH standard will align with the CAH emergency services requirement at 42 C.F.R. § 485.618(d), requiring such individuals to be on call and immediately available by telephone or radio contact, and available on site within specified timeframes.[48] CMS seeks comment on the proposed staffing requirements for the provision of emergency services in an REH to gain insight on the appropriateness of not requiring a practitioner to be on-site at the REH at all times.[49]

In response to comments provided on the REH RFI, CMS decided not to propose a requirement that a board-certified emergency physician would need to serve as the REH medical director.[50]

Nursing Services

Since REHs will not provide inpatient services, the nursing program CoPs are similar to the corresponding requirements in the ASC CfCs. Thus, nursing services must be available 24-hours a day, furnished and supervised by a registered nurse to meet the needs of patients, and in accordance with recognized standards of practice. Nursing leadership must be provided by a licensed registered nurse, who will be responsible for the operation of the nursing service.[51]

Discharge Planning

Unlike the CAH CoPs, there is no requirement proposed that REHs track patient readmissions, given that REHs do not provide inpatient services. Otherwise, the REH discharge planning requirements are effectively identical to CAHs CoPs.[52]

Patient's Rights

CMS is proposing CoPs for patient's rights that largely align with hospital requirements, although the requirements are less proscriptive for REHs given the different scope of services and patient populations that REHs serve.[53]

For example, CMS notes that use of restraints and seclusion in REHs is expected to be less frequent than in hospitals given the lower volume of patients.[54] The proposed REH CoPs related to the use of restraints and seclusion contain the same definitions as hospital CoPs, and contain identical requirements that restraints and seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm; and that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.[55] However, in place of the prescriptive requirements directing the use of restraints and seclusions in hospitals contained at 42 C.F.R. §§ 482.13(e)(4)–(16), the REH CoPs instead simply state that the REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.[56]

In total, the patient's rights CoPs include requirements related to notice of rights; patient exercise of rights; privacy, safety, and confidentiality of patient records; use of restraints and seclusion; staff training for use of restraints and seclusion; death reporting requirements; and patient visitation rights.[57]

Agreements

As required by statute, CMS proposes to require an REH to have in effect a transfer agreement with at least one certified hospital that is a level I or level II trauma center for patients requiring emergency medical care beyond the capabilities of the REH. The trauma center must be: (1) licensed as a hospital or approved as meeting licensing standards established by the state; and (2) licensed or designated by the state or local government authority as a level I or level II trauma center or verified as such by the American College of Surgeons.[58] The trauma center may be located in a different state than the REH. REHs may also have transfer agreements with hospitals that are not level I or II trauma centers.[59]

SNF Distinct Part Unit

While an REH by definition may not provide acute inpatient hospital care, it may establish a distinct part unit licensed and certified as a SNF to furnish post-REH or post-hospital extended care services.[60] As with other SNF distinct part units, CMS notes that the unit in the REH must be physically distinguishable from the REH, must be fiscally separate for cost reporting purposes, and the beds in the certified distinct part SNF unit of an REH must meet the requirements applicable to distinct part SNFs.[61]

Emergency Medical Treatment and Labor Act (EMTALA)

CMS proposes to amend the definitions of “hospital” and “participating hospital” under the EMTALA regulation[62] to include REHs so that the requirements of the Emergency Medical Treatment and Labor Act apply to REHs.

WHAT'S NEXT

If these CoPs are finalized as proposed, we expect the REH CoPs to take effect on 1 January 2023, to align with the date on which CMS has stated Medicare payment for REH services will be available. As discussed above, CMS has indicated that the REH Proposed Rule is the first of several CMS rulemakings addressing REHs and REH services. As such, while rural hospitals and CAHs that are eligible for enrollment as an REH need not take immediate action, such hospitals may wish to assess whether enrollment as an REH would be appropriate for the organization and beneficial to the community in which they operate. In particular, conversion to an REH by rural hospitals that already furnish emergency services may be a viable option, given that the proposed REH CoPs are based largely on existing hospital and CAH CoPs, and provide significant flexibility for purposes of burden reduction.

We will continue to monitor these important developments and provide updates on subsequent REH rulemakings.

K&L Gates' Health Care practice routinely assists health systems, hospitals, and other providers and suppliers with legal advice and strategic considerations, including providing advice on enrollment, certification, and reimbursement matters and assisting clients with public comments on proposed and final rulemakings. Contact the authors of this article or another K&L Gates lawyer for assistance with the REH Proposed Rule or to receive updates on Medicare enrollment and reimbursement.

FOOTNOTES

[1] Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates, 87 Fed. Reg. 40,350 (proposed July 6, 2022). While not the focus of this client alert, the REH Proposed Rule also includes proposed changes to the CAH CoPs, including adding a definition of “primary roads” to the Status and Location CoP at § 485.610 and proposing a new Patient Rights CoP at § 485.614.

[2] 42 C.F.R. pt. 485, subpt. F.

[3] 42 C.F.R. pt. 482.

[4] 42 C.F.R. pt. 416, Subpt. C.

[5] Pub. L. No. 116-260 (Dec. 27, 2020).

[6] 42 U.S.C. § 1395m(x)(1).

[7] *Id*. at § 1395m(x)(2).

[8] 87 Fed. Reg. at 40,388 (to be codified at 42 C.F.R. § 485.502).

[9] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals, 86 Fed. Reg. 42,018, 42,285–89 (proposed August 4, 2021).

[10] 87 Fed. Reg. at 40,353.

[11] *Id*.

[12] *Id*. at 40,388 (to be codified at 42 C.F.R. § 485.504).

[13] *Id*. (to be codified at 42 C.F.R. § 485.506).

[14] Note CMS's commentary suggests § 485.508(a) should include compliance with applicable state and local laws and regulations, as well as Federal laws, id. at 40,353, but the regulatory text as proposed includes reference only to applicable Federal laws, id. at 40,388 (to be codified at 42 C.F.R. § 485.508).

[15] *Id*. at 40,388 (to be codified at 42 C.F.R. § 485.508).

[16] *Id*. (to be codified at 42 C.F.R. § 485.508(b)).

[17] 87 Fed. Reg. at 40,354 (to be codified at 42 C.F.R. § 485.510).

[18] *Id*. (to be codified at 42 C.F.R. § 485.510(a)(6)(ii)).

[19] 42 C.F.R. § 482.22(a); 42 C.F.R. § 485.631(d).

[20] 87 Fed. Reg. at 40,354-55 (to be codified at 42 C.F.R. §§ 485.510(a)(8)–(9)).

[21] Social Security Act § 1861(kkk)(2)(D)(iv), as amended by Section 125(a)(1)(B) of the CAA.

[22] 87 Fed. Reg. at 40,356.

[23] *Id*.

[24] *Id*.

[25] 87 Fed. Reg. at 40,356 (to be codified at 42 C.F.R. § 485.516).

[26] *Id*. (to be codified at 42 C.F.R. § 485.516(a)).

[27] *Id*. (to be codified at 42 C.F.R. § 485.518).

[28] 87 Fed. Reg. at 40,356.

[29] See 42 C.F.R. § 485.635(b)(2) (listing the specific laboratory services that should be provided by the CAH, which includes chemical examination of urine, hemoglobin or hematocrit, blood glucose, examination of stool specimens for occult blood, pregnancy tests, and primary culturing for transmittal to a certified laboratory).

[30] 87 Fed. Reg. at 40,356.

[31] *Id*.

[32] 87 Fed. Reg. at 40,358.

[33] *Id*.

[34] 87 Fed. Reg. at 40,358 (to be codified at 42 C.F.R. § 485.524(a)).

[35] *Id*.

[36] 87 Fed. Reg. at 40,360 (to be codified at 42 C.F.R. § 485.524(a)(1)).

[37] 87 Fed. Reg. at 40,359.

[38] *Id*. at 40,360.

[39] 87 Fed. Reg. at 40,359.

[40] *Id*. at 40,360.

[41] 87 Fed. Reg. at 40,360.

[42] 87 Fed. Reg. at 40,360 (to be codified at 42 C.F.R. §§ 485.524(a)(2)–(4)).

[43] 87 Fed. Reg. at 40,361 (to be codified at 42 C.F.R. § 485.526).

[44] 87 Fed. Reg. at 40,362 (to be codified at 42 C.F.R. § 485.526(d)).

[45] 87 Fed. Reg. at 40,363.

[46] 87 Fed. Reg. at 40,363 (to be codified at 42 C.F.R. § 485.528(b)(4)).

[47] *Id*. (to be codified at 42 C.F.R. § 485.528(b)).

[48] *Id*. (to be codified at 42 C.F.R. § 485.528(c)(2)).

[49] 87 Fed. Reg. at 40,356.

[50] 87 Fed. Reg. at 40,363.

[51] *Id*. (to be codified at 42 C.F.R. § 485.530).

[52] 87 Fed. Reg. at 40,363–64.

[53] 87 Fed. Reg.at 40,364. CMS is also proposing to introduce similar patient's rights CoPs for CAHs.

[54] *Id*.

[55] 87 Fed. Reg. at 40,366 (to be codified at 42 C.F.R. § 485.534(e)).

[56] *Id*. (to be codified at 42 C.F.R. § 485.534(e)(4)).

[57] 87 Fed. Reg. at 40,365–67.

[58] 87 Fed. Reg. at 40,368 (to be codified at 42 C.F.R. § 485.538).

[59] 87 Fed. Reg. 40,368–69.

[60] 87 Fed. Reg. at 40,372 (to be codified at 42 C.F.R. § 485.546).

[61] 42 C.F.R. pt. 483, subpt. B.

[62] 42 C.F.R. § 489.24.

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